

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON FINAL RULE ON FITNESS FOR DUTY

Location: ROCKVILLE, MARYLAND

Date: FEBRUARY 8, 1989

Pages: 81

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BRIEFING ON FINAL RULE ON FITNESS FOR DUTY

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PUBLIC MEETING

- - -

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Wednesday, February 8, 1989

The Commission met in open session, pursuant
to notice, at 10:00 a.m., the Honorable LANDO W. ZECH,
JR., Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

LANDO W. ZECH, JR., Chairman of the Commission
THOMAS M. ROBERTS, Member of the Commission
KENNETH C. ROGERS, Member of the Commission
KENNETH M. CARR, Member of the Commission
JAMES R. CURTISS, Member of the Commission

1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE
2 SAMUEL J. CHILK, Secretary
3 WILLIAM C. PARLER, General Counsel
4 VICTOR STELLO, JR., Executive Director for
5 Operations
6 FRANK MIRAGLIA, Associate Director NRR
7 BRIAN GRIMES, Director Division Reactor and DRIS
8 LOREN BUSH, Section Leader
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P-R-O-C-E-E-D-I-N-G-S

10:00 a.m.

CHAIRMAN ZECH: Good morning, ladies and gentlemen.

The purpose of today's briefing is for the NRC staff to brief the Commission on the draft final rule on Fitness-for-Duty, which could be applicable to nuclear power reactor licensees.

The staff briefed the Commission on the draft proposed rule on Fitness-for-Duty on June 24, 1988. Following the briefing, the Commission approved with modifications publication of the proposed rule in the *Federal Register* for public comment and, because of the importance of the rule, requested that the staff provide a proposed final rule to the Commission no later than 10 weeks after the close of the comment period. And I would like to commend the staff for meeting that challenge.

Today's meeting is an information briefing. There will be no vote taken today. The staff has provided the Commission with the draft final rulemaking on Fitness-for-Duty programs in SECY-89-030 and requests that Commission comments by February the 17th, 1989.

The Commission believes that the nuclear

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1 power reactor licensees should ensure that nuclear
2 power plant personnel are reliable, trustworthy,
3 mentally and physical fit to perform their duties
4 safely and competently. Nuclear power plant personnel
5 should not be under the influence of any substance,
6 legal or illegal, which adversely effects their
7 ability to perform their safety related duties. This
8 was the intent of the NRC Fitness-for-Duty policy
9 statement which resulted in improvements in this area.
10 And it is the intent of the draft final rule before
11 the Commission, which we expect will bring additional
12 safety benefits.

13 The Institute of Nuclear Power Operations,
14 INPO, reported to the Commission in December 1987 that
15 all utilities had a fitness-for-duty program in place.
16 The Commission recognizes and commends the efforts by
17 licensees in implementing fitness-for-duty programs
18 and in ensuring that nuclear power plant operations
19 are free of the effects of alcohol and drugs.

20 Much has been accomplished and a lot has
21 been learned from the programs that are now in place
22 at the operating nuclear power plants. In fact, it is
23 based on the evaluation of this experience that the
24 Commission has decided rulemaking is appropriate at
25 this time.

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1 The rule is able to take into account the
2 many positive aspects of existing training programs
3 and the experiences gained from their implementation,
4 as well as the standards established for the federal
5 government's drug testing program in which NRC is a
6 participant. Although many licensees have excellent
7 fitness-for-duty programs, the Commission is concerned
8 that there are significant differences among licensees
9 in some key program elements. A federal rule could
10 provide uniformity at the desired level by providing
11 minimum program standards.

12 For example, not all licensees have been
13 conducting random testing; some because of union
14 intervention or prohibition by state laws. While the
15 NRC has always had the authority to deal with any
16 significant fitness-for-duty programs which could
17 adversely effect the operational safety of the plant,
18 the proposed fitness-for-duty rule will establish
19 minimum standards to promote public health and safety,
20 including a uniform requirement for random drug
21 testing.

22 I am in favor of a drug-free workplace
23 everywhere. In this regard I would like to note that
24 the Nuclear Regulatory Commission took a leadership
25 role in developing a drug testing plan for its own

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1 employees. NRC's drug testing program is in place and
2 being implemented today except for random drug testing
3 for bargaining unit employees in key positions, which
4 will be implemented as soon as matters related to the
5 implementation of the program are negotiated with the
6 National Treasury Employees Union.

7 I understand that the slides for today's
8 briefing are a little late today and they're still
9 coming. And I presume they'll be passed out as soon
10 as they are available.

11 Do any of my fellow Commissioners have any
12 opening comments before we begin? If not, Mr. Stello,
13 you may proceed.

14 MR. STELLO: Thank you, Mr. Chairman.

15 I have here with me at the table Frank
16 Miraglia, Brian Grimes and Loren Bush from NRR. And
17 Brian Grimes will be doing the briefing and I'll ask
18 him to introduce some of the key players from our
19 contractor who have helped with this.

20 There's two particular points that I think
21 are important to make to the Commission that I want to
22 make at the outset. One is to assure that there is
23 within the National Institute of Drug Abuse a set of
24 standards of which drugs ought to be tested at what
25 levels. As you will note from the comments, we had

1 considerable comment in terms of whether the levels
2 ought to be lowered or changed in one shape or
3 another, as well as two drugs which I've identified in
4 the paper that are not now on the list that ought to
5 be added on the list.

6 My preference and what I recommend to the
7 Commission is that we ought to let the National
8 Institute of Drug Abuse set those standards and those
9 levels and we ought to get the comments to them and
10 have them work out what ought to be done, not just for
11 the testing program for the nuclear industry, our own
12 as well, but throughout the federal government as well
13 as throughout the rest of the industry.

14 There are a variety of places within the
15 federal government where drug programs are being put
16 into place and I think we ought to have at least a
17 consistent and uniform table of what drugs ought to be
18 tested and what the appropriate levels ought to be set
19 for indicating a drug problem.

20 I believe we ought to, and we will, get all
21 of the comments related to this matter over to the
22 National Institute of Drug Abuse for their
23 consideration and, hopefully, further revision at some
24 time in the future.

25 The second point that I would emphasize is

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1 that as the Commission is aware, we have added the
2 issue of how to deal with alcohol, which is not an
3 easy issue. I think we are on the cutting edge on
4 that issue as well. And that's one that is not an
5 easy issue to resolve. I think we have proposed a way
6 to deal with that issue that will assure that problems
7 related to alcohol are identified and properly dealt
8 with and we've, I think, have a sensible program for
9 that purpose.

10 But those two points are particular points
11 that I think I would urge the Commission give careful
12 consideration as to how we ought to go forward.

13 With that brief introduction of what I think
14 the two key issues are, I'll ask Brian Grimes to
15 introduce some people from the contractor's and then
16 we'll get on with the briefing.

17 Brian?

18 CHAIRMAN ZECH: Thank you very much. You
19 may proceed.

20 MR. GRIMES: In addition to Mr. Bush, who
21 has been the principal staff on this effort, we have
22 with us today two people from Battelle Human Affairs
23 Research Center who have played key roles in the
24 contractor's support for this. And I'd like to
25 introduce and recognize Doctor Valerie Barnes and

1 Doctor John Olson. Stand.

2 CHAIRMAN ZECH: Thank you very much for
3 being with us today as well as for your assistance on
4 the program.

5 MR. GRIMES: If I could have slide 2. This
6 is the first one behind the cover page and I'll
7 proceed with the briefing.

8 (Slide)

9 MR. GRIMES: That first note that has a
10 little bit of history that a general rule requiring
11 fitness-for-duty programs was first proposed in 1982.
12 In 1984 the Commission deferred to industry efforts,
13 and in 1986 issued a policy statement establishing a
14 trial period for evaluation of these efforts. At the
15 end of this period, in December of 1987, as you
16 mentioned, Mr. Chairman, the Commission decided that
17 rulemaking was appropriate and after extensive staff
18 work and detailed Commission consideration, a proposed
19 rule was published on September 22, 1988.

20 We have, since that time, held a public
21 workshop on October 17, 1989 during the comment
22 period. The comment period ended --

23 CHAIRMAN ZECH: October 17, 1988.

24 MR. GRIMES: I'm sorry. 1988. The comment
25 period ended November 21, 1988. We received a large

1 number of public comments; there were 378 comment
2 letters, over 3,000 individual comments when we count
3 those from the public workshop. And when we've
4 compiled those to combine common comments, we ended up
5 with over 800 individual subjects to be addressed. So
6 there was a high degree of interest here and we've
7 tried to take all of those comments into consideration
8 and have made many changes to the rule in response to
9 those comments.

10 (Slide)

11 MR. GRIMES: Number 3. This and the next
12 slide indicate the principal issues which are also
13 listed in the same order in the Commission paper. And
14 they include alternatives to random chemical tests,
15 random testing rates, alternatives to HHS procedural
16 guidelines, whether or not split samples should be
17 required, the inclusion of alcohol. And then on to
18 number 4.

19 (Slide)

20 MR. GRIMES: Cut-off levels for drugs, drugs
21 to be tested, whether or not we should require a
22 record keeping form, whether the scope should be
23 expanded to construction or other areas, date for
24 implementation and how we are going to implement the
25 rule. And lastly, the enforcement policies associated

1 with this. And I'd like to now go through each of
2 those subjects as they are gone through in the
3 Commission paper and respond to any questions in those
4 areas.

5 (Slide)

6 MR. GRIMES: Number 5, Alternatives To
7 Random Tests. We believe the alterative effects of
8 random testing based on a reasonable likelihood of
9 detection is well established and one of the key
10 points of the rule is to enable utilities to conduct
11 random testing. It's one of the chief reasons for
12 issuance of the rule.

13 We -- the staff believes that other
14 techniques do not adequately address all the issues
15 that we need to address, which include past -- the
16 potential for past, present or future impairment,
17 introduction of drugs into the workplace and whether
18 an individual will follow rigorous procedural rules
19 that are required in the nuclear industry, the
20 reliability and trustworthiness aspects of this.

21 We therefore recommend continuing as the
22 proposed rule did with random testing requirement.

23 (Slide)

24 MR. GRIMES: Slide 6, the Random Testing
25 Rates. We've presented five options to the Commission

1 and recommended option 5. Based on our review of the
2 information, it appears to the staff that the high
3 rate, which is between 200 and 300 percent per year we
4 believe for the military and the Navy specifically, is
5 not necessarily required for licensees. We think
6 there's a substantially different type of population
7 and the utilities with random testing in progress have
8 shown significantly lower positive rates than the
9 military experience, which we believe illustrates that
10 there is a somewhat different problem involved in
11 terms of population. But we have retained for
12 Commission's consideration the five options.

13 The first two are those that were listed in
14 the proposed rule, a performance objective of ensuring
15 90 percent per year were tested with a lower testing
16 rate for those tested to try to minimize the number of
17 second and third tests of individuals.

18 Option 2 was a straight 300 percent rate.

19 Option 3, which we looked at during the
20 comment period, was something which would be
21 equivalent to about a 200 percent rate where an
22 individual would be tested on a particular day and
23 then immediately a randomly selected day during the
24 next year would be picked for that individual. That
25 would assure that the time of testing was random, but

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1 that every individual will be tested at least once
2 during the year. This is somewhat more complex in
3 terms of record keeping and security, and the staff
4 does not recommend this option.

5 Option 4 is an option that some utilities
6 have in place now, at least one utility, the Clinton
7 plant I believe, where they test on an unannounced
8 basis each worker every year and not necessarily
9 random. They make sure that everybody gets tested at
10 some time that the worker does not know about during
11 the year. And then in addition, they have a random
12 rate above that, which I believe in the Clinton case
13 is something like 20 percent. The option presented
14 here would be to test in that way and use a 50 percent
15 rate.

16 Option 5, which is the one the Commission--
17 or the staff recommends to the Commission is a flat
18 rate of about 100 percent per year. We believe that
19 the one utility that is using that has seen only about
20 .5 percent positives per year. It seems to be having
21 a substantial deterrent effect and so we believe that
22 that may be an adequate rate.

23 Now, one thing that the Commission may want
24 to consider is that we do not have any good data on
25 the rate versus deterrence. And so it's very

1 difficult -- it's a judgment call to pick a number in
2 this area. The Commission could set a particular rate
3 for two or three years and then have it lowered and
4 then evaluate whether the deterrent effect as measured
5 by the positive test results is the same or less. And
6 if it's less, then to increase back up to the higher
7 rate. So that is noted in the Commission paper as an
8 option with any of these -- with any of these rates.

9 CHAIRMAN ZECH: Before you go on, what was
10 your rationale for not picking 300 percent?

11 MR. GRIMES: Essentially, as noted in the
12 Commission paper, that the deterrence provided by the
13 two to 300 percent rate in the Navy program, for
14 example, results in about a five percent positive rate
15 per year in terms of testing and an implied rate of
16 even more undetected in that program. The Navy
17 believes, perhaps, 15 percent are using -- actually
18 using, at least occasionally, drugs or alcohol.
19 Sorry--I'm sorry.

20 Loren, I've forgotten whether they test for
21 alcohol, so I may have misspoken.

22 MR. BUSH: I don't know.

23 MR. GRIMES: I don't -- I may have misspoken
24 on alcohol.

25 CHAIRMAN ZECH: Well the 300 percent testing

1 is -- my understanding is that that would fairly well
2 ensure that 100 percent of the people got tested at
3 least once a year.

4 MR. GRIMES: Yes.

5 CHAIRMAN ZECH: Some more, but --

6 MR. GRIMES: And some many more times. And
7 the --

8 CHAIRMAN ZECH: Yes.

9 MR. GRIMES: One of the disadvantages to
10 that is even with a 100 percent rate, one or two
11 individuals may get tested five or six times during
12 the year. With a 300 percent rate, some unlucky
13 person could be tested every couple of weeks. So we
14 thought the impact on plant morale and just the taking
15 people away from their work if not required, it would
16 be better if we could use a lower rate. And the
17 nuclear industry seems to be getting lower rates, of
18 those that are doing random testing, seems to be
19 getting lower positive rates with lower testing rates.

20 CHAIRMAN ZECH: Okay. Why don't you pick
21 option 4?

22 MR. GRIMES: Option 4 is a viable option.
23 It involves some security problems in terms of keeping
24 private the -- the data on which a worker is to be
25 tested on an unannounced basis.

1 Loran, can you fill in on rational and--

2 MR. BUSH: Yes. The -- I guess the --it's a
3 perception as to what is the purpose of the random
4 testing program. And we view it as being primarily a
5 deterrent. And the deterrent value is the perception
6 on the part of the employees as to whether or not
7 they're going to be tested. So -- and that it's
8 unpredictable.

9 In other words, if -- with any kind of
10 scheduled once a year test, once an employee has been
11 -- had that test, then -- and we've had cases where
12 the employee feels well he's had his test and now he
13 doesn't have to worry about it again, which is why we
14 overloaded with a fifty percent rate. But the 50
15 percent rate is not very high frequency as a
16 deterrent. So I guess we felt that the overall
17 deterrence would be better achieved with a 100 percent
18 rate --

19 CHAIRMAN ZECH: Okay.

20 MR. BUSH: -- with this option.

21 COMMISSIONER CARR: Well, he doesn't know
22 when the second date is coming up.

23 MR. BUSH: No, that's true.

24 COMMISSIONER CARR: It could be the next
25 day.

1 MR. BUSH: That's true. He could make a U-
2 turn as he comes out of the collection facility.

3 CHAIRMAN ZECH: All right, let's proceed.

4 MR. GRIMES: I would say that option--
5 after option 5, option 4 would be the staff's next
6 choice.

7 CHAIRMAN ZECH: All right. Let's proceed.

8 MR. BUSH: I might point out something so
9 that everybody understands. The Navy program, their
10 objective is to test 20 percent of the command each
11 month. And I understand in practice that there is
12 something on the order of 10 to 15 percent that are
13 actually randomly tested, that the difference is
14 filled in by command sweep tests, for-cause tests, and
15 reenlistment tests and things of this nature. So
16 there's -- I think there's some misconception that the
17 Navy is doing a 300 percent per year random test.

18 CHAIRMAN ZECH: But the testing is very
19 effective.

20 MR. BUSH: Yes.

21 CHAIRMAN ZECH: I presume you know that?

22 MR. BUSH: Yes.

23 CHAIRMAN ZECH: Yes.

24 MR. GRIMES: It's substantially reduced the
25 amount of drug use.

1 MR. BUSH: Yes. Right.

2 CHAIRMAN ZECH: The most recent requirement
3 is less than 2 percent. 2.6.

4 MR. BUSH: Yes. 2.2 Yes.

5 CHAIRMAN ZECH: All right, let's proceed.

6 (Slide)

7 MR. GRIMES: Slide 8. The alternatives to
8 the HHS procedural guidelines were -- are proposed by
9 the staff because of comments that we received that
10 direct application or incorporation of the HHS
11 guidelines would be inappropriate, that they contain
12 many specific references to federal conditions that
13 didn't apply. In addition, they specifically limit
14 drugs which can be tested for without application to
15 the Secretary of HHS. They do not allow on-site
16 testing as the initial screening and there is not an
17 option in the guidelines to split samples, although I
18 understand the NRC has -- is receiving permission to
19 split samples itself.

20 So we have adapted the HHS guidelines as NRC
21 guidelines and have followed the Department of
22 Transportation in this regard. Department of
23 Transportation has -- has done a similar thing. And
24 in the back of the Commission paper there is a
25 comparative text of the HHS guidelines, the Department

1 of Transportation guidelines and the proposed NRC
2 guidelines.

3 (Slide)

4 MR. GRIMES: Number 9, Split Samples. The
5 staff proposes to allow but not mandate splitting of
6 samples, that this could gain some additional
7 confidence in the reliability of the testing process.
8 But some of the same conditions which could invalidate
9 a process without a split sample also apply to split
10 samples, particularly anything which could be
11 subversion by the testing staff might apply to either
12 case. So we think there -- it could be used to gain
13 additional confidence, but it's not absolutely
14 required to meet the existing guidelines.

15 (Slide)

16 MR. GRIMES: Number 10. One significant
17 change from the rule and something the Commission
18 asked for a specific comment on in the proposed rule
19 was whether alcohol should be included with some
20 specific -- be specifically addressed rather than only
21 generally addressed in the rule. And we have proposed
22 that alcohol testing be performed in conjunction with
23 testing for other drugs. This is being done now by
24 some utility programs at present.

25 (Slide)

1 MR. GRIMES: The second -- number 11
2 continues with the alcohol discussion. There are two
3 options that are presented to the Commission. First,
4 that in terms of whether or not we specify a cut-off
5 level. First we could specify no cut-off level and
6 recommend that -- and require that utilities evaluate
7 any amount of alcohol detected on a test, or the
8 second would be specify a 0.04 cut-off level, which
9 DOT has adopted, and then in addition tell licensees
10 to evaluate any lower amount. This would give an
11 absolute ceiling on the amount that would be
12 considered a positive test. So those are the two
13 options presented.

14 The staff has recommended that a 0.04 cut-
15 off level be selected.

16 CHAIRMAN ZECH: So this would be -- these
17 tests would be done at the same time that the drug
18 test was being done?

19 MR. GRIMES: Yes. Anytime drug testing --

20 CHAIRMAN ZECH: Any -- any time.

21 COMMISSIONER ROGERS: And also, I think,
22 for-cause.

23 MR. GRIMES: Yes. Same.

24 CHAIRMAN ZECH: The number for-cause or for
25 other --

1 MR. GRIMES: Yes.

2 CHAIRMAN ZECH: -- reasons, suspicion.

3 MR. GRIMES: Yes.

4 CHAIRMAN ZECH: Is that correct?

5 MR. GRIMES: That's correct.

6 CHAIRMAN ZECH: All right. Let's continue.

7 (Slide)

8 MR. GRIMES: Number -- number 12.

9 COMMISSIONER ROGERS: Excuse me. On that,
10 does that mean that there would be a blood test or is
11 that --

12 MR. GRIMES: No, that's a breathilizer
13 test --

14 COMMISSIONER ROGERS: The breathilizer test?

15 MR. GRIMES: -- but there is a provision
16 that if the individual is not satisfied, that he be
17 given the opportunity to have a blood test, which is
18 more clinically accurate.

19 CHAIRMAN ZECH: All right.

20 MR. GRIMES: Number 12 continues with the
21 alcohol discussion. And we also require licensees to
22 address an abstinence period, although we have not
23 specified what that period should be, and ask
24 licensees to set disciplinary actions. We have not
25 required the same actions for -- as for drug use. The

1 other aspect that licensees must address is the item
2 of call-ins. Somebody has called in. We believe the
3 individual should -- can't have been expected to
4 abstain for the required period, but should be
5 required to declare whether -- that alcohol has been
6 used. If it has been used, and then there should be a
7 licensee procedure to make a decision, conscious
8 decision, on whether to use that individual and under
9 what conditions to use that individual if he has used
10 alcohol and if his services are required. So
11 something like escorted status or breathalyzer test to
12 establish what level of impairment might be there.

13 COMMISSIONER ROGERS: Why did you not choose
14 to really take on the abstinence question of that
15 period? Isn't that really something that ought to be,
16 more or less, a common denominator of alcohol
17 programs? How much variability are we willing to
18 tolerate in this kind of thing?

19 MR. GRIMES: Well, we got varying advice as
20 to the appropriate period and it ranged from eight
21 hours down to two hours. And we decided that at this
22 point we weren't sure enough of ourselves to come out
23 and say what a good period was that -- we believe
24 there should be some abstinence period, but it's--
25 alcohol disappears from the blood stream in a fairly

1 rapid rate and you want to make sure people are not--
2 are not impaired from this source.

3 As far as -- if I had to pick a number, I
4 guess I'd pick something like eight hours, but we
5 didn't get uniform advice on the exact period.

6 COMMISSIONER ROGERS: So but then you're not
7 going to get uniform proposals from the industry,
8 either.

9 MR. GRIMES: That's -- that's correct.

10 COMMISSIONER ROGERS: And you have to make a
11 decision. On what basis are you going to make a
12 decision and licensee A --

13 MR. GRIMES: Well, you --

14 COMMISSIONER ROGERS: -- see A versus
15 licensee B on this.

16 MR. GRIMES: At this point, we would go with
17 the -- whatever the licensees selected and --

18 COMMISSIONER ROGERS: Well, suppose they
19 picked something that's ridiculous, in our opinion?
20 Do we go with that?

21 MR. GRIMES: No, we --

22 COMMISSIONER ROGERS: And then what's the
23 basis for deciding it's ridiculous?

24 MR. GRIMES: I would guess the --

25 COMMISSIONER CARR: Aren't there other

1 programs that use eight hours?

2 MR. BUSH: The FAA has --

3 MR. GRIMES: Yes, the FAA.

4 MR. BUSH: -- for their expectation, pilots
5 abstain eight hours before serving as a crew member,
6 yes.

7 MR. GRIMES: A long -- a long time period is
8 -- is also difficult to -- to enforce and you may get
9 a lot of allegations --

10 COMMISSIONER ROGERS: Well, but these are
11 all the problems and we know it's a problem area.

12 MR. GRIMES: Yes.

13 COMMISSIONER ROGERS: There's no question
14 that these are problems. But aren't we just ducking
15 the issue of making a decision here and putting it
16 back someplace else when we really ought to -- to
17 decide what the reason is? How much variability are
18 we willing to tolerate and --

19 MR. BUSH: There were a number of suggestion
20 that we not even have an abstinence period in the
21 rule. That the abstinence period is a tool for
22 achieving the 0.04 cut-off level or less that we--
23 you now, adhering to that.

24 MR. GRIMES: And one could provide adequate
25 guidance to -- the abstinence is kind of a form of

1 guidance to employees. Even the eight hour period
2 does not ensure that somebody who has drunk --

3 MR. GRIMES: -- heavily will not exceed 0.04
4 at the time he reports to work or an individual --

5 MR. BUSH: Yes.

6 MR. GRIMES: -- can have variability in
7 response to alcohol. So it's not an absolute
8 assurance that -- it's more of a guidance that you
9 should use -- certainly not use alcohol in excess and
10 that you should abstain for some period to try to
11 ensure that you do not have significant amount of
12 alcohol in your blood at the time you report to work.

13 Some licensees also have much tighter rules
14 than 0.04. Some with any evidence of alcohol on
15 reporting to scheduled work would take action against
16 the employee. So it's a -- that is a variable area
17 also.

18 It was a new area to us and we --

19 MR. MIRAGLIA: I think given the fact that
20 we took a 0.04 cut-off level, we were at a view that
21 since there is that variability, 0.04 abstinence--
22 for some individuals two hour abstinence would get you
23 to that, others would be, perhaps, longer periods.
24 With the cut-off level we felt that we need not speak
25 to the abstinent level, other than saying that there

1 should be one and there should be some guidance to the
2 employees as to what abstinence would mean in
3 achieving that normal. And I think that's where--
4 that's how we came out.

5 MR. STELLO: I think the bottom line is that
6 there is no strongly held feeling on the issue and
7 certainly we would not object at all if the
8 Commission, as a matter of policy, included abstinence
9 for a period of eight hours, recognizing that, you
10 know, we are suggesting that ought to be the right
11 policy.

12 The difficulty we're going to have and the
13 licensee will have is in trying to administer
14 enforcing the policy, which is going to be extra
15 ordinarily difficult, nigh on impossible. Someone
16 whose --

17 COMMISSIONER ROGERS: Isn't it going to be
18 more difficult, though, if they all choose a different
19 one than if there is a --

20 MR. STELLO: No matter which one is chosen.
21 My point is that enforcement will be an extremely
22 difficult issue and I have no problem with suggesting
23 that as a uniform matter we suggest or require in the
24 rule that all licensees will adopt a period of eight
25 hours of abstinence as the basis to move forward.

1 We don't -- there's no really strongly held
2 view. It's a very difficult call as a policy matter,
3 you know, in the Commission's deliberation whatever
4 you come out -- you know, with the final judgment
5 ought to be.

6 There's no strongly held view, there's -- we
7 were not able to gather anything which would tell us
8 the right answer. And the only thing I see as
9 precedent already set for pilots, as I recall, for --

10 MR. GRIMES: FAA.

11 MR. STELLO: -- to abstain eight hours. And
12 that seems like a reasonable approach. We certainly
13 would not have a problem with that.

14 CHAIRMAN ZECH: I guess one -- one
15 consideration, or perhaps you did consider it, would
16 be in case of emergencies. I recognize that this is--
17 this whole abstinence question is not an easy one
18 because if FAA has it, they usually know when they're
19 going to fly and they can have -- schedule. Our
20 people also have a schedule, generally speaking, but
21 there could be an emergency situation that I suppose
22 could discourage somebody from -- who might have had
23 one beer from coming in and helping in the emergency
24 where he might have, you know, even if it was seven
25 hours ago or something that, you know, feel he

1 shouldn't do that.

2 So I recognize that it isn't easy, but it
3 seems to me that the abstinence part should at least
4 be considered. Did you discuss or consider the
5 emergency situation where you might call people in?

6 MR. GRIMES: Yes. We did specifically speak
7 to call-ins and say licensees must have the individual
8 declare whether he has used and then have a procedure
9 to decide whether or not to use that individual.

10 CHAIRMAN ZECH: The judgment call?

11 MR. GRIMES: Yes.

12 MR. STELLO: Under no circumstances did we
13 want to preclude having a licensee prevented from
14 calling in people with particular expertise that may
15 have consumed some alcohol and say he's not able to
16 come in. He may be the best individual to deal with a
17 particular issue. We wanted to be sure that the
18 licensee was not precluded from using those
19 individuals. That, perhaps, is the --

20 CHAIRMAN ZECH: You might have to have some
21 kind of a special provision for someone who says --

22 MR. STELLO: And we have.

23 CHAIRMAN ZECH: -- he's had something to
24 drink. Come in and get --

25 MR. STELLO: And the important thing is --

1 CHAIRMAN ZECH: -- inspected and --

2 MR. STELLO: Well, the individual tells the
3 licensee when he's called in. "Yes, I've had--
4 consumed alcohol."

5 CHAIRMAN ZECH: Uh-huh.

6 MR. STELLO: And he has to make the judgment
7 on it. You know, "I'm -- I've had too much, I can't
8 do it. But no, I have -- I'm not impaired but I have
9 used alcohol" and then supervisor has to make the
10 judgment that for the purpose --

11 CHAIRMAN ZECH: But the supervisor makes the
12 judgments. Somebody --

13 MR. STELLO: Yes.

14 CHAIRMAN ZECH: -- I presume, on duty makes
15 the judgment.

16 MR. STELLO: Yes. That's correct.

17 CHAIRMAN ZECH: Well, you considered all
18 these things, I take it?

19 MR. STELLO: Yes, sir. That's a very
20 important point, too.

21 CHAIRMAN ZECH: Let's proceed then.

22 MR. GRIMES: I would just note for the last
23 item on page 12 is that there will be a reporting of
24 alcohol events as for drug events for licensed
25 operators and supervisors.

1 COMMISSIONER CARR: Why did you limit it to
2 licensed operators and supervisors?

3 MR. GRIMES: We felt that in most cases we
4 would like the licensee to take care of these fitness
5 problems throughout his plant that occur on a day-to-
6 day basis and that the NRC doesn't need to know on a
7 real time basis. We can go out and inspect them.

8 COMMISSIONER CARR: It's going to screw your
9 data. You're going to come back and tell me it's a
10 very low percentage and all I'm going to say it's a
11 very low percentage of operators and supervisors.

12 MR. GRIMES: No. I think when we go out and
13 inspect, we will identify the total percentages.
14 Those will be kept in licensee records and we -- but
15 as far as reportability, the only ones we wanted to
16 really hear about are the ones that we might want to
17 follow individually.

18 COMMISSIONER CARR: But they'll all be
19 recorded?

20 MR. GRIMES: Yes. And --

21 MR. BUSH: But there's a difference here.
22 This is talking about a report that's made promptly
23 after the event and then the rest of the data is
24 something that can be gathered --

25 COMMISSIONER ROGERS: Twenty-four hours or

1 something? During a 24 hour period?

2 MR. BUSH: Well, one of the things we talked
3 about, and maybe we'll get into it later, was there
4 was some interest on the part of staff to have the
5 data provided -- summary data provided periodically,
6 once every six months or once a year. And that's
7 something that we'll get into later.

8 MR. GRIMES: Yes, we'll cover that later.

9 (Slide)

10 MR. GRIMES: The Cut-off Levels For Drugs,
11 number 13. As Mr. Stello discussed, there are a
12 couple of drugs for which from a technical standpoint
13 it would be preferable to have lower levels and, in
14 fact, licensees, number 14 --

15 (Slide)

16 MR. GRIMES: -- have found a number of their
17 -- a large number of their marijuana positives to be
18 below the HHS cut-off levels of 190 ng/ml. So there
19 seems to be a reason to press on this issue and the
20 choice, which Mr. Stello has recommended, is that we
21 ask NIDA and the HHS to come up with what their
22 judgment is on how far these ought to be lowered.

23 (Slide)

24 MR. GRIMES: We do -- number 15 -- pose
25 deferring to the expertise at this time of HHS and

1 NIDA and propose bringing to their attention the
2 information we've developed through the nuclear
3 programs that are in place and in the meantime, adhere
4 to the HHS cut-off levels.

5 COMMISSIONER CARR: Why don't we take
6 advantage of what we already know as long as we know
7 it? If we're getting 80 percent -- 70 to 80 percent
8 of the positives at a lower level, we ought to check
9 at a lower level.

10 CHAIRMAN ZECH: Anything to prevent us from
11 doing that?

12 COMMISSIONER CARR: No.

13 MR. GRIMES: No.

14 MR. STELLO: No. I think that to cause the
15 NRC to start to take the place of performing the
16 function of NIDA is not the best thing. You could
17 have federal agencies developing a whole variety of
18 cut-off levels that are all different.

19 COMMISSIONER CARR: And we can set the rules
20 we want to to protect public health and safety.

21 MR. GRIMES: Excuse me.

22 MR. PARLER: Certainly on the basis of our--
23 the agency's experience, etcetera, etcetera, it's this
24 agency that has the responsibility, not NIDA or anyone
25 else. So I would certainly think that if we're

1 dealing in our own area with a problem and information
2 that we know about, that people would really be way
3 out in left field if they would interpret that as us
4 trying to do NIDA's job.

5 COMMISSIONER CARR: And if you tell me we're
6 going to miss 70 to 80 percent of the people by not
7 having a lower level, then I'd like to lower the
8 level.

9 MR. STELLO: That's the thing, that's true
10 for our own program. And --

11 COMMISSIONER CARR: Fine. If you'd told me
12 that then, I'd have lowered that one.

13 MR. STELLO: Well, I'm not so sure we can by
14 law lower that one, the one that applies to us.

15 COMMISSIONER CARR: Fight that in court.

16 MR. STELLO: It seems to me that a more
17 desirable way to proceed is to let NIDA, who was
18 charged by the federal government, has the expertise
19 and the confidence to set those standards and not have
20 other federal agencies -- I don't think that the NRC
21 has anything that I would advance as particularly
22 expert in making these judgments. That's with NIDA,
23 that's where I think it ought to be. That's my
24 recommendation.

25 The Commission, of course, I think if it

1 wishes, it can set any lower standard it wish, it
2 could add the other drugs that have been recommended
3 if it wishes. I think we're free to do that. As a
4 matter of policy, I just don't think it's the right
5 way to go and don't recommend going that way. I would
6 leave it to the federal agency where those experts
7 are.

8 COMMISSIONER ROGERS: Isn't that the range,
9 the 20 to 100 range, where you're running into the
10 fullest positive problem? Isn't that -- didn't I read
11 in some of your materials here that there are a number
12 of so-called false positives that show up in the
13 testing at greater than 20 but less than 100?

14 MR. BUSH: I think you're talking about the
15 passive inhalation issue, and --

16 COMMISSIONER ROGERS: No, not just that.
17 Other substances that would show up as false marijuana
18 --

19 MR. BUSH: Close reactions. Well, that's
20 true with any of the substances of the drugs being
21 tested --

22 COMMISSIONER CARR: We're only talking one
23 substance, aren't we?

24 MR. GRIMES: Marijuana. Two substances.

25 MR. BUSH: Yes.

1 MR. GRIMES: Marijuana primarily for the
2 higher rates of positives, but also amphetamines --

3 MR. BUSH: Yes. On the passive inhalation,
4 there are studies where under a laboratory setting,
5 we're talking a room of 8 x 10. where there were like
6 16 marijuana cigarettes smoked and people passively
7 inhaled the smoke and after a couple of days they
8 started showing positive results.

9 CHAIRMAN ZECH: At what levels?

10 MR. BUSH: At the 20 nanogram levels.
11 Basically, the way it works out, is the smoke of 16
12 marijuana cigarettes passively inhaled is pretty
13 equivalent to active smoking of one marijuana
14 cigarette.

15 COMMISSIONER ROGERS: Yes, well that's not
16 the problem I'm worried about.

17 ~~COMMISSIONER ROGERS:~~ You know, I'm not too
18 concerned about that, I think. If that shows up, that
19 may be pretty good because somebody's keeping bad
20 company.

21 MR. BUSH: Yes.

22 COMMISSIONER ROGERS: But I'm -- I -- I'm
23 concerned about the problem of false positives coming
24 from other substances that show up in this -- in
25 this--

1 MR. BUSH: The poppy seeds.

2 MR. GRIMES: And there may be more in those
3 ranges.

4 COMMISSIONER ROGERS: Poppy seeds, other
5 over-the-counter and nonprescription drugs and
6 prescription drugs.

7 MR. GRIMES: Yes.

8 COMMISSIONER ROGERS: If I recall what I've
9 read here in your materials, is that's where you begin
10 to see those things turn up greater than 20 but less
11 than 100 nanograms.

12 MR. BUSH: The cut-off levels for the
13 legitimate drugs should have --

14 MR. GRIMES: And they're different cut-offs,
15 don't forget.

16 MR. BUSH: -- any legitimate medical
17 purposes, the cut-off levels are above the normal
18 therapeutic doses. So we -- you know, from that
19 aspect you wouldn't be collecting people who were
20 taking cough medications and things of that nature as
21 long as --

22 MR. GRIMES: I guess --

23 COMMISSIONER CARR: Well each substance has
24 a different cut-off level and it's --

25 MR. BUSH: Yes.

1 MR. GRIMES: Could I just --

2 COMMISSIONER CARR: The one we're talking
3 about here where they're catching people at 70 to 80
4 percent are just these two particular substances that
5 we want to lower the cut-off level from the HHS
6 Guidelines?

7 MR. BUSH: Yes.

8 MR. GRIMES: Yes. If I could make two
9 comments --

10 COMMISSIONER CARR: Some of us might want
11 to.

12 MR. GRIMES: First, the cross reaction only
13 applies to the initial screening and does not apply to
14 the gas chromatographic confirmatory test. So the
15 cross reaction false indication does not get through--
16 all the way through the process. So there may be
17 additional --

18 COMMISSIONER ROGERS: Yes.

19 MR. GRIMES: -- items sent to the lab --

20 COMMISSIONER ROGERS: Yes.

21 MR. GRIMES: -- is the effect here rather
22 than additional number falsely identified through the
23 whole process.

24 I guess the second point is we have at least
25 one utility that said on their drug testing, they get

1 a very high rate, almost 100 percent rate, of
2 confessions or admissions to drug use when they face
3 people with these test results so we have no real
4 experience of falsely accusing people in this area.

5 COMMISSIONER CURTISS: Is NIDA looking at
6 this issue now and is not --

7 MR. BUSH: Oh, yes. Yes. This was an issue
8 that was raised during the comment period on the HHS
9 Guidelines. My understanding is that the HHS or NIDA
10 specifically set the cut-off levels for marijuana
11 where they did because they envisioned a testing
12 program nationwide that was going to be applied to
13 several millions of people. And they were looking at
14 the potential impacts on the laboratories. And the
15 problems are not so much with the accuracy of the
16 test, but potential laboratory errors. And they felt
17 that the more specimens that needed to be processed
18 for the confirmatory testing, then the greater the
19 potential there was for laboratory errors. So they
20 set the cut-off levels initially at -- for marijuana
21 at 100 nanograms really to limit the number of
22 presumptive positive tests that would have to go
23 through the confirmatory testing procedure.

24 Doctor Walsh, whose the Director of the
25 Office of Workplace Initiatives and the grandfather,

1 if you would, of the HHS Guidelines, said that yes
2 they are planning on lowering the cut-off levels for
3 marijuana after they've gathered enough data on the
4 laboratory experiences with the federal program.

5 COMMISSIONER CURTISS: Do we have a feel for
6 how long that would take?

7 MR. BUSH: He said sometime this year, but
8 that -- I would not bet on that.

9 MR. STELLO: Could I just repeat, Mr.
10 Chairman, I feel uncomfortable with placing the NRC in
11 a position to try on a scientific and policy basis to
12 defend setting levels different than the agency in the
13 federal government, NIDA, responsible for that. And
14 you've heard of some of the kinds of judgments that go
15 in there. I feel awful uncomfortable coming forward
16 and telling the Commission we have the kind of
17 understanding and expertise within the Commission to
18 make those kinds of judgments. And that's why I made
19 the recommendation I did.

20 CHAIRMAN ZECH: All right. We appreciate
21 that.

22 MR. STELLO: It makes me feel very
23 uncomfortable.

24 CHAIRMAN ZECH: Let's proceed.

25 (Slide)

1 MR. GRIMES: Okay. Number 16, Mr. Stello's
2 comment apply exactly to this next topic also, which
3 is whether we add drugs in addition to alcohol to the
4 panel of five that HHS lists. The staff had proposed
5 on a technical basis that benzodiazepines and
6 barbiturates being substances which are commonly
7 abused, particularly in connection with alcohol use,
8 should be added from a technical standpoint to the
9 protocol. While we do encourage licensees to test for
10 other drugs --

11 (Slide)

12 MR. GRIMES: -- number 17 --

13 COMMISSIONER ROGERS: Are those two over-
14 the-counter or are they all prescription?

15 MR. BUSH: Both.

16 MR. GRIMES: They can be both.

17 MR. BUSH: They're very commonly abused, as
18 Brian said, and my understanding is most licensee
19 programs currently include these drugs.

20 MR. GRIMES: And the recommendation is
21 there, number 17 also, that we bring this to the
22 attention of HHS and NIDA and ask them to make a
23 determination on adding these drugs rather than having
24 the NRC out front in this matter.

25 CHAIRMAN ZECH: Mr. Stello, do you agree

1 with that recommendation?

2 MR. STELLO: That is my recommendation.
3 Yes.

4 CHAIRMAN ZECH: It was my understanding that
5 there was a discussion on that amongst the staff and a
6 kind of a debate as to whether or not they should be
7 included.

8 MR. STELLO: I guess I ought to let Brian
9 speak for our staff.

10 MR. GRIMES: Yes. I think it is the same
11 condition as applies to the cut-off levels. From a
12 technical standpoint we believe they should be added.
13 But the policy consideration, I defer to Mr. Stello on
14 the policy considerations.

15 CHAIRMAN ZECH: Well, in your recommendation
16 you recommend they should be added, is that --

17 MR. STELLO: No, I recommend they not be
18 added. That we refer to NIDA as to if they ought to
19 be added and how because that's where I believe the
20 expertise lies with making these judgments, and I do
21 not want to place us in a position --

22 CHAIRMAN ZECH: Yes. I just wanted to
23 clarify that.

24 MR. STELLO: Yes, sir.

25 CHAIRMAN ZECH: I think I understand.

1 COMMISSIONER CARR: Would NIDA work any
2 faster if we put them in?

3 MR. BUSH: Whatever it is we want them to do
4 in our rule, and NIDA has no authority to tell us to
5 take it out. I think what Mr. Stello is really
6 talking to is the concern about comparability between
7 what we're asking the industry to do and what we have
8 already expected government wide, and in particular
9 with our own employees.

10 CHAIRMAN ZECH: All right, let's proceed.

11 MR. GRIMES: Okay.

12 (Slide)

13 MR. GRIMES: Number 18. The proposed rule
14 had a proposed record keeping form. Most respondents
15 asked for a deletion of the form. We believe there is
16 a benefit to collecting data in a standard format to
17 assure that the right data is collected from everyone
18 and to facilitate analysis and auditing of the
19 programs.

20 (Slide)

21 MR. GRIMES: Number 19. We did talk to
22 NUMARC about this and they are developing some
23 detailed guidelines which -- for implementation which
24 include a standard data collection form. And so at
25 this point the staff has not included the standard

1 form in the rule itself. If the NUMARC effort is not
2 timely or adequate in terms of collecting this data on
3 an industry wide basis, then the staff would propose
4 additional action. But at this point if the industry
5 will agree to -- on a uniform basis to collect this
6 data, there may not be a reason to put a specific form
7 in the rule itself.

8 COMMISSIONER CARR: Well, what's wrong with
9 that form?

10 MR. GRIMES: Well, one of the things that is
11 wrong with putting a rule -- a detailed form into a
12 rule is it's hard to -- hard to change. The -- we
13 were -- I guess the industry form, that draft form
14 that we saw in a meeting a few weeks ago, differed
15 from our form in some detail and, Loren, can you
16 remember what -- what it didn't have?

17 MR. BUSH: Yes.

18 MR. GRIMES: I think it spoke to most of the
19 areas of concern to us and looked like a fairly good
20 effort.

21 MR. BUSH: Yes. It didn't give a detailed
22 breakout of the -- what we refer to as the pro-active
23 efforts. And the reason we had included that in our
24 initially proposed form was trying to understand the
25 impacts of some of the things that the licensees might

1 do on the overall program. For example, if they were
2 doing searches of the workplace or they were using
3 drug detector dogs, there was no requirement that they
4 do so but if they were, we wanted to understand that
5 the reason they were having, if they were, rule or --

6 COMMISSIONER CARR: Somebody --

7 MR. BUSH: Yes.

8 COMMISSIONER CARR: Somebody reports zero,
9 you had a reason to figure out why, huh?

10 MR. BUSH: Yes. And then we also had some
11 detailed breakout on the experiences of the employee
12 assistance program. Our purposes there was to -- the
13 term that's used in that particular discipline is the
14 penetration rates as to how many people come forward
15 so refer in the program. And so you get some feeling
16 as to how successful that effort is.

17 So that's the primary differences.

18 MR. GRIMES: But I think -- I wouldn't like
19 to keep the rule to the -- we have a very -- fairly
20 prescriptive appendix now which specifies the things
21 we need to -- we think need to be specified to protect
22 employees. But to the extent we cannot put detail in
23 the rule, it may be better to allow the industry to
24 take some initiative and try to collect this
25 information or propose a standard form that they could

1 have a consensus on.

2 COMMISSIONER CARR: And what are you going
3 to do in the meantime?

4 MR. GRIMES: Well, we expect that this form
5 will be developed and available when these programs
6 are put into work.

7 COMMISSIONER CARR: Inside the 180 days?

8 MR. GRIMES: Yes.

9 COMMISSIONER CARR: And what if it's not?

10 MR. GRIMES: Then I think we would probably
11 come back to the Commission and propose an amendment
12 to the rule.

13 COMMISSIONER CARR: All right.

14 CHAIRMAN ZECH: The data and the experiences
15 that went with this rule once it's put into effect, it
16 seems to me, are very important and I hope that we
17 would have some kind of a plan to track the data, keep
18 informed of the experiences and -- so that we can
19 improve the rule if it looks like we should. It's
20 still a relatively new area. There has been
21 experiences in other agencies and branch of the
22 government. On the other hand, I hope that -- the
23 data's important and experience is important. We need
24 some kind of a system to monitor it and track it so we
25 can see should the rule be changed. No reason the

1 rule, once we've put it out, has to remain forever.
2 And I think it is important that we get good data,
3 check the experiences that we've had and have some
4 kind of a plan to look at it in the future to see
5 how's it going. I'd suggest we do that.

6 COMMISSIONER ROGERS: I'd just like to
7 really reenforce that. It seems to me the
8 measurability of the effectiveness of this program is
9 very important and that means comparable data. And I
10 think that it's very important at the outset we
11 collect data on a uniform basis.

12 Now, there may be some optional things that
13 people could supply or not, but certain kinds of data,
14 it would seem to me, are absolutely musts and that
15 there should -- that shouldn't option. I can't tell
16 you what they are, but I'm sure you people can tell.
17 So that if one's trying to create a database here to
18 look at to see exactly how effective this program is,
19 then there has to be a uniform basis for establishing
20 that database. There may be some optional elements
21 that are in there or not, but some key elements just
22 have to be there in the same basis.

23 COMMISSIONER CARR: I would agree to that.
24 Some of those things you could find out when you go
25 look at their program. You could find out whether

1 they used dogs or not by when you go out and visit the
2 site. You wouldn't necessarily have to have that on
3 the form. But --

4 CHAIRMAN ZECH: All right, let's proceed.

5 MR. GRIMES: Thank you.

6 (Slide)

7 MR. GRIMES: Number 20. With respect to
8 scope expansions of the rule, in the proposed rule we
9 did -- the Commission did ask for a comment whether it
10 should be applied to nonpower reactors, fuel
11 facilities and other licensees. All comments were
12 against applying the rule to these facilities. I
13 guess the staff has not, in the time scale of this
14 rule, focused on those -- the need or what should be
15 done at those facilities, but proposes not to act on
16 those matters at this time. We think the thing that
17 needs to be addressed at this point immediately is the
18 power reactor situation.

19 COMMISSIONER CARR: Well, that doesn't mean
20 you're not coming back to fuel facilities?

21 MR. GRIMES: That's right.

22 CHAIRMAN ZECH: I'd hope you'd keep fuel
23 facilities on your list. At least if we don't put it
24 in this rule, then we have something you can continue
25 to look at. I don't know why we don't include it

1 right off hand but -- can you give me any rational?

2 MR. GRIMES: Well, it's--the reason for going
3 for requirements on power reactors first
4 is--

5 CHAIRMAN ZECH: We don't want these drugs in
6 the fuel facilities either.

7 MR. GRIMES: Right. Right.

8 CHAIRMAN ZECH: Go ahead.

9 MR. GRIMES: Is the more direct impact on
10 the health and safety of the public of failures which,
11 in the fitness programs which might cause actual
12 effects on the public.

13 CHAIRMAN ZECH: I understand.

14 MR. GRIMES: Those are more remote in a fuel
15 facility.

16 CHAIRMAN ZECH: We don't want any radiation
17 released to the atmosphere. I understand that.

18 MR. GRIMES: Right.

19 CHAIRMAN ZECH: But also in the fuel
20 facilities we want to make sure that they're
21 performing their duties properly and that they don't
22 put together some kind of a fuel element or whatever
23 that really is not the quality that we expect.

24 So, I hope you'll look at this one and the
25 other areas, too, perhaps, especially fuel facilities.

1 It seems to me that this ought to be something --

2 MR. STELLO: We will.

3 CHAIRMAN ZECH: -- you'll continue to watch.

4 MR. GRIMES: In the area of construction
5 permit expansion, we think it is appropriate to--
6 extended to construction permits, although there is a
7 less direct relationship to hazard to public health
8 and safety. In other words, during construction you
9 want to take all the measures you can to make sure
10 that the facility is built correctly and you have a
11 lot of over checks and testing and things, which are
12 designed to show this. So that acts by individuals
13 don't have as direct a relationship to releases to the
14 public as they would in an operating nuclear power
15 plant. However --

16 CHAIRMAN ZECH: I agree with that and I
17 think that's a good recommendation. But, by the same
18 token, I think it's related somewhat --

19 MR. GRIMES: Yes.

20 CHAIRMAN ZECH: -- for example to the fuel
21 facilities. You want -- we want good construction at
22 our power plants, I agree. That's fine. It seems to
23 me we also want good performance in our fuel
24 facilities. There is a link in my judgment, but I
25 hope you'll look at that.

1 MR. GRIMES: Okay. The staff has
2 recommended extension to construction permit sites for
3 the general program elements. We haven't gone into
4 the detail.

5 COMMISSIONER ROBERTS: For the licensee
6 only?

7 MR. GRIMES: No. It would be for the
8 licensee and his contractors.

9 COMMISSIONER ROBERTS: And subcontractors?

10 MR. GRIMES: Yes. Anyone with -- again, on-
11 site access. Same rules for unescorted access on a
12 site.

13 (Slide)

14 MR. GRIMES: Number 22. The date for
15 implementation got a lot of comments. The proposed
16 rule had proposed 90 days for many of the program
17 elements and 180 days for chemical testing. There
18 were a lot of comments that there was administrative--
19 administrative difficulties in readjusting contracts,
20 both with testing labs and unions and other parties
21 involved, contractors and so that a longer time period
22 would be appropriate. So we have -- we are
23 recommending that all of the requirements be at the
24 180 day time mark. This does not extend the time when
25 chemical testing must be implemented from what was

1 proposed, but does extend the 90 days for putting the
2 program elements in place to the 180 day mark and give
3 a little more time to get the paperwork in place to
4 support the program. And we believe this is a
5 reasonable accommodation of the practical
6 considerations that were brought up in the comments.

7 CHAIRMAN ZECH: Have you looked at the
8 capability of the laboratories to handle the samples?

9 MR. GRIMES: Yes. We've talked to NIDA
10 about that. They have not -- have said there should
11 be no program. This month in January, HHS published
12 its first set of certified laboratories, ten
13 laboratories, which are now certified and they will be
14 on a monthly basis updating that certification list.
15 And they expect that to grow substantially. So we
16 don't believe that there is a problem in that regard.

17 CHAIRMAN ZECH: All right.

18 (Slide)

19 MR. GRIMES: Number 23. To assure that the
20 written policies and procedures meet our expectations,
21 we're asking licensees to certify implementation of
22 the rule and to report the cut-off levels.

23 (Slide)

24 MR. GRIMES: And number 24. We intend to
25 have a temporary instruction to our regional

1 inspectors so that they will look at each licensee
2 program to make sure that it is complete and being
3 implemented adequately.

4 COMMISSIONER CARR: Why did you want them to
5 report lower cut-off levels, just for curiosity?

6 MR. GRIMES: Well, partly to determine
7 whether there was a large number of utilities, for
8 example, using lower cut-off levels in a particular
9 area then we might want to focus in as we go out on
10 their experience with those lower cut-off levels. If
11 only one utility is using a cut-off level on a
12 particular drug, it's probably not worth our while to
13 -- to go out and collect information on it. If we can
14 learn something from lower cut-off levels, I think we
15 should. It's kind of a trigger there and will give us
16 a baseline as to what is going -- what is being used
17 in the industry.

18 MR. STELLO: I think it would be very, very
19 useful information for NIDA when they're considering
20 this as well.

21 COMMISSIONER ROGERS: Well, I think also
22 that in this data collection if somebody's using a
23 lower cut-off level, they ought to collect the data
24 that's divided into those -- what is above the
25 standard cut-off level that everybody else is using

1 and what they're picking up below that so that they're
2 not mixed in and they can't say, "Well, we didn't
3 separate them and we can't tell you the difference."
4 That's very important that there be a common -- that
5 you emphasize that commonality --

6 MR. GRIMES: Yes.

7 COMMISSIONER ROGERS: -- of data collection.
8 And if they want to set a lower cut-off level, then
9 they have the data that shows what in addition they
10 picked up in that lower level.

11 MR. GRIMES: Yes. That is specified by the
12 rule that they will report at the levels we set as
13 well as their own levels. They will record, rather,
14 at those levels.

15 (Slide)

16 MR. GRIMES: Number 25. Just to mention
17 that we are also issuing some examples for the
18 enforcement policy on our program breakdowns or
19 failures which might cause us to take enforcement
20 action in this area.

21 (Slide)

22 MR. GRIMES: Number 26.

23 CHAIRMAN ZECH: Before you go on to that --

24 MR. GRIMES: Yes.

25 CHAIRMAN ZECH: As I understand your

1 proposal, it seems to me that there should be
2 consideration of a direct requirement imposed on the
3 license operators themselves. And as I understand it,
4 that's not included so that enforcement action should
5 be taken or could be taken against the operator
6 himself who we license. It's against the licensee, as
7 I understand it, but not --

8 MR. GRIMES: Yes.

9 CHAIRMAN ZECH: -- a provision against the
10 individual reactor operator, for example, that we
11 specifically license. Is that correct?

12 MR. STELLO: I would think we could take the
13 action against the individual licensee.

14 CHAIRMAN ZECH: Well, that's what I'm
15 asking.

16 MR. PARLER: Mr. Chairman, may I comment?

17 CHAIRMAN ZECH: Please.

18 MR. PARLER: All that the -- the discussion
19 at this point relates in context to the discussion a
20 few minutes ago about the need and the recommendation
21 to consider whether the PFR 56, the proposed final
22 rule if it becomes effective should be extended to
23 other areas, that is a detail of the program, the
24 testing, etcetera, etcetera. Aside from that, if any
25 fitness-for-duty problem, even now, is detected in any

1 area, a fitness-for-duty problem or question which
2 possibly could effect the public health and safety, we
3 do have the authority to proceed with enforcement
4 action.

5 CHAIRMAN ZECH: On an individual --

6 MR. PARLER: Usually it is against the
7 licensees for the material or for the facilities. But
8 in the case of an operator, those people happen to be
9 licensed, so we, indeed, could proceed against those
10 individuals and, in fact, there is a proceeding, at
11 least one going on now, where we are doing this--
12 doing just that.

13 I have recommended -- I will recommend that
14 some language be put not in the rule, but in the
15 introductory statement which would make what I've just
16 talked about as clear as we can.

17 CHAIRMAN ZECH: I think it should be
18 clarified.

19 MR. STELLO: Mr. Chairman, I would indicate,
20 if my recollection serves me right, we've already
21 issued and there is pending now an enforcement
22 proceeding on a licensed operator --

23 CHAIRMAN ZECH: Yes.

24 MR. PARLER: I just said that.

25 CHAIRMAN ZECH: Yes. That's right. And we

1 know we can do that for public health and safety,
2 broad considerations. And that's broad authority we
3 have. But in this specific area we're talking about
4 drugs and alcohol, it seems to me it might clarify the
5 situation and emphasize it that we would --

6 MR. STELLO: General Counsel had an
7 excellent idea. We'll put -- make -- clarify it in
8 the statement of consideration.

9 MR. PARLER: We don't want to discuss it in
10 too much detail right at this point because we do have
11 an ongoing --

12 CHAIRMAN ZECH: Yes, I understand that.

13 MR. PARLER: -- case. And we have our legal
14 theories.

15 CHAIRMAN ZECH: Right. Well, let's just
16 proceed then, if we've made our point.

17 MR. STELLO: Yes, sir.

18 MR. GRIMES: All right, number 26. Just to
19 go over other changes to the proposed rule that are
20 before the Commission for consideration.

21 We have specified in the final rule that a
22 test is not confirmed positive until the medical
23 review officer reviews the test results. And this
24 would speak to the cases where there may be a cross
25 reaction from foods or other drugs. These -- we've

1 prohibited licensees from taking action on those
2 initial screening results and required that the
3 medical review officer complete his evaluation before
4 it's actually a positive.

5 COMMISSIONER ROBERTS: Who is that medical
6 review officer?

7 MR. GRIMES: Beg your pardon, who is?

8 COMMISSIONER ROBERTS: Yes.

9 MR. GRIMES: A licensed physician who is
10 hired by the licensee.

11 MR. BUSH: Who has a background --

12 COMMISSIONER ROBERTS: Each -- each licensee
13 would have a designated --

14 MR. GRIMES: Medical review officer, yes.

15 MR. BUSH: Yes. The guidelines specifies
16 qualifications.

17 COMMISSIONER ROBERTS: Not an employee of
18 the testing lab?

19 MR. BUSH: No.

20 MR. GRIMES: No. We're also specifying that
21 this process must be completed within ten days of the
22 initial test so that there's not a long delay in lab
23 work or something doesn't get addressed promptly.

24 Going along, as I said, we're limiting the
25 access to the results of those preliminary tests until

1 they're confirmed.

2 And another change, the third bullet on the
3 page, relates to the verification of employment
4 history. We're trying to make that pretty exactly
5 consistent with the access authorization policy
6 statement and industry guidelines there.

7 (Slide)

8 MR. GRIMES: Number 27. We are making more
9 explicit in the general performance objectives are
10 concerned about reliability and trustworthiness in
11 addition to impairment, potential for impairment. We
12 got a number of comments, the second bullet--
13 relating to the second bullet, which said that
14 specifying a screening test immediately prior to
15 access was too vague and asked for a quantification.
16 We have specified that the screening test must be done
17 within 60 days prior to the initial granting of
18 unescorted access.

19 We've also specified specifically that the
20 testing laboratories must be HHS certified, even
21 though they will be testing for other than the--
22 maybe testing for other than the HHS panel of drugs.
23 For other cut-off levels they must be at least
24 certified by HHS to provide a very high standard of
25 reliability for the testing.

1 COMMISSIONER ROBERTS: Did you say earlier
2 how many laboratories currently have the HHS
3 certification?

4 MR. GRIMES: Yes. Ten.

5 COMMISSIONER ROBERTS: Ten?

6 MR. GRIMES: Ten -- the initial publication
7 listed ten and that included the --

8 COMMISSIONER ROBERTS: Throughout the whole
9 country?

10 MR. GRIMES: Yes. They're distributed
11 throughout the whole country and HHS is in the process
12 of evaluating others.

13 (Slide)

14 MR. GRIMES: Number 28. We also specified
15 that --

16 CHAIRMAN ZECH: But you have checked to see
17 that those 10 laboratories do, indeed, have the
18 capacity for handling our drug program?

19 MR. GRIMES: Yes, particularly when on-site
20 screening programs are taken into account.

21 CHAIRMAN ZECH: Yes.

22 MR. GRIMES: The volume that goes off for
23 confirmation of these laboratories will vary from
24 site-to-site, but they should not overwhelm the
25 laboratories compared to the other federal government

1 requirements.

2 CHAIRMAN ZECH: All right. Thank you.

3 Let's proceed.

4 MR. GRIMES: Number 28 required that during
5 the access authorization checking that there be a
6 signed release to support the inquiry of other
7 facilities so it's clear that those other facilities
8 are authorized to release fitness-for-duty information
9 from past employment at that licensee. If the
10 individual does not want to sign the release, of
11 course, then the hiring licensee would not grant
12 unescorted access.

13 We've increased the frequency of testing in
14 certain cases during the first four months following a
15 reinstatement after a three year or five year
16 prohibition from access.

17 (Slide)

18 MR. GRIMES: Number 29. The -- we've tried
19 to clarify the appeals process. We now make it
20 explicit that all persons tested, whether they're
21 contract or employees, have a right to some kind of
22 appeal on the test results. It can be an independent
23 licensee manager or it could be an existing grievance
24 procedure.

25 In those cases where a licensee relies on a

1 contractor program, than the contractor appeals
2 process would have to include this. The licensee
3 would not include this. But where the licensee tests
4 a contractor under its program, then it would have to
5 have an appeal on that test result.

6 (Slide)

7 MR. GRIMES: Number 30, which is the last--

8 COMMISSIONER ROGERS: Excuse me. Just you
9 say that the appeals process applies to the test
10 results only. What do you have in mind in emphasizing
11 that?

12 MR. GRIMES: I think the intent there was to
13 say that if the utility feels he's been --

14 COMMISSIONER ROGERS: Not the penalty?

15 MR. GRIMES: I mean if the individual feels
16 that he has had some other injury from the hiring
17 contractor, some other reason why he's not hired, that
18 that doesn't apply. We're focusing on test results.

19 Number 30. We added some categories of
20 persons authorized access. For example, to personal
21 information. For example, those responsible for
22 deciding matters on review and appeal and auditors and
23 we've restricted the law enforcement access that we
24 had in the proposed rule to conditions under a court
25 order.

1 That completes the presentation on the
2 principal issues and the principal changes that were
3 made to this point. And the staff's recommendation is
4 that the Commission approve the rule as recommended in
5 -- with the conditions recommended in the staff paper
6 and that we proceed from this point to implement a
7 fitness-for-duty program for power reactors.

8 CHAIRMAN ZECH: Thank you very much.

9 MR. STELLO: We're through, Mr. Chairman.

10 CHAIRMAN ZECH: All right. Thank you.

11 Questions from my fellow Commissioners.
12 Commissioner Roberts?

13 COMMISSIONER ROBERTS: No.

14 CHAIRMAN ZECH: Commissioner Carr?

15 COMMISSIONER CARR: Yes, I've got one -- one
16 area I think that's left open and it's caused me a lot
17 of problems in the past. And that's what happens if
18 the civilian authorities bust a guy for drugs and it's
19 totally off-site, hasn't anything to do with the
20 utility. He's in Fort Lauderdale for Easter vacation.
21 He's tried there, found guilty and comes back. He's
22 clean when he gets back. What do we do? How do we
23 handle those guys who do what we don't want them to do
24 off-site? I can't find it anywhere in here. I can
25 find where it says "any acts by any person licensed to

1 operate a power reactor by any supervisory personnel
2 assigned involving the sale, use or possession
3 resulting in confirmed positive tests involving use of
4 alcohol." Those have to be reported to us, but that's
5 the only paragraph I could find that looks like it
6 will have anything to do with so-called off-site, non
7 duty type use or abuse.

8 MR. BUSH: Well, there's two problems there.
9 Number one, is licensee acquiring the information and,
10 obviously, requiring -- they could require the
11 employee to report it. That doesn't necessarily mean
12 that he will report it, as you can well understand.

13 Typically the licensees, that would probably
14 fall under the aspect of criminal conduct since he was
15 apprehended and there was probably a conviction
16 involved. And typically their personnel policies
17 indicate that some sort of personnel or disciplinary
18 action will be taken if criminal conduct is --

19 COMMISSIONER CARR: A lot of places it's a
20 misdemeanor to even have possession, you know.

21 MR. BUSH: That's unfortunately true,
22 because the courts are so overloaded that unless you
23 have a bale of marijuana, they drop the charge.

24 COMMISSIONER CARR: I don't -- I don't know
25 how to plug that hole, but I'm concerned about it

1 especially in some states.

2 MR. GRIMES: Yes, we expect licensees to
3 continue as they do now to consider known off-site
4 behavior in their --

5 COMMISSIONER CARR: Well, if you know about
6 it, you can always use that as a for-cause test.

7 MR. GRIMES: Or a reason to test frequently
8 or something.

9 MR. STELLO: It seems to me that that would
10 be the same thing as though he were caught by a random
11 test.

12 COMMISSIONER CARR: Well, it's --

13 MR. STELLO: It ought to have the same
14 effect as being --

15 COMMISSIONER CARR: Yes, if you can find
16 out.

17 MR. STELLO: I see. If you found out --

18 COMMISSIONER CARR: My question is, how are
19 we going to find those out, I guess.

20 MR. GRIMES: We do not have a way of
21 tracking that.

22 MR. BUSH: Theoretically, when a person is
23 initially applying for employment, he submits a
24 fingerprint card to the FBI. And the Fort Lauderdale
25 police department should forward that information to

1 the FBI to their repository. But then --

2 MR. GRIMES: That applies to this screening,
3 but again this applies to not only drug testing but
4 any kind of fingerprinting --

5 COMMISSIONER CARR: You can take the case of
6 the seller who is not a user in the local community
7 and you'll never catch him in a screening test.

8 MR. BUSH: That's true. That's true.

9 MR. GRIMES: This applies to armed robbery
10 as well. Our access authorization goes through it
11 once, but subsequent acts are not tracked.

12 COMMISSIONER CARR: Okay. I don't have a
13 solution for it, but I do worry about it.

14 MR. BUSH: Okay.

15 CHAIRMAN ZECH: Mr. Rogers?

16 COMMISSIONER ROGERS: A couple of thoughts.
17 One on the uses of the samples for other purposes.
18 You addressed that in section 11.2.2 but I'm still a
19 little concerned. I'm not sure what we can do, if
20 anything, of -- in the case of a use of these tests by
21 a licensee for a totally different purpose from the
22 drug abuse screening.

23 We're requiring them to conduct these tests
24 and set them up, but they could be used for other
25 purposes, other personnel actions and so on and so

1 forth.

2 MR. GRIMES: Well, we tried to specify in
3 the guidelines 2.1.d of the appendix -- here, I'll
4 read that, which says "specimens collected under NRC
5 regulations requiring compliance with this part may
6 only be designated or approved for testing as
7 described in this part and shall not be used to
8 conduct any other analysis or test without the
9 permission of the tested individual."

10 MR. STELLO: I don't think that's the
11 Commissioner's question. I think he's wondering --

12 COMMISSIONER ROGERS: No. I don't think that
13 quite covers it. It might, but --

14 MR. GRIMES: It might -- yes.

15 COMMISSIONER ROGERS: It doesn't really
16 address the use of it, it addressed the kinds of
17 further tests that would be done.

18 MR. GRIMES: Tests performed.

19 COMMISSIONER ROGERS: And it might cover it,
20 but I know that there have been some situations that
21 have come up when -- where random drug tests were
22 extended, that the samples were used for --to look for
23 other things, pregnancy for example, and then action
24 was taken, personnel action was taken on the basis of
25 that data. Now, the data was collected only for drug

1 test, it was not collected for another purpose, and
2 yet the organization, not one of our licensees, then
3 used it for a different kind of personnel action. And
4 it just occurs to me that we're opening through this
5 the door through this process which we're insisting on
6 for other uses. I'm not sure what authority we have
7 to prevent that, if any. But it's something that one
8 thinks about a little bit.

9 MR. BUSH: This language is borrowed from--

10 COMMISSIONER CARR: It sounds like your
11 paragraph fixed that.

12 MR. GRIMES: Yes.

13 MR. BUSH: Yes.

14 MR. GRIMES: Well, it says it shall not be
15 used to conduct any other analysis or test. But if
16 there is something in the existing test result, for
17 example, the medical review officer sees a gas
18 chromatograph readout, which is a complete readout of
19 all the blips on the curve, and if he can interpret
20 that in some way even though the test was only done
21 for the purpose of the test --

22 COMMISSIONER ROGERS: Precisely. Yes.

23 MR. GRIMES: I see your point.

24 COMMISSIONER ROGERS: Then it's used for
25 another purpose. Now, I'm not sure. I don't know

1 whether General Counsel could throw any light on this
2 as to what we can have to say about that, if anything.

3 MR. PARLER: Well, maybe I should think
4 about it further and I will after the meeting. But
5 for just right now, we're talking about an area where
6 the utilities are free and the licensees are free, at
7 least initially, to come up with programs such as this
8 to serve their own needs. They have a program which
9 produces certain information. It would seem to me
10 that unless it has to do -- the improper use of it has
11 to do with our public health and safety
12 responsibilities, certainly is, there are questions as
13 to the scope of our authority. That doesn't mean that
14 the utilities would be free to do whatever they want.
15 There might be state laws, there may be union
16 agreements. And, indeed, if the information were used
17 allegedly in the eyes of an employee to take
18 disciplinary action against the employee, presumably
19 for the space on the information that you're talking
20 about but in the eyes of the employee is really based
21 some other information, such as raising safety
22 questions, we do in our regulations and there is a
23 federal law section 210 that gives the employee
24 certain protection there if the employee proves his or
25 her case and also the right to be made whole for any

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1 injuries that are suffered. But beyond that, I would
2 have to think further.

3 MR. BUSH: I might point out that this
4 language was borrowed from the HHS Guidelines and I
5 guess there's an assumption on our part that there was
6 some kind of legal review. And the language --

7 COMMISSIONER ROGERS: It sounds pretty good.

8 MR. BUSH: -- as I understand it, was
9 intended to accomplish just exactly what you've
10 pointed out, Commissioner Rogers.

11 COMMISSIONER ROGERS: Well, but I never
12 assumed that that necessarily --

13 MR. BUSH: Yes.

14 COMMISSIONER ROGERS: -- is the case.

15 MR. BUSH: Correct.

16 COMMISSIONER ROGERS: Assumptions are always
17 bad.

18 MR. GRIMES: I'll agree with that.

19 COMMISSIONER ROGERS: One should always look
20 because everybody assumes that somebody looked and
21 nobody looked.

22 But I don't know if there's any more to say
23 on that, but I would like to hear from General Counsel
24 on it.

25 There is a comment in the SECY that I'd just

1 like to comment on on page 7. There's a statement
2 that the staff believes that any blood alcohol content
3 while an employee is on duty is cause for concern.
4 Now what do you mean by "any?" I have a lot of
5 trouble with such a word which is non-quantitative and
6 its meaning, in a sense, depends on time because any
7 means detectable, and detectable is something which is
8 changing all the time. As instrumentation improves,
9 we can begin to detect things that we never could see
10 before.

11 And so, I don't know that your -- that that
12 point of view that you express there is reflected
13 again in any way in your document, but if it is, I'd
14 like to know about it.

15 MR. GRIMES: I think it was a poor choice of
16 words and a better choice would have been we believe
17 that any amount should be evaluated. I think the
18 concern was too strongly -- too strong of words.

19 COMMISSIONER ROGERS: Well, it's the
20 question of any because we don't know what any means.

21 MR. GRIMES: That's right.

22 COMMISSIONER ROGERS: And does the amount of
23 alcohol that appears in a person's blood after having
24 had a dinner with a dessert that had some sherry in
25 it, does that give you cause for concern? It might,

1 it might not. But I'd like to know what "any" means.
2 It's a very broad gauged statement.

3 MR. GRIMES: I think --

4 MR. STELLO: We talked about this very
5 extensively. I think the simple problem is we don't
6 want to conclude that someone with 0.039 percent
7 alcohol is okay.

8 COMMISSIONER ROGERS: Okay.

9 MR. STELLO: It varies from individual to
10 individual. The concept, the idea is simple. Even
11 though you didn't exceed the number, someone ought to
12 be asking a question, well if there's a belief that
13 someone has, in fact, consumed some alcohol --

14 COMMISSIONER ROGERS: Yes.

15 MR. STELLO: -- are they okay? I think
16 that's the thrust of what we're looking for rather
17 than trying to hang our head on -- where I think there
18 is general belief that even, you know, numbers less
19 than 0.04, there might be any problem. That's--
20 that's the idea.

21 COMMISSIONER ROGERS: Well, I accept that,
22 but any means any.

23 MR. GRIMES: Yes.

24 COMMISSIONER ROGERS: And that means any
25 that could be detected by any means. And that's -- I

1 have a little trouble with going quite that far with
2 it.

3 MR. GRIMES: I think the words were --

4 COMMISSIONER ROGERS: I think it needs just
5 maybe a little bit of clarification.

6 MR. STELLO: I think, for example, as I
7 recall, a diabetic consistently would show an alcohol
8 level that's measurable in their blood all the time.

9 COMMISSIONER ROGERS: Yes.

10 MR. BUSH: Sugars and fruit will turn into
11 alcohol --

12 MR. GRIMES: So there is some level that is
13 on evaluation dismissed.

14 MR. STELLO: But I think -- what we were
15 trying to get at, what I said, is not trying to be
16 precise that --

17 COMMISSIONER ROGERS: Likely to cause
18 impairment -- any level likely to cause impairment.

19 MR. STELLO: Yes. What you're concerned
20 about is if there's impairment, the individual ought
21 not to be on shift.

22 COMMISSIONER ROGERS: And the other thing
23 relates to this question of prescription and over-the-
24 counter drugs. We're talking about fitness-for-duty
25 here. Some of the subsidiary reports that we received

1 on these are very interesting, but it's not clear to
2 me what the conclusions of those are insofar as this
3 rule reflects that concern. Where do we stand in the
4 rule with respect to impairment by prescription or
5 over-the-counter drugs?

6 MR. GRIMES: Those are included in our
7 general concern and any impairment that is detected
8 the rule says no matter from what cause, you should
9 take action to take the person off shift. We've left
10 -- and some of the drugs tested for, for example,
11 amphetamines may be included in prescription drugs
12 also. So in a way, there's an overlap there.

13 Benzodiazepines and barbiturates are two
14 specific things that are in that class. Whether or
15 not we included them here, some licensees do test for
16 them.

17 The way we've spoken to that in the rule is
18 mainly in the sanctions we've said for those
19 substances the sanctions that we specified for the
20 legal drugs and the panel of drugs are not to be
21 automatically implied, but as in the case of alcohol
22 each licensee must have a system to consider those.
23 And we would hope that guidance would be provided to
24 licensees on the nature of substances that might cause
25 impairment and that the licensees would appropriately

1 test as the technology changes for other drugs that
2 might cause that impairment.

3 We've left the sanctions to be determined on
4 a case-by-case basis there.

5 COMMISSIONER ROGERS: Well, I know we're
6 probably not finished with this. It's the first
7 start, and it seems to me a very good one, on the
8 whole problem.

9 What do you envision as a review process and
10 some kind of a time in which we might revisit this
11 whole program to see how well it's worked, where it
12 might be improved, changed?

13 MR. STELLO: About a year or 18 months after
14 its inception.

15 COMMISSIONER CARR: After the 360 -- I mean
16 after the 180 days?

17 MR. STELLO: Yes. After we start actually
18 collecting information and data. After about a year
19 to 18 months I think it's time to go back and start
20 seeing what we learned from that information.

21 COMMISSIONER ROGERS: Good. Good. Thank
22 you.

23 CHAIRMAN ZECH: Mr. Curtiss?

24 COMMISSIONER CURTISS: Just a quick comment.
25 I thought the SECY paper and the manner in which the

1 issues were laid out, the presentation, the options
2 was very well done. I'd like to commend everybody who
3 contributed to this briefing. Thank you.

4 CHAIRMAN ZECH: Let me just ask a question--
5 really make a comment on the cut-off. It seems to me
6 that what the staff has said is that they're
7 suggesting that we go with the cut-offs that are
8 fairly well established by the federal government, and
9 I understand that that -- that would have, certainly,
10 the strength of the federal government decisions that
11 have already been made. There was a discussion of
12 whether or not we should lower those cut-offs levels,
13 and we understand that's within our authority to do
14 so.

15 I would suggest that my -- that we might
16 want to consider if we do go along with what the staff
17 has recommended as regards cut-offs, that we might
18 want to -- and if we don't want to accept a lower
19 level, which we could, of course, as we've been told.
20 But if we don't want to do that, perhaps we could
21 accept the cut-offs as presented by the staff and then
22 go forward with the notice of proposed rulemaking to
23 change the cut-off levels and during that time ask the
24 National Institute for Drug Abuse as well as HHS to
25 comment on it. In other words, to see if we couldn't

1 get a rather authoritative review as to whether it
2 would be appropriate or not for us to lower these
3 levels. That's something I think we might want to
4 consider if we don't want to lower the cut-off levels
5 ourselves. And as the staff has pointed out, it may
6 not be -- the staff doesn't seem to have the
7 confidence that we could do that now.

8 MR. BUSH: Mr. Chairman?

9 CHAIRMAN ZECH: Yes.

10 MR. BUSH: NUMARC and the licensees, a
11 couple of the testing laboratories and some other
12 people, consultants who have some knowledge in this
13 area, all recommended lower cut-off levels.

14 MR. GRIMES: Well, I think what Mr. Bush is
15 saying is from a technical standpoint that there isn't
16 a problem. But the problems relate to the policy.

17 CHAIRMAN ZECH: I understand that. I
18 understand that. And you have told us to --

19 MR. BUSH: We've already gotten public
20 comments in the recommendations to lower.

21 COMMISSIONER CARR: It's a policy matter,
22 Mr. Chairman.

23 CHAIRMAN ZECH: That's right.

24 COMMISSIONER CARR: I would think we'd want
25 to go with the lower levels and then ask them for a

1 review and --

2 CHAIRMAN ZECH: We can do that.

3 COMMISSIONER CARR: -- change them up.

4 CHAIRMAN ZECH: We can do that. We can --

5 COMMISSIONER CARR: It's harder to go down
6 than it is up.

7 CHAIRMAN ZECH: We can go at the lower level
8 and say that's what we've decided based on the best
9 judgment we have. I'm just suggesting that if we
10 didn't want to do that, there's another alternative,
11 and that's to go with the notice of proposed
12 rulemaking.

13 So we have options, is what I'm trying to
14 say. We can either go with it if we have the
15 confidence and recognize that the comments have been
16 received, would give us the assurances to go with it,
17 let it stand or if we don't want to do that, we still
18 have another alternative and that would be to go with
19 the notice of proposed rulemaking and force the issue
20 itself.

21 I'm just suggesting that's an alternative,
22 that's all.

23 MR. STELLO: Mr. Chairman.

24 CHAIRMAN ZECH: Yes.

25 MR. STELLO: There are many options that

1 concern this level. Whatever the Commission decides,
2 we'll do. I just feel very, very nervous about us
3 getting into an area we really haven't worked in yet.
4 And maybe --

5 CHAIRMAN ZECH: Well, I understand your
6 position. That's why I'm presenting this other
7 proposed rulemaking, perhaps, as an alternative to
8 what you're suggesting. In other words, if we don't
9 feel confidence enough to lower it --

10 COMMISSIONER CARR: If EDL doesn't like it,
11 lead the field in this --

12 CHAIRMAN ZECH: Yes.

13 COMMISSIONER CARR: But I've led the field
14 in it a long time. I don't mind stepping out again.

15 CHAIRMAN ZECH: So what we're saying is
16 that, you know, if we decide to go ahead, that will be
17 our responsibility. We'll accept that. But if we
18 feel that your strong advice is overwhelming, then
19 perhaps we can go the other way. I'm just suggesting
20 to my colleagues that we might want to think about
21 that.

22 Well, let me also commend the staff for an
23 excellent briefing, but more than that more the way
24 you've handled this very important issue for a long
25 period of time. A lot of fine people on the staff

1 here have worked on it. I know you've had experts,
2 consultants helping you, too. And we thank those of
3 you are here today for your contributions.

4 I do think it's a responsible action on our
5 part. We have taken a while to come to a rule, but I
6 think again the utilities do merit recognition for
7 putting in place each one of them, their own drug
8 policy, and have had in place now for some period of
9 time. But we do feel, I think, that because of the
10 inconsistencies in the utilities that a drug is
11 appropriate. At least I feel that way. So I would
12 encourage my fellow Commissioners to act promptly on
13 the proposal that's before us and try to make a
14 decision on this when we can.

15 I believe it's a responsible action to take
16 and I think this is the time to take it.

17 Any other comments? If not, we stand
18 adjourned. Thank you very much.

19 (Whereupon, the briefing was adjourned at
20 11:35 a.m.)
21
22
23
24
25

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting
of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON FINAL RULE ON FITNESS FOR DUTY

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: FEBRUARY 8, 1989

were transcribed by me. I further certify that said transcription
is accurate and complete, to the best of my ability, and that the
transcript is a true and accurate record of the foregoing events.

Judy Hadley

Reporter's name: _____
(if other than transcriber)

COMMISSION BRIEFING ON FINAL
FITNESS-FOR-DUTY-RULE

FEBRUARY 8, 1989

BACKGROUND

- °PROPOSED RULE PUBLISHED SEPTEMBER 22, 1988
- °COMMENT PERIOD ENDED NOVEMBER 21, 1988
- °NUMEROUS PUBLIC COMMENTS ANALYZED AND
MANY INCORPORATED

PRINCIPAL ISSUES

- ALTERNATIVES TO RANDOM CHEMICAL TESTS
- RANDOM TESTING RATES
- ALTERNATIVES TO HHS GUIDELINES
- SPLIT SAMPLES
- ALCOHOL

PRINCIPAL ISSUES (CONT'D)

- CUT-OFF LEVELS FOR DRUGS
- DRUGS TO BE TESTED
- RECORD KEEPING FORM
- CONSTRUCTION AND OTHER SCOPE DECISIONS
- DATE FOR IMPLEMENTATION
- IMPLEMENTATION
- ENFORCEMENT POLICY

ALTERNATIVES TO RANDOM TESTS

- NO ALTERNATIVES CURRENTLY AVAILABLE
- OTHER TECHNIQUES NOT RELIABLE AND
DO NOT ADDRESS IMPAIRMENT AND
TRUSTWORTHINESS

RANDOM TESTING RATES

- HIGH RATE USED FOR MILITARY MAY NOT BE ESSENTIAL FOR LICENSEES
- NO COMMENTERS SUPPORTED 300% RATE
- OPTION 1: TEST RATE TO ENSURE 90% TESTED AND 30% RATE FOR THOSE TESTED
- OPTION 2: 300% RATE

RANDOM TESTING RATES (CONT'D)

- ° OPTION 3: RANDOM ASSIGNMENT OF DAY TO
BE TESTED (ESTIMATED RATE
200%)
- ° OPTION 4: TEST ALL WORKERS ONCE EACH
YEAR, AND 50% RATE
- ° OPTION 5: 100% RATE
- ° CONSIDER LOWER RATE AFTER 2 OR 3 YEARS

ALTERNATIVES TO HHS GUIDELINES

- HHS GUIDELINES CONTAIN TERMINOLOGY AND PROVISIONS INAPPROPRIATE FOR NUCLEAR INDUSTRY.
 - LIMITATIONS ON DRUGS TO BE TESTED
 - NO ON-SITE TESTING PROVISIONS
 - NO OPTION TO SPLIT SPECIMEN SAMPLES
- HHS GUIDELINES ADAPTED AS APPENDIX A

SPLIT SAMPLES

- SPLITTING OF SAMPLES PERMITTED BUT NOT MANDATED
- USE WHERE ADDITIONAL CONFIDENCE IN THE PROCESS IS SOUGHT BY WORKFORCE

ALCOHOL

- RULE WOULD REQUIRE TESTING FOR ALCOHOL
IN CONJUNCTION WITH ALL TESTS FOR DRUGS

ALCOHOL (CONT'D)

- ° SAFETY IMPLICATIONS OF LOW ALCOHOL LEVELS SHOULD BE CONSIDERED BY LICENSEES, AND:
 - OPTION 1: NO CUT-OFF LEVEL SPECIFIED:
SET BY EACH LICENSEE
 - OPTION 2: 0.04% BAC SPECIFIED (USED
BY DOT ADMINISTRATIONS)

ALCOHOL (CONT'D)

- LICENSEE POLICY MUST ADDRESS ABSTINENCE AND CALL-INS
- DISCIPLINARY ACTION SET BY LICENSEES - STRINGENT ACTIONS ENCOURAGED
- ALCOHOL EVENTS INVOLVING LICENSED OPERATORS AND SUPERVISORS REPORTABLE.

CUT-OFF LEVELS FOR DRUGS

- ° COMMENTS BY LICENSEES SUPPORT LOWER CUT-OFF LEVELS THAN HHS FOR MARIJUANA AND AMPHETAMINES
- ° MOST LICENSEES USE LEVELS LOWER THAN THE HHS CUT-OFF LEVELS FOR MARIJUANA.

CUT-OFF LEVELS (CONT'D)

- LOWER CUT-OFF LEVELS PROVIDE GREATER PROBABILITY OF DETECTION

- 70 TO 80% OF MARIJUANA POSITIVES ARE BETWEEN 20 AND 100 NG/ML

CUT-OFF LEVELS (CONT'D)

- POLICY CONSIDERATIONS FOR ADOPTION OF NATIONAL STANDARD
 - EXPERTISE OF HHS AND NIDA
 - USE BY DOT ADMINISTRATIONS
- RULE ADHERES TO HHS CUT-OFF LEVELS BUT PERMITS LOWER LEVELS

DRUGS TO BE TESTED

- STAFF PROPOSED ALCOHOL, BENZODIAZEPINES, AND BARBITURATES BE ADDED TO THE HHS TESTING PROTOCOL.
- LICENSEES ENCOURAGED TO TEST FOR OTHER DRUGS.

DRUGS TO BE TESTED (CONT'D)

- EDO RECOMMENDS ADDING ALCOHOL BUT REQUESTING HHS TO EVALUATE BENZODIAZEPINES AND BARBITURATES PRIOR TO ADDITION.

RECORD KEEPING FORM

- ° MOST RESPONDENTS ASKED FOR DELETION OF FORM
- ° COLLECTING DATA IN STANDARD FORMAT WOULD:
 - ASSURE THAT APPROPRIATE DATA IS COLLECTED
 - FACILITATE ANALYSIS AND AUDITS

RECORD KEEPING (CONT'D)

- ° NUMARC DEVELOPING STANDARD DATA COLLECTION. STAFF WILL TAKE ACTION IF NUMARC EFFORT NOT TIMELY OR ADEQUATE.

CONSTRUCTION AND OTHER SCOPE EXPANSIONS

- ALL COMMENTS AGAINST APPLYING RULE TO NON-POWER REACTORS, FUEL FACILITIES, AND OTHER LICENSEES
- CONSTRUCTION PERMIT HOLDERS FAVORED EXPANSION OF RULE TO CONSTRUCTION SITES.

CONSTRUCTION (CONT'D)

- RULE WOULD SET GENERAL REQUIREMENTS
FOR SELECTED PROGRAM ELEMENTS FOR
CONSTRUCTION

DATE FOR IMPLEMENTATION

- SEVERAL REQUESTS FOR EXTENSION OF IMPLEMENTATION
- RULE WOULD REQUIRE ALL ELEMENTS IMPLEMENTED WITHIN 180 DAYS

IMPLEMENTATION

TO ASSURE THAT WRITTEN POLICIES AND
PROCEDURES MEET BASIC EXPECTATIONS AND
OTHER ELEMENTS ARE IMPLEMENTED:

- ° LICENSEES WILL CERTIFY IMPLEMENTATION
AND REPORT LOWER CUT-OFF LEVELS

IMPLEMENTATION (CONT'D)

- TEMPORARY INSTRUCTION FOR INITIAL REGIONAL INSPECTION WILL ENSURE THAT EACH LICENSEE PROGRAM IS REVIEWED FOR GENERAL COMPLETENESS AND ADEQUATE IMPLEMENTATION.

ENFORCEMENT POLICY

- ENFORCEMENT POLICY AMENDMENT PROPOSED
TO INCLUDE FFD IN SUPPLEMENT VII

OTHER CHANGES TO THE RULE

- TEST NOT CONFIRMED POSITIVE UNTIL MRO REVIEW OF TEST RESULTS; MUST BE COMPLETED WITHIN 10 DAYS
- LIMIT ACCESS TO RESULTS OF PRELIMINARY TESTS
- BEST-EFFORT VERIFICATION OF EMPLOYMENT HISTORY MEETS "SUITABLE INQUIRY"

OTHER CHANGES (CONT'D)

- RELIABILITY AND TRUSTWORTHINESS ADDED TO GENERAL PERFORMANCE OBJECTIVES.
- PERIOD FOR TESTING PRIOR TO UNESCORTED ACCESS SPECIFIED AS 60 DAYS
- TESTING LABORATORIES SHALL BE HHS-CERTIFIED.

OTHER CHANGES (CONT'D)

- SIGNED RELEASE TO SUPPORT "SUITABLE INQUIRY"
- INCREASED FREQUENCY OF TESTING FOR FIRST 4 MONTHS FOLLOWING REINSTATEMENT

OTHER CHANGES (CONT'D)

- ° APPEALS PROCESS CLARIFIED
 - INCLUDES ALL PERSONS TESTED
 - APPLIES TO TEST RESULTS ONLY

OTHER CHANGES (CONT')

- ADDITIONAL CATEGORIES OF PERSONS
AUTHORIZED ACCESS TO PERSONAL
INFORMATION.
 - THOSE RESPONSIBLE FOR DECIDING
MATTERS ON REVIEW AND APPEAL
 - PURSUANT TO A COURT ORDER
 - AUDITORS



RULEMAKING ISSUE

January 31, 1989

SECY-89-030

For: The Commissioners (Affirmation)

From: Victor Stello, Jr.
Executive Director for Operations

Subject: FINAL RULEMAKING - FITNESS-FOR-DUTY PROGRAMS

Purpose: To obtain Commission approval to publish a final rule.

Background: A Staff Requirements Memorandum of September 12, 1988, directed the staff to publish the proposed Fitness-for-Duty Rule for public comment. The proposed rule was published in the Federal Register on September 22, 1988. The comment period closed on November 21, 1988; 378 letters were received. On October 17, 1988, a public meeting was held at which Dr. Walsh and Commander Irving from the National Institute on Drug Abuse and members of the NRC staff and their contractor answered questions on the proposed rule and received comments. The meeting was transcribed and the comments have been considered along with the written comments received. To expedite consideration of this matter, the policy-related comments were collated and summarized, and summary responses were developed. These responses are provided in the enclosed Federal Register Notice (FRN), which will accompany the final rule. A more detailed compilation of the large number of comments received and their disposition will be forwarded to the Commission under separate cover.

On November 21, 1988, the Department of Transportation (DOT) and its operating administrations (e.g., the Federal Aviation Administration, Federal Railroad Administration, Federal Highway Administration, etc.) published several final rules (53FR47002) to establish drug programs in the transportation industry. The DOT adopted a modification of the Department of Health and Human Services (HHS) Guidelines. The DOT administrations adopted a 50 percent annual rate for random testing (most of these rules start at an annual rate of 25 percent and build to 50 percent within 1 year).

Three issue papers developed by the Battelle Human Affairs Research Center were forwarded to the Commission under separate cover. These papers deal with alcohol, prescription drugs, and Commissioner Rogers' questions to the staff.

CONTACT: Loren L. Bush, NRR
492-0944

Discussion: Principal Issues and Proposed Staff Resolutions

The comments received and the staff responses to these comments are summarized in the Supplementary Information of the enclosed Federal Register Notice. These areas are

1. General Overview
2. Need for Rule
3. Impairment vs. Reliability
4. Scope of Rule
5. Chemical Testing
6. Reliability of Test Results
7. Training and Behavioral Observation
8. For-Cause Testing
9. Sanctions
10. Impairment from Other Causes (Prescription Drugs and Alcohol)
11. Confidentiality of Test Results
12. Employee Assistance Programs
13. HHS Guidelines
14. Relationship to Access Authorization
15. Reporting and Record Keeping
16. Audits of Fitness-for-Duty Programs
17. Implementation Schedule
18. Legal Issues
19. Costs/Benefits

The following discussion extracts for Commission consideration the issues the staff believes are the principal ones now before the Commission with regard to the final rule, along with the proposed resolutions for these issues. In two cases, alcohol and the rate of random tests, alternatives are presented for a Commission policy choice. The issues raised in the 10 specific questions on which the Commission sought comment are also discussed. Cross references to the location of the answers to matters raised by each question are given in Enclosure 1. Cross references to the issues raised by Commissioner Roberts' questions are given in Enclosure 2.

Alternatives to Random Chemical Tests

As discussed in the response to Commissioner Rogers' questions previously transmitted to the Commission, the staff continues to conclude that no alternatives are currently available that would substitute for random chemical tests for drugs. Other techniques do not provide reliable methods of detecting relevant impairment for drugs, including alcohol. In addition, such techniques do not address the potential for impairment or such issues as trustworthiness and reliability which the staff believes to be the principal underpinnings of the rule and an important part

of the access authorization program. The use of illicit substances or the misuse of licit substances (1) raises questions as to past, present, and future impairment of employees affecting workplace tasks, (2) raises concern with regard to introduction of drugs to others in the workplace, and (3) brings into question whether the individual will follow rigorous procedural requirements with the integrity required in the nuclear power industry to ensure public health and safety.

Random Testing Rates

In the area of alternative rates and sampling procedures, the staff has developed options and indicated its preference in each case but has left the specific alternative to be required as a policy choice for the Commission. A comparison of the results from the U.S. Navy program and information submitted by several licensees with random testing programs indicates that the high rate of testing that appears needed in the military may not be essential for the nuclear power industry. In this regard, the Navy, using a 300 percent-per-year testing rate, finds about 5 percent of its tests positive. Commenters in the nuclear industry with random testing programs reported less than 1 percent positive tests, with a utility using a 100 percent-per-year rate reporting 0.5 percent positive tests. These results are particularly noteworthy as most licensees use cut-off levels lower than the Department of Defense (DOD); one licensee lowered its cut-off level for marijuana from 100 ng/ml (the DOD level) to 20 ng/ml (used by most licensees) and tripled the rate of positive tests. It would appear that if the same testing standards were used, the DOD and nuclear industry experiences would be even more divergent. This result appears to reflect a substantially different tested population. Because there may be negative effects on individual employee morale from the high numbers of tests of individuals and from the disruption of the workplace, and because substantially higher deterrence appears to have been achieved in the nuclear power industry with rates of 100 percent-per-year or lower, a testing rate as high as 300 percent-per-year may not be appropriate. However, this option has been retained for Commission consideration along with other options as follows:

1. Alternative A from the draft rule sets two goals; the first goal requires that at least 90 percent of the workforce be tested and the second goal requires that the testing rate for the already-tested population during a year not be set lower than a rate equal to 30 percent of the workforce. The disadvantage of this alternative is its complexity of administration and the creation of a lesser deterrent during part of the year.

2. Alternative B from the draft rule requires testing at a rate equal to 300 percent of the workforce. The disadvantage of this alternative is the possible excessive disruption of work activities and the testing of a few individuals at a very high rate which may affect morale. The cost of this rate may be excessive given the reported low number of positive tests for testing rates at 100 percent per year or lower in the nuclear industry. As discussed above, this option is not recommended.
3. In this method, each worker is randomly assigned a day during the succeeding 365 days on which he or she will be tested, and then, after testing, is randomly assigned a day in the following 365-day period. The worker could be tested several times in one year but is guaranteed at least one test per year. This process allows for testing of the entire workforce during any 365-day period and reduces the testing rate in comparison to Alternative B (the estimated rate is 200 percent). However, there is a possibility that more workers may be selected for testing on a given day than the licensee has a capacity to test. Another disadvantage of this alternative is the need to select testing dates well in advance and the security problems that may result.
4. In this method, all workers are subjected to unannounced testing once during the year, and random testing at a low rate (e.g., 50 percent) is also performed during the year to ensure ongoing deterrence. The staff believes that certain restrictions would need to be placed on unannounced testing methods to ensure an adequate deterrent effect if this option were selected. For example, the testing would need to be done on an individual rather than on a work-unit basis, would need to be performed throughout the year, and would require the selection process to immediately precede testing so that the system would be less vulnerable to prior notice to individuals. The one union local that supported random testing was a local from a site with a program close to that of option 4. The positive test rate has declined using a 20 percent-per-year random test rate at this facility (Clinton).
5. In this method, random testing is conducted at a rate equal to 100 percent of the workforce, resulting in about two-thirds of the workers being tested during the course of a given year. This method would be easy to administer, should provide adequate deterrence, and is the same as that used for NRC employees. The staff recommends this option.

Several other alternatives proposed by commenters were eliminated by the staff. For the time being, the staff believes that testing rates substantially below the 100-percent rate and not supported by other testing (as in options 1 and 4) would not ensure adequate deterrence.

Proposals that workers not be retested until all other workers are tested and proposals that there be a specified maximum number of times that workers are tested within a year cannot be supported because they would make the process nonrandom and would defeat some of the deterrent value of testing.

For any of the options listed above, the Commission may wish to consider an initial high rate for a 2-year period, followed by a somewhat lower rate with a subsequent evaluation of any loss of deterrence at the lower testing rates.

Alternatives to HHS Guidelines

Several commenters suggested that an alternative to the HHS Guidelines is the College of American Pathologists (CAP) Forensic Urine Drug Testing (FUDT) program. Other suggested alternatives were the "AFL-CIO Guide for Drug and Alcohol Testing on the Job," and state laboratory certification programs. Staff has concluded that none of the proposed alternatives match the rigor required by the HHS Guidelines.

Although a few commenters indicated that the HHS Guidelines should be adopted by the NRC in their entirety, a persuasive majority stated that although the HHS Guidelines provide many excellent procedures for ensuring the quality of drug testing programs, they also contain terminology and provisions that are inappropriate for application to the nuclear power industry. The staff agrees with the commenters that such inappropriate terminology and provisions include (1) references to "agencies," to Public Law 100-71, to the Privacy Act, and to the HHS Secretary; (2) limitations in the panel of drugs for which certified laboratories can test; (3) a potential conflict with onsite testing because of the HHS requirement that all testing be done by certified laboratories; and (4) the lack of an option to split specimen samples. To ensure that the HHS Guidelines are appropriately adapted to the proposed rule, many commenters, including NUMARC, recommended that the pertinent sections of the HHS Guidelines be incorporated into the rule itself or that the NRC develop its own guidelines.

A similar course of adapting pertinent parts of the HHS Guidelines for application to a regulated industry was recently chosen by the Department of Transportation. A comparative text of the HHS Guidelines, the DOT Guidelines and the staff's proposal for NRC Guidelines is given in Enclosure 5. The NRC Guidelines would be issued as Appendix A to 10 CFR Part 26.

Split Samples

One of the measures proposed by commenters to provide greater assurance of a fair appeals process was the use of split samples whereby the collected specimen is split into two (or three)

portions and at least one is retained until no longer needed for an appealed retest. The HHS Guidelines require that specimens of positive confirmation tests be retained at the testing laboratory. Because of the high degree of assurance of the integrity of the test results provided by procedural safeguards (such as the chain-of-custody and HHS-certified laboratory procedures), and because some of the same (albeit minimal) chain-of-custody concerns would exist irrespective of the procedural safeguards (even with split samples), the proposed final rule permits, but does not mandate, split samples. This approach may be used by licensees when additional confidence in the process is sought by the workforce.

Alcohol

The staff believes that sufficient information is now available to provide effective regulations on alcohol as a fitness-for-duty concern. An extensive discussion of alcohol is contained in the contractor discussion paper forwarded under separate cover to the Commission. Although most commenters who favored testing for alcohol also favored specification of a cut-off level, the staff believes that the licensee should consider the safety implications of lower alcohol levels. Two options are offered for Commission consideration:

1. Specify no blood alcohol content (BAC) cut-off level but require an evaluation and appropriate actions at any detected BAC.
2. Specify a BAC cut-off level of 0.04 percent for which licensees would individually set sanctions but require an evaluation and appropriate actions at any lower BAC level. The staff recommends this option.

Both options would include random, as well as for-cause and pre-access, testing for alcohol. Screening would be by breath tests with confirmatory testing by a second breath test or by testing of a blood sample if requested by the individual. Both options would also include establishment of a required period of abstinence preceding all scheduled work with a provision for specific reporting of alcohol use by individuals summoned by a call-in. The licensee would have the option of using key individuals who have consumed alcohol before being called in, but the licensee would need to establish suitable controls and procedures (such as a fitness evaluation or escorted status).

Disciplinary action in response to the use of alcohol within the protected area or a determination of unfitness because of consumption of alcohol would be established by licensees. Licensees would be encouraged in the Supplementary Information to the Federal Register Notice to establish stringent sanctions, similar to those for drugs, to discourage drug abusers from turning to alcohol abuse and to heighten workforce sensitivity to the significance of potential impairment. Both use of alcohol within the protected area and determinations of unfitness because of alcohol for scheduled shift work that involve supervisory personnel or licensed reactor operators would be reportable to the NRC within 24 hours.

The DOT's operating administrations have set 0.04 percent BAC for their regulated activities. The Federal Highway Administration's (FHWA's) rule on alcohol (53 FR 39044) will require the States to adopt a cut-off level of 0.04 percent for alcohol for commercial operators to prevent a withholding of Federal-aid highway funds. The FHWA rule also requires a 1-year disqualification for individuals with an 0.04 percent BAC or above and a 24-hour out-of-service sanction for those with any measured BAC or any detected presence of alcohol. Although significant impairment does not appear to occur until a BAC higher than 0.04 percent is present, the staff believes that any blood alcohol content while an employee is on duty is cause for concern.

Cut-off Levels for Drugs

NUMARC, many licensees, and several other commenters held that some of the cut-off levels established in the HHS Guidelines were not stringent enough for some drugs. These commenters were of the opinion that all licensees should use the same cut-off levels consistent with minimum standards set by the NRC to enable them to better withstand challenges in court and to facilitate a more manageable tracking system.

The staff has concluded that 100 ng/ml as an initial screening cut-off level set by the HHS Guidelines would not detect a number of marijuana abusers. For example, recent use of marijuana (i.e., within 6 hours after ingestion) may frequently result in urinary metabolite concentrations that are above 20 ng/ml and below 100 ng/ml. Because marijuana metabolites are lipid soluble and are generally excreted into the urine for a greater period of time than water-soluble drugs, marijuana metabolites may be present in the urine at levels between 20 ng/ml and 100 ng/ml for relatively long intervals. However, these levels usually remain below 100 ng/ml.

Lower cut-off levels would provide a greater probability of detection. One licensee lowered its cut-off level for the initial screening test for marijuana from 100 ng/ml to 20 ng/ml, and the positive rate tripled. When licensees have set the initial screening level at 20 ng/ml, 80 percent of positive tests for marijuana are initially screened between 20 and 100 ng/ml. Six of the seven licensed reactor operators who tested positive for marijuana during 1988 were found during initial screening tests to have metabolites at the following ng/ml levels: 110, >100, 96, 95, 70, 65, 50, and 16. In the last example, the operator also tested positive for cocaine. These data are incomplete; the licensee for one of the licensed operators was unwilling to provide data.

High cut-off levels focus on detection of frequent users. Earlier detection (of occasional users) enhances the probability that the employee can be rehabilitated and retained.

Although the NRC rule would permit lower cut-off levels to be established by licensees, it is likely that some employee bargaining and arbitration processes would result in cut-off levels that are not lower than those specified by NRC. The staff has received assurances that the National Institute on Drug Abuse (NIDA) does not object to lower cut-off levels that are technologically defensible. The only technological consideration that bears on low cut-off levels is that levels as high as 30 ng/ml for the immunoassay screening test have been achieved under laboratory conditions from passive inhalation in which the subjects were exposed to heavy concentrations of marijuana smoke in a confined space for an extended time.

Although lower cut-off levels may be preferable from a technical standpoint, we conclude that, from a policy standpoint, it is undesirable for the NRC to take the lead in this area and that the NRC should await changes to the HHS standards before lowering the cut-off levels further. The Committee to Review Generic Requirements (CRGR) is of the opinion that HHS and NIDA have more expertise in this area than the staff and, therefore a departure from a standard set by HHS and NIDA was not appropriate. The CRGR also recommended that the Commission be made aware of the industry experience with positives at lower cut-off levels, which are reported above. The final rule reflects the adherence to the HHS cut-off levels.

Drugs To Be Tested

NUMARC, many licensees, and several other commenters recommended that several additional drugs be included in the testing protocol. NUMARC and a few other commenters thought that inclusion of the additional drugs should be recommended, while others thought the testing of additional drugs should be required.

Appendix A to the rule adds three substances to the testing protocol: alcohol, benzodiazepines, and barbiturates. Therapeutic doses of benzodiazepines and barbiturates can impair; significant impairment can result from abuse of any of these three substances, especially if taken in combination. The rule will encourage licensees to test for other drugs.

Although the staff has recommended that benzodiazepines and barbiturates be added to the panel of drugs to be tested, I recommend that benzodiazepines and barbiturates not be included at this time. The NRC should request that the Department of Health and Human Services, through the National Institute on Drug Abuse, review the merits of the inclusion of these classes of drugs in drug testing programs. The addition of these substances is a substantial change from the HHS Guidelines and NIDA is regarded as the federal expert in this matter. I agree that the procedural departures from the HHS guidelines which the staff has recommended are appropriate.

Record Keeping Form

A proposed standard data form was published with the rule and comments were requested as to whether it should be part of the rule. Virtually all respondents asked for deletion of the form. The staff believes that collecting data in a standard format would ensure that appropriate data is collected and would facilitate periodic analysis and audits. NUMARC has indicated that industry guidelines will be developed that will include standard data collection elements. The staff therefore proposes that a requirement not be included in the rule at this time. The NUMARC working group has been informed that if the industry guidance does not prove timely or adequate, the staff may take further action in this regard.

Construction and Other Scope Expansions

Most commenters had no comment on expansion of the rule to cover construction sites or said that the scope of the rule should not be expanded from that proposed. However, the commenters favoring expansion of the scope of the rule to cover construction sites were holders of construction permits.

The staff believes that a higher degree of assurance of the adequacy of construction and testing activities could be obtained by requiring fitness-for-duty programs at construction sites. The staff also recognizes, however, that no immediate public health and safety hazard could result from substance abuse at construction sites and that the quality assurance programs of the utility should ensure an adequate level of

confidence that errors from any source, including drug or alcohol use, would be detected and corrected. The staff recommends a general requirement for random testing at construction sites because (1) random testing is a current practice at some construction sites, (2) permit holders might be prevented from performing random testing absent a Federal requirement, and (3) there is a need to take all reasonable measures to ensure the integrity of the work performed at the site. Written procedures and a general requirement for an Employee Assistance Program, an appeals process, and protection of records would also be included.

All comments were against applying the rule to non-power reactor facilities, fuel facilities, and other licensees. The staff sees no need to address these matters on the time scale of this rulemaking.

Date for Implementation

Several commenters requested that the implementation date for the program be extended from 90 days to 180 days, which would result in the same date as required for implementation of the chemical test provisions of the rule. The principal reason given for this extension was the need to complete all the administrative matters, particularly the renegotiation of contracts. The staff agrees that this extension is reasonable. Other commenters requested an extension of the chemical testing implementation date. The staff believes that such an extension should not be granted in view of the safety importance of this rule and the fact that the Commission's intent in this regard has been clear to the industry for some time.

Implementation

To ensure that the written policies and procedures have been developed and meet basic expectations and that other program elements such as training and random testing have been implemented, the following actions are proposed:

1. Licensees are required by the final rule to certify to the NRC that their fitness-for-duty programs are implemented and to specify cutoff levels which are more stringent than the rule specifies. Licensees may request less stringent requirements as exemptions in accordance with §26.6 of the rule.
2. The final rule puts licensees on notice that the Commission may at any time review the written policy and procedures to ensure that they meet the performance objectives.
3. A temporary instruction will be issued to the regions to ensure that each licensee plan is reviewed for general completeness and adequate implementation

The staff believes that these actions are also consistent with the Chairman's commitments in testimony before the Subcommittee on General Oversight and Investigations of the House Committee on Interior and Insular Affairs regarding review of licensee plans.

Enforcement Policy

Accompanying the final rule are amendments to the Commission's General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. These changes, which are to be made to Supplement VII, "Miscellaneous Actions," provide examples by which violations of 10 CFR Part 26 may be categorized. A description of the changes is provided in the Federal Register Notice.

Comparison of 10 CFR Part 26 to the Program for NRC Employees

The drug testing program for NRC employees implemented in response to Executive Order 12564 differs from the proposed final rule in a few key areas.

- o With respect to program scope, the NRC program, as currently written, applies to NRC employees permitted unescorted access to vital areas and does not cover NRC contractors and consultants. However, as a practical matter, requests for unescorted access to protected areas will not normally be made unless the NRC employee is in a testing-designated position. The industry program will cover all persons authorized unescorted access to protected areas, except for NRC personnel (and a few others under specific conditions).
- o With respect to tested substances, the industry program will include testing for all five HHS-prescribed substances, alcohol, benzodiazepines, and barbiturates. The NRC program tests for the five HHS-prescribed substances. Licensees need not petition NRC to test for other drugs; the NRC would need to petition HHS if it desires to test for drugs other than the five specified by HHS.
- o With respect to cut-off levels, the NRC Federal program is required to adhere to the cut-off levels set by HHS. NIDA has under consideration some reduction in cut-off levels for marijuana for Federal programs and has indicated to the staff that it would have no objection to the use of lower cut-off levels for the nuclear industry.

- o With respect to testing frequency, the staff recommends a random testing rate of 100 percent per year for the nuclear industry, which is the same rate as that for the program for NRC employees.
- o With respect to measures to ensure validity and accuracy of test results, the NRC testing guidelines for the nuclear industry, in addition to repeating applicable sections of the HHS guidelines, would
 - require licensees to use a tamperproof sealing system on specimen containers
 - provide guidance for written procedures, instructions, and training
 - provide requirements to prevent subversion of testing
 - permit licensees to collect urine specimens in facilities normally used for other purposes, provided specified security measures are taken
 - permit licensees to split samples
 - permit an individual to request a confirmatory blood test for alcohol

In addition, the rule will permit licensees to conduct initial onsite screening tests of specimens; HHS Guidelines permit only HHS-certified laboratories to conduct such tests.

Coordination: The Office of General Counsel (OGC) has no objections to publishing the rule.

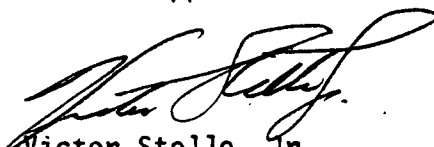
Recommendations: That the Commission:

1. a) Approve publication of the final rule as set forth in the FRN with the stipulation that benzodiazepines and barbiturates be removed from the panel of drugs to be tested. The final rule will add a new Part 26 to require a licensee authorized to operate or construct a nuclear power reactor to implement a fitness-for-duty program.
- b) Approve publication of the amendments to Appendix C to 10 CFR Part 2 as an effective policy statement.
2. Approve option 5 for random testing rates and approve option 2 for the alcohol action level.

3. Direct the staff to (i) request the Secretary, HHS through the National Institute on Drug Abuse, to review the merits of adding benzodiazepines and barbiturates to the classes of tested drugs, both with respect to the NRC rule for the nuclear power industry, and with respect to the NRC and other federal programs, (ii) provide NIDA information on the procedural modifications the NRC has made to further protect individual rights, and (iii) provide NIDA information concerning industry experiences with their fitness-for-duty programs.
4. Certify in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this rule will not have a significant economic impact on a substantial number of small entities. This certification is included in the enclosed FRN.
5. Note:
 - a. That the notice of final rulemaking in Enclosure 3 will be published in the Federal Register allowing 180 days for implementation.
 - b. That, in accordance with 10 CFR Part 51, the staff prepared an environmental assessment and a finding of no significant impact which was included in the FRN concerning the proposed rule.
 - c. That this final rule contains information collection requirements that are subject to review by the Office of Management and Budget.
 - d. That the Subcommittee on Nuclear Regulation of the Senate Committee on Environment and Public Works, the Senate Committee on Governmental Affairs, the Subcommittee on Energy and the Environment of the House Committee on Interior and Insular Affairs, the Subcommittee on General Oversight and Investigations of the House Committee on Interior and Insular Affairs, the Subcommittee on Energy and Power of the House Committee on Energy and Commerce, the Subcommittee on Environment, Energy and Natural Resources of the House Committee on Government Operations, and the House Select Committee on Narcotics Abuse and Control will be informed (Enclosure 7).

- e. That a public announcement will be issued (Enclosure 8).
- f. That the Office of Administration and Resources Management (ARM) will send copies of the final rule to all affected licensees and other interested persons following Commission approval for publication of the final rule.
- g. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it as required by the Regulatory Flexibility Act.

Scheduling: This paper should be scheduled at an open session if a discussion with the staff is desired before approval.



Victor Stello, Jr.
Executive Director
for Operations

Enclosures:

- 1. Cross-reference: 10 Specific Commission Questions
- 2. Cross-reference: Commissioner Roberts' Questions
- 3. Notice of Final Rulemaking
- 4. Annotated copy of Rule changes
- 5. NRC Guidelines (Comparative Text)
- 6. Backfit Analysis
- 7. Draft Congressional Letters
- 8. Draft Press Release

Commissioners' comments or consent should be provided directly to the Office of the Secretary by c.o.b. Friday, February 17, 1989.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Friday, February 10, 1989, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an Open Meeting during the Week of February 20, 1989. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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Enclosure 1

Cross-reference: 10 Specific Commission Questions

CROSS-REFERENCE FOR ANALYSIS OF RESPONSES RELATING
TO THE TEN SPECIFIC QUESTIONS POSED BY THE COMMISSION
IN THE FEDERAL REGISTER NOTICE

1. Are there practical alternatives to random testing, not discussed herein, that provide equivalent deterrence and detection of drug use?

See: 1. Section 5, "Chemical Testing" in the discussion on comments and responses in this proposed FRN

2. Chapter 4 of NUREG/CR 5227

3. Proposed rule at 53 FR 36805

4. Technical paper on Commissioner Rogers' questions related to Detection of Impairment forwarded under separate cover.

2. What practical alternatives, not discussed herein, exist that could determine physical and mental impairment?

No practical alternatives were provided by commenters

But see: 1. Chapter 5 of NUREG/CR 5227

2. Proposed rule at 53 FR 36797, 36807, 36808

3. Technical paper on Commissioner Rogers' Questions related to Detection of Impairment forwarded under separate cover.

3. What rates of random testing and retesting provide an acceptable probability of detection and adequate deterrence? What should be the basis for any future modifications in the rate for random testing? Chairman Zech and Commissioner Carr believe, in view of the military's experience with testing cited in section IV of this notice, that a 300 percent annual testing frequency is more appropriate to ensure that the testing program provides an adequate deterrent. They request specific comments as to whether a 300 percent annual testing frequency (Alternative B) or Alternative A in §26.24(a)(2) in the proposed rule is the more effective testing scheme. Is there some other alternative that should be considered? Data to support recommendations are requested.

See: 1. Section 5, "Chemical Testing" in the discussion on comments and responses in this proposed FRN.

2. Chapter 4 of NUREG/CR 5227

3. Proposed rule at 53 FR 36810

4. Are there effective alternatives to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" issued by Health and Human Services (HHS)

on April 11, 1988 (53 FR 11970) that the Commission should adopt as minimum standards for fitness-for-duty programs at nuclear power plants?

See: Section 13, "HHS Guidelines" in the discussion on comments and responses in this proposed FRN.

5. Are there any additional quality control measures or appeal procedures that should be considered to protect the rights of individuals being tested, to ensure that individuals are not misidentified in the process as drug users, and to provide a mechanism to correct any errors? Specifically, who should have access to knowledge of the results of unconfirmed initial test results (employee, immediate supervisor, higher management levels)? What procedures are necessary to assure appropriate privacy?

See: 1. Section 11, "Confidentiality of Test Results," and Section 18, "Legal Issues" in the discussion on comments and responses in this proposed FRN.

2. Chapter 5 of NUREG/CR 5227

3. HHS Guidelines (53 FR 11970)

6. Should the Commission provide general guidance on potential impairments, such as alcohol abuse and prescription drugs? How should such guidance be implemented in a fitness-for-duty program? Should any random testing program be expanded to encompass legal drugs and alcohol? If so, should the response to a positive test for alcohol be the same as for illegal drugs? What should be the response to a positive test for legal drugs?

See: 1. Section 10, "Impairment from Other Causes" in the discussion on comments and responses in this proposed FRN.

2. Chapter 2 of NUREG/CR 5227

3. Technical paper on Alcohol Use as a FFD Concern (Battelle) forwarded under separate cover

4. Technical paper on Prescription and OTC Drug Use (Battelle) forwarded under separate cover.

7. How long should a person be barred from performing activities within the scope of the proposed rule following removal under the fitness-for-duty policy, and under what circumstances should reinstatement be allowed? How long should records of this removal be retained to facilitate future employment decisions?

See: 1. Section 9, "Sanctions" in the discussion on comments and responses in this proposed FRN.

2. Chapter 7 of NUREG/CR 5227

3. Proposed Rule at 53 FR 36814

8. Are the categories of workers identified for testing appropriate, or is some other population (whole site, control room operators only) necessary/sufficient for safety?

See: 1. Section 4, "Scope of Rule" in the discussion on comments and responses in this proposed FRN.

2. Proposed Rule at 53 FR 36817

9. Should training on the items covered under 3, 4, and 5 of §26.22(a) be provided to all employees covered under the rule so each employee can recognize drugs, indications of the use, sale, or possession of drugs, and impairment of a person covered under the rule and know what action to take?

See: Section 7, "Training and Behavioral Observation" in the discussion on comments and responses in this proposed FRN

10. Finally, the Commission is especially interested in receiving comments on the extent to which NRC regulations on fitness for duty should address other regulated activities not currently within the scope of this proposed rule. Regulated activities being considered for rulemaking or a Commission statement of policy include:

- ° The construction and preoperational testing of nuclear power plants prior to the issuance of a license and the loading of nuclear fuel.
- ° The operation of nonpower reactors used in academic, research, and commercial applications.
- ° Fuel cycle facilities involved in the possession and processing of plutonium or uranium in highly enriched, low enriched, or natural uranium forms.
- ° The utilization of nuclear materials in other activities such as radiography, product irradiation, radiopharmaceutical production, nuclear medicine, uranium milling activities, production and use of various sources, and radioactive waste disposal activities.

See: Section 4, "Scope of Rule" in the discussion on comments and responses in this proposed FRN

Enclosure 2

Cross-reference: Commissioner Roberts' Questions

CROSS-REFERENCE FOR ANALYSIS OF RESPONSES
RELATING TO THE QUESTIONS POSED BY COMMISSIONER ROBERTS
IN THE FEDERAL REGISTER NOTICE

1. I still find no nexus made between the categories of workers chosen for testing and their safety related duties. "The rule would, with limited exceptions, apply to all individuals granted unescorted access to protected areas, and to any licensee or contractor personnel required to respond to the licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures." I would like to see a documented basis for this. Why not the whole site? Why not only control room operators? This may be the correct class of workers but I would like a rationale.

See: Section 4, "Scope of Rule" in the discussion on comments and responses in this proposed FRN

2. The rule portends to provide reasonable assurance that workers are not impaired from a variety of substances, yet it is only focused on illegal drugs. I would like comments on the nature of the impairment suffered by abusing legal drug and alcohol. If the industry program is sufficient to provide a reasonable assurance that legal drugs and alcohol are not causing impairment of workers at nuclear power plants, why is it not sufficient--in conjunction with the local law enforcement agencies--to provide the assurance for illegal drugs? Why are alcohol and abuse of legal drugs excluded from our area of concern?

See: 1. Section 10, "Impairment from Other Causes" in the discussion on comments and responses in this proposed FRN

2. Chapter 2 of NUREG/CR 5227

3. Technical paper on Alcohol Use as a FFD Concern (Battelle)
forwarded under separate cover

4. Technical paper on Prescription and OTC Drug Use (Battelle)
forwarded under separate cover.

3. The staff does an excellent job in describing the effects of marijuana, cocaine, opiates, phencyclidine, and amphetamines and of citing expert works to support their descriptions. I note that each one of the categories of drugs to be tested have observable effects. Given that the purpose of random testing is detection and deterrence, it seems to me that testing for cause would be the preferred alternative since it can also offer detection and deterrence while having a much better chance of being found to be constitutional.

See: 1. Section 5, "Chemical Testing" in the discussion on comments and responses in this proposed FRN.

2. Chapter 4 of NUREG/CR 5227

3. Proposed Rule at 53 FR 36806

4. Technical paper on Commissioner Rogers' Questions related to Detection of Impairment forwarded under separate cover.

4. Finally, I am concerned that we indicate the illegal drugs to be tested, the frequency of the tests, the mode of testing and yet are silent, other than for a "do good" statement, on the details of procedures to ensure protection of the rights of those tested. How is the NRC going to ensure that those rights are protected? If we rely on the unions to protect their members, how are we going to assure there will be "uniform program standards" within the industry?

See: 1. Section 11, "Confidentiality of Test Results," and Section 18, "Legal Issues" in the discussion on comments and responses in this proposed FRN.

2. Chapter 5 of NUREG/CR5227

3. HHS Guidelines (53 FR 11970) as adapted as NRC Guidelines (Appendix A to 10 CFR Part 26)

Enclosure 3

Notice of Final Rulemaking

Nuclear Regulatory Commission

10 CFR Parts 2 & 26

Fitness-for-Duty Programs

Agency: Nuclear Regulatory Commission

Action: Final rule and statement of policy

Summary: The Nuclear Regulatory Commission is issuing its regulations to require licensees authorized to construct or operate nuclear power reactors to implement a fitness-for-duty program. The general objective of this program is to provide reasonable assurance that nuclear power plant personnel are reliable, trustworthy, and not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties. A fitness-for-duty program developed under the requirements of this rule is intended to create an environment which is free of drugs and the effects of such substances.

The Commission is taking this action to significantly increase assurance of public health and safety. The scientific evidence is conclusive that significant decrements in cognitive and physical task performance result from intoxication due to illicit drug abuse, as well as the use and misuse of legal substances. Given the addictive and impairing nature of certain drugs, while recognizing that the presence of drug metabolites does not necessarily relate directly to a current impaired state, the presence of drugs does strongly suggest the likelihood of past, present, or future impairment affecting job activities. In addition, the NRC believes that the reliability, integrity, and trustworthiness of persons working within nuclear power plants is important to assure public health and safety. Since there is an underlying assumption that workers will abide by the licensee's policies and procedures, any involvement with illegal drugs

shows that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the individual may not scrupulously follow rigorous procedural requirements with the integrity required in the nuclear power industry to assure public health and safety. In addition, the Commission is revising its enforcement policy to reflect this fitness-for-duty rule.

Dates: This rule is effective (30 days after publication).

FOR FURTHER INFORMATION CONTACT: Loren Bush, Reactor Safeguards Branch,
Division of Reactor Inspection and Safeguards, Office of Nuclear
Reactor Regulation, U.S. Nuclear Regulatory Commission,
Washington, DC 20555, Telephone: (301) 492-0944.

SUPPLEMENTARY INFORMATION:

Background

On September 22, 1988, the Nuclear Regulatory Commission published in the Federal Register (53 FR 36795) proposed amendments that would issue a new regulation 10 CFR Part 26, "Fitness-for-Duty Program," which would require licensees who are authorized to operate nuclear power reactors to implement a fitness-for-duty program that met uniform standards established by the rule to promote the public health and safety.

Interested parties were invited to submit comments in connection with the proposed amendments within 60 days after publication in the Federal Register. There were 3,079 comments made by 378 responders. A detailed summary and analysis of the comments are contained in NUREG _____ "Fitness-for-Duty in the Nuclear Power Industry: Responses to Public Comments". Upon consideration of the comments received both in writing and during the public meeting held on October 17, 1988,^o and other factors involved, the Nuclear Regulatory Commission has adopted the proposed regulations, with certain modifications generally set forth below.

COMMENTS AND RESPONSES TO THE PROPOSED RULE

1.0 GENERAL OVERVIEW

Summary of Comments

The NRC received 378 comment letters in response to the Notice of Proposed Rulemaking (NPRM). The NRC considered all comments submitted in a timely manner in response to the NPRM and comments and questions received during a public hearing on the draft rule held by the NRC. The comment period for the NPRM closed on November 21, 1988.

Comments were received from the general public; from workers in nuclear power plants; from union locals, national and international headquarters of unions; from the Nuclear Management and Resources Council (NUMARC), 55 power reactor licensees, several non-power reactor licensees; from several vendor and contractor organizations; and from other interested parties.

There were several major issues presented by the commenters. These are summarized along with the NRC responses in the sections that follow. An overview of these comments is provided in this section.

Of primary concern to roughly half of all commenters was the requirement for random drug testing. Although these commenters clearly objected to the use of illegal drugs within the nuclear power industry, this provision of the proposed rule drew a strong negative reaction from private citizens, labor unions, and workers covered by the proposed rule. Vigorous objections were stated based on the perceptions of invasion of privacy and conflict with Constitutional rights resulting from the drug testing provision. Many of these commenters stressed that the level of substance abuse in the nuclear power industry is insufficient to justify such strong action, that nuclear power plant workers have demonstrated their reliability over the years, and that it is both demoralizing and insulting to require proof of their reliability through random drug tests. Other issues were raised concerning the legality of the

proposed rule, including its relationship to labor laws and state and local statutes. These objections are summarized more fully in the following sections.

Those commenters opposing random testing were usually supportive of one or more alternatives. Foremost among these was a combination of supervisor behavioral observation and for-cause testing. While a few commenters opposed chemical testing of any type, most of the commenters, including union organizations and members, expressed support for for-cause testing. Pre-access authorization testing also received some support and very little opposition.

A major criticism of the proposed rule was raised concerning whether the NRC was basing the rule on concerns about on-the-job impairment or on concerns about basic employee reliability, or even upon more general concerns with public morality. Some commenters expressed the opinion that off-site drug use should not be a concern of the NRC, and that the NRC should not require a testing program that is not directly oriented to detecting current impairment.

In contrast, most licensees and NUMARC provided general support for the provision for random testing, viewing it as an effective deterrent to the use of illegal drugs. However, they did object to the possibility that they would be too severely limited by the provision that licensee testing programs must follow the HHS Guidelines. They wanted greater flexibility in the establishment of cut-off levels and the panel of drugs to be covered. Most of the licensees expressed concern over the testing rate to be required by the rule, indicating that it should be at an annual rate equivalent to or less than 100 percent of the workforce subject to testing. They further objected to any provisions that would make the licensee responsible for providing employee assistance program services to contractor personnel and objected to the extent and type of training required by the proposed rule. Other issues raised and more detail on these issues are provided in the sections that follow.

2.0 NEED FOR RULE

2.1 Summary of Comments

A number of commenters raised the issue that there was insufficient evidence of a drug abuse problem in the nuclear power industry to justify the need for the rule. Several commenters indicated that the NRC has failed to establish a factual record regarding the nature and extent of the drug abuse problem. Also mentioned was the opinion that the apparent lack of uniformity among nuclear utility programs is not sufficient justification by the NRC for the rule.

2.2 Summary of Responses

Although drug use among nuclear power plant workers may not be as widespread as in other segments of the population, the NRC does have information to indicate that there is a sufficient problem in the nuclear power industry to warrant the fitness-for-duty rule. For example, data provided by one licensee indicates that 47 of approximately 4,000 random tests of employees were positive, 4 percent of the applicants for employment have tested positive for drug use, and 30 employees and 60 contractors tested positive for cause. Pre-access testing of nearly 12,000 contractor personnel resulted in a 5 percent positive rate. Another licensee reported that approximately 2 percent of approximately 5,000 tests of employees and contractors were positive, 179 persons tested positive for cause, and that the drugs involved included PCP, marijuana, cocaine, amphetamines, barbiturates, alcohol and other drugs. Nationally, among licensees implementing random drug testing programs, an average of around 1 percent of the random tests are positive.

In the first nine months of 1988 there were 387 events involving drug and alcohol reported to the NRC. These events included licensee and contractor employees in all organizational levels and disciplines. Of particular concern to the NRC is that during the last year (1988), 11 licensed reactor operators were reported as being involved with drugs and two were reported as abusing alcohol; none were using these substances while on duty.

The number of significant events reported to the NRC that involve drug use or abuse has been increasing dramatically since 1985. There was a 44 percent increase in reported events between 1985 and 1986. A 73 percent increase was experienced in 1987. This increase appears to be related to the emphasis on fitness for duty by nuclear power licensees and the recently revised safeguard reporting requirements that contained explicit guidance for reporting of drug-related events. However, the increase may also be an indication of an increase in the incidence of drug problems at nuclear power plants.

These data provide sufficient evidence of a significant level of drug use by those employed in the nuclear power industry to support the need for a fitness-for-duty rule. Pursuant to the NRC's statutory authority to protect the public health and safety, the NRC must acknowledge that nuclear power plant workers are not immune to, nor insulated from, drug use or abuse of substances that may affect safety-critical job performance. The NRC believes that any drug use in the nuclear power industry warrants prevention and proactive intervention by the NRC to ensure public safety. The NRC believes that this view is consistent with the increasing awareness of nuclear power licensees that have, as addressed in their comments, drug testing and rehabilitation programs for their workers.

3.0 IMPAIRMENT VS. RELIABILITY

3.1 Summary of Comments

A number of commenters questioned whether certain provisions of the rule, such as random drug testing, were based on concern over on-the-job impairment or were based on concern over the reliability and trustworthiness of the worker. One set of commenters expressed the strongly held belief that mandatory chemical testing is only appropriate if there is evidence to suggest that workers are impaired on the job. Commenters also stated that, because urinalysis does not measure impairment, the detection of illicit drug use through urinalysis is irrelevant to the safe operation of nuclear power plants, and thus should not be an element of the rule. Two commenters requested further evidence regarding the impact of off-the-job drug use on job performance. One commenter stated that, although a positive urinalysis test result does not establish whether an individual was impaired at the time that the sample was given, it allows the employer to determine drug use and conclude reasonably that the possibility exists for future impairment which can impact workplace safety.

Other commenters noted that impairment is not the sole issue. A fundamental concern of drug abuse predominantly relates to the reliability and trustworthiness of the worker who knowingly uses drugs which are illegal. Several commenters, including NUMARC, noted the importance of worker reliability and trustworthiness in an access authorization program, and stated that the use of illegal drugs on or off the job could adversely affect the safety of nuclear power plant operations, or adversely reflect on the integrity, reliability and trustworthiness of workers with unescorted access who are responsible for nuclear power plant safety.

A number of commenters objected to specific wording in the proposed rule related to impairment. These commenters stated that the term "impairment" is imprecise and subject to various interpretations. Another commenter stated

that few nuclear power plant workers are qualified to make a judgment of worker impairment, and that the term presumes an initial standard by which the worker's job performance can be measured.

3.2 Summary of Responses

The NRC recognizes that illicit drug abuse and the misuse of legal substances such as alcohol, prescription drugs, and over-the-counter medications can impair workers in the performance of their safety-related duties and result in significantly reduced workforce reliability. The scientific evidence is conclusive that significant decrements in cognitive and physical task performance result from intoxication due to illicit drug abuse, as well as the use and misuse of legal substances. The NRC understands that, except in the case of alcohol, chemical test results do not reveal any direct information regarding drug impairment per se. However, the NRC disagrees with the argument made by commenters that, as a result, chemical tests do not provide information that is relevant to a fitness-for-duty program. The NRC believes that the reliability, integrity, and trustworthiness of workers within nuclear power plants are important to public health and safety. The granting of a license is based on the assumption that workers will abide by the licensees' policies and procedures in all areas. Indications of lack of reliability, integrity or trustworthiness, therefore, even so far as they pertain to off-site behaviors, are relevant to the NRC's need to assure that nuclear power plants are operated safely. The relationship between reliability, integrity and impairment is by no means indirect in the case of drug abuse. Most of the substances under consideration are either physically or psychologically addictive to many individuals. The NRC cannot be confident of the individual's ability to limit the use of addictive substances to situations that do not adversely affect plant safety.

Illegal drug use can result in on-duty impairment. There is a possibility that that a worker who uses illegal drugs off-duty may be impaired from those drugs

while on-duty, and, even if the worker does not use drugs while on duty he or she may be impaired from either hangover or withdrawal effects associated with drug use. In addition to impairment, any illegal drug use establishes that the worker cannot be relied upon to obey laws of a health and safety nature, indicating that the worker also may not be reliable in terms of scrupulously following the rules and regulations that have been established in the nuclear workplace to ensure the protection of public health and safety. For these reasons, a worker who uses illegal drugs may not be sufficiently trustworthy or reliable to perform his or her duties on the job in a manner that assures public health and safety. In contrast, the legitimate use of legal drugs does not automatically demonstrate this lack of reliability. However, workers who do use alcohol or legal drugs are expected to use those substances responsibly. Irresponsible use of these substances in a manner that results or is likely to result in on-duty impairment, or otherwise demonstrates a disregard for public health and safety, is considered substance misuse within the scope of this rule.

The debilitating effects of long-term drug abuse are also well documented in the scientific literature, and have the potential for affecting complex physical and cognitive functions long after the effects of acute intoxication have dissipated. For example, residual effects of intoxication may persist when the worker returns to work the following day. Hangover effects, withdrawal symptoms, and cycles of drug abuse and abstinence can also result in decreased reliability and diligence. Off-site drug use may also result in increased absenteeism, medical costs, and staffing requirements, thus having adverse effects on overall workforce reliability. Ultimately, drug abuse directly and indirectly affects activities which bear on safety. It is therefore a reasonable conclusion that the abuse of illicit drugs and the misuse of licit drugs pose safety concerns in the nuclear power industry and is predictive of a lack of reliability, integrity, and trustworthiness.

The wide range of potential on-the-job impairment is complex in nature and difficult to observe, and therefore requires a broad approach to assure nuclear power plant safety. In addition to supervisory observation, other means are required to detect drug abuse, psychological stress, and physical injury or illness. To detect illicit drug abuse and the misuse of alcohol and

other licit substances, the NRC has adopted a mandatory chemical testing protocol for these drugs. The rule provides for mandatory chemical testing prior to the initial granting of unescorted access or assignment to activities within the scope of the rule (Section 26.24(a)[1]). Mandatory chemical testing is to be conducted on a random basis to effectively detect and deter illicit substance abuse and misuse (Section 26.24(a)[2]). For-cause testing is to be conducted after an accident in which the contribution of employee performance cannot be ruled out or based on reasonable suspicion that an individual is intoxicated or demonstrates behavior indicative of substance abuse or other involvement with drugs (Section 26.24(a)[3]). Following a positive test for drug abuse, follow-up chemical testing will be used on an unannounced basis to verify abstention from the use of drugs or misuse of alcohol and other licit drugs (26.24(a)[4]).

The NRC agrees that on-the-job impairment is a result of many complex factors, and that impairment is a complex phenomenon, depending on the cause of impairment, individual circumstances, and the job task at hand. The NRC recognizes that on-the-job impairment may result from substance abuse, psychological stress, or physical injury or ailment which can pose unacceptable safety risks, and the rule reflects this position. The NRC believes that trained, competent, reliable, and trustworthy workers are essential for the safe operation of nuclear power plants. The fitness-for-duty rule addresses the potential for worker impairment of any kind, including substance abuse that could affect the safe operation of nuclear power plants. In the assessment of a worker's application for access authorization, the background of the worker, psychological state, and criminal record are assessed. Similarly, any use of or involvement with illicit drugs, on or off duty, and the misuse of alcohol and other licit drugs provide evidence that the worker may not be fit for duty.

The NRC recognizes that even with a relatively high rate of random testing and with vigilance on the part of licensees to detect impairment or potential impairment in the workplace, the existence of drug problems within the workplace cannot be entirely eliminated. The undetected presence of drugs can be inferred from even a low positive test rate. However, the NRC concludes

that the design features, redundancy of safety systems, and extensive training for unexpected equipment and personnel malfunctions provide reasonable assurance that the public health and safety is protected provided drug abuse continues to be aggressively addressed by the nuclear industry. The final rule provides reasonable measures to assure that nuclear power plant workers can safely, competently, and reliably perform their duties.

4.0 SCOPE OF RULE

4.1 Summary of Comments

4.1.1 Non-Power Reactors and other Licensees

Several comments were received from universities and others involved with research reactors or other non-power reactors. The commenters stated that there is no need to extend coverage of the rule to these facilities because drug-related problem has been demonstrated to exist and that a relatively minor threat is posed by these facilities to the public safety. Unbearable costs and impracticality were also cited as arguments against inclusion of these facilities in the rule. A few comments were received from individuals involved with SNM handling, making the same general points. There were no comments supportive of expanding coverage of the rule to facility types other than nuclear power reactors.

4.1.2 Construction

Comments were received from two licensees recommending that the language of the rule be changed to include plants during the construction phase.

4.1.3 Types of Workers Covered

The random testing provisions of the proposed rule would apply to all persons granted unescorted access to protected areas at operating nuclear power reactors. Most of the commenters who objected to this provision commented to the effect that including all individuals with unescorted access to protected areas is unnecessary, and asserted that many of these individuals, e.g., vendors, secretaries, clerks, and some engineering and management personnel, have no potential for precipitating or escalating a safety-related incident. As an alternative, it was suggested that only those licensee or contractor personnel with unescorted access to vital plant areas should be subject to random testing, since this more-limited group was viewed as including all individuals with the capacity to do significant, safety-related harm.

4.1.4 Contractors

Many commenters pointed out the lack of specificity concerning licensee vs. contractor responsibilities. Most of these, mainly from licensees, were of the opinion that the contractor should have full responsibility for a qualified fitness-for-duty program.

4.1.5 Technical Support Center (TSC) and Emergency Operations Facility (EOF) Staff

Several comments received on this issue stated that licensee or contractor personnel who may be required to respond to the TSC or EOF have been granted unescorted access and so are already covered under the rule and need not be specifically mentioned in Section 26.3. Commenters questioned whether any non-licensee or non-contractor personnel involved with the TSC or EOF would have to be covered under the fitness-for-duty program.

4.1.6 NRC Staff and NRC Representatives

Many commenters contended that NRC staff should be subject to the same fitness-for-duty requirements, including random testing, as are licensee staff. Some thought that NRC representatives should be subject to these requirements also.

4.2 Summary of Responses

4.2.1 Non-Power Reactors and other Licensees

The NRC sees no reason at this time to extend coverage of the rule to other facility types. No modifications to the rule are required to satisfy the concerns addressed by the comments, because the rule is presently limited to nuclear power reactors. The NRC may consider extending the coverage of the rule at a future time.

4.2.2 Construction

The NRC agrees with the comments received that licensees holding construction permits should fall under the scope of this rule to the extent that a minimum program is provided. Wording indicating the provisions of the rule that pertain to construction sites has been added at Sections 26.2(a) and (b).

4.2.3 Types of Workers Covered

The NRC believes that the inclusion of all workers with unescorted access to the protected area within the scope of the rule is the proper response to the threat constituted by substance abuse. All such workers have the ability to carry in and distribute impairing substances. All such workers can engage in deliberate or accidental actions that can lead to challenges to safety systems or interfere with the ability of other workers to safely operate and maintain the plant. Although Federal requirements preempt State and local concerns in the area of radiological safety, in those states that support an on-site presence requiring unescorted access, the NRC may consider providing access to the chemical testing portions of the NRC's fitness-for-duty program if so requested by the individual states.

4.2.4 Contractors

The NRC believes that it is appropriate to hold licensees responsible for all workers to whom the licensee grants unescorted access, whether the workers are licensee employees or contractor or vendor personnel. The manner in which the licensee assures that contractor and vendor personnel are subject to the requirements of the fitness-for-duty program described in this part is left to licensee discretion, however. For example, nothing in the rule prohibits licensees from accepting the fitness-for-duty programs of their large contractors and vendors when those programs are effective and meet the requirements of this part. At their discretion, licensees may also choose to provide chemical testing and training for contractor and vendor personnel who are granted unescorted access to protected areas of a plant. This provision would likely be used when the contracting organizations have insufficient resources to support their own fitness-for-duty programs. The rule would

require the licensee to provide a procedure to enable a contractor employee to appeal the results of an alcohol and drug test; this would not apply where the contractor is administering his own alcohol and drug testing. In recognition of the temporary relationship between licensees and most of their contractors and vendors, the NRC does not require the licensees to ensure that EAP services are provided to contract workers. However, nothing in the rule prohibits licensees from making these services available to contractor employees.

4.2.5 Technical Support Center (TSC) and Emergency Operations Facility (EOF) Staff

The NRC believes that it is particularly important that individuals who have TSC and EOF assignments related to nuclear power plant safety can be relied on to perform under the emergency conditions that would require them physically to report to the TSC or the EOF. To clarify the Commission's intentions in this matter, the words "physically report" have been added to Section 26.2(a) of the rule. State and local representatives who may be present in licensee emergency facilities located outside the protected area and do not have responsibilities directly affecting reactor safety are not covered by the rule. Otherwise, these representatives would be covered by the licensee's program, or as an alternative, be covered by the NRC's program. Licensee employees, contractors, or vendor representatives who are unexpectedly called to licensee emergency facilities during an accident are also not covered by the rule as this group is ill defined and likely to be used only in supplementary capabilities.

4.2.6 NRC Staff and NRC Representatives

The NRC agrees with the commenters who asserted that NRC staff and representatives should also be subject to fitness-for-duty requirements. However, the NRC cannot allow the access of its employees to any part of the licensee's nuclear power facilities to be restricted. The NRC needs prompt, unfettered access to properly perform its regulatory duties and the proper performance of these duties requires public confidence that NRC employees not be intimidated

or impeded in any way by those they are responsible for regulating. In general, the NRC expects that any NRC employee who requires unescorted access will be subject to the chemical testing provisions of the NRC's fitness-for-duty program. The Commission must reserve the right to obtain unescorted access for any of its employees.

The NRC also agrees that its contractors must be fit for duty and may cover certain of its contractors under the chemical testing provisions of the NRC plan. The Commission expects that NRC contractors who are granted unescorted access will either be subject to the NRC's program, the licensee's program, or to a program that the NRC accepts as adequate. To be consistent with the Commission's intent, "representatives" has been deleted from Section 26.2(a) of the rule, and replaced with "employees."

5.0 CHEMICAL TESTING

5.1 Summary of Comments

A large number of comments were received concerning the chemical testing provisions of the rule. These pertained primarily to the random testing provisions, but comments were also received concerning testing before granting unescorted access, for-cause testing, and follow-up testing.

The comments on random testing were directed both toward random testing, in general, and the proposed use of urinalysis as a testing technique, in particular. Comments were received that provided statements of general support or opposition to the random testing provisions. Comments were also received that raised questions about specific elements of the random testing program in the proposed rule.

5.1.1 Opposition to Random Testing

Opposition to random testing was expressed by numerous individuals; several unions including the Brotherhood of Carpenters and Joiners of America, the Utility Workers of America, and the International Brotherhood of Electrical Workers; over 200 union members as part of a letter writing campaign; one utility; and a few other organizations. While most explicitly supported the goal of a drug-free workplace, opposition to random testing as a means to achieve this goal was stated in the strongest terms.

A number of reasons were given for opposition to random testing. Many commenters were specifically opposed to random testing as an unwarranted invasion of privacy. Numerous commenters expressed the opinion that random testing is an infringement of Constitutional rights. Several questioned whether the extent of the drug problem in the nuclear industry warranted such drastic action.

Other reasons cited for opposition to random testing included:

- The view that random testing is ineffective in achieving the NRC's goals of deterrence and detection,
- Better techniques are available for deterring and detecting drug use,
- Random testing is excessively burdensome and expensive,
- Random testing is embarrassing and demeaning,
- Random testing creates morale problems and may thus lead to the loss of qualified and drug-free workers from the industry, and
- Inaccuracies in the testing process will lead to innocent people being accused and punished for wrong-doing.

5.1.2 Support for Random Testing

While many licensees viewed random testing as only one part of a comprehensive fitness-for-duty program, most licensees and NUMARC expressed strong support for random testing as a major component of an effective program. This view was shared by several other organizations, such as contractors and vendors, as well as many individuals. NUMARC cited industry experience that the implementation of random testing programs has typically resulted in lower levels of drug problems.

Local No. 51 of the International Brotherhood of Electrical Workers expressed support for random testing when it is supplemented by behavioral observation. The Local reported that the affected workforce at the Illinois Power Company Clinton Nuclear Station is tested on a random basis each day and that this testing program, coupled with behavioral observation, has apparently proven to be a deterrent to drug abuse. This testing program was achieved through collective bargaining and is considered by the Local to be a valuable working practice. A check with the utility revealed that 100 percent of the workforce is given an

unannounced test on an annual basis; and in addition, all persons are subject to random testing at a 20 percent rate. Since the rate of positive tests has significantly declined, the utility may plan to lower the rates.

5.1.3 Alternatives to Random Testing

A number of comments were received in response to the NRC's request for information on alternatives to random testing. The unions and affiliated locals and individuals, a number of other individuals, two licensees, and a few other organizations expressed the opinion that the goals of random testing could better be addressed through other methods. The majority of these commenters stated that a combination of behavioral observation, primarily on the part of the supervisor, and for-cause testing was both adequate and effective. Opinions were expressed that behavioral observation and for-cause testing have the advantages of not subjecting everyone to needless tests, dealing with fitness-for-duty problems in addition to drug abuse, and being more likely to stand up under review of the courts than random urinalysis. Most licensees also supported behavioral observation and for-cause testing, although not as a substitute for random testing.

A number of commenters suggested specific observational techniques including computer-assisted neurophysiological and neuropsychological tests, physical skills tests such as those used by law enforcement personnel, and Ocular Kinetics. Others suggested that the annual physical be used to screen for drug abuse, either through chemical testing or observation. Unannounced, random medical examinations were also proposed. Sacramento Municipal Utility District provided a detailed description of its program based on screening by trained medical personnel. This program was also cited by a few other commenters.

Several commenters proposed that drug awareness and health education were more effective deterrents. Other commenters stated that greater emphasis on rehabilitation would be more effective than random drug testing.

A few commenters suggested that pre-employment or pre-access drug screening was adequate. A few additional commenters preferred announced or periodic unannounced testing to random testing. Finally, a few commenters suggested that the NRC direct its attention to the underlying causes of drug abuse,

such as the alleged poor work environment at nuclear power plants, rather than at detecting and punishing drug users.

5.1.4 Specific Changes in Random Drug Testing Provisions

Among the commenters who generally accepted the provision for random drug testing, a number of comments were received concerning the specific approach outlined in the proposed rule. Many of these comments, such as those having to do with drug types and cut-off levels, are summarized elsewhere. One major concern, however, had to do with the rate of testing to be required by the NRC.

Although the NRC had specifically requested comments on the preferred rate of testing, many commenters felt that the intention of the NRC was to require testing at a rate of 300 percent annually. Most of the comments received, therefore, addressed whether a 300 percent annual rate of testing should be imposed.

The 300 percent testing rate received very little support among those who otherwise supported random testing. NUMARC and most licensees stated that industry experience demonstrated that many fitness-for-duty programs had been successful with substantially lower rates of testing. Several commenters stated the opinion that a 300 percent testing rate would be unnecessarily burdensome to the licensee in terms of costs, and to the individual in terms of repeated testing. A number of commenters questioned whether information from military experience that was apparently used in the NRC's decision to propose a 300 percent testing rate was appropriate to the nuclear power industry with its older and more stable workforce. Finally, one commenter questioned whether the testing laboratories could effectively handle the workload implied by a 300 percent testing rate.

Numerous commenters suggested alternatives to the 300 percent testing rate. Proposals ranged from a 5 percent per year rate to a 200 percent per year rate. However, NUMARC and most licensees proposed a 100 percent annual test rate for the random testing program. They further requested that the 100 percent rate be reevaluated based on the experience of utilities, and be reduced to a 25

percent rate if warranted by experience. A few commenters requested that the testing rate be left to the discretion of the individual licensee, because would be most knowledgeable about their particular situations.

A number of other testing strategies were proposed. One basic approach that was favored by several commenters was to require unannounced annual testing of all workers, augmented by random testing at a lower rate, such as 25 percent per year. Several other commenters suggested techniques for protecting individuals from being over tested. These included a request that a worker not be re-tested until all other workers have been tested, a request that tested workers be subjected to a lower rate of testing for the balance of the year, and that there be limits imposed on the maximum number of tests for a particular worker in a given year.

Commenters also expressed the opinion that workers of different types should be tested at different rates. A few commenters expressed the opinion that the testing rate should be relaxed for workers in non-safety critical jobs. Many commenters requested that licensees be allowed to establish different testing programs for their own, versus contractor or vendor, employees. Specifically, a number of utilities stated that treating all workers as one population would result in those workers who are permanently on-site being tested more frequently than those workers who are on-site for only part of the year. By having separate testing populations for licensee and contractor or vendor employees, the commenters felt that the burden of testing would be distributed more fairly.

Two inquiries were received concerning policy for those randomly selected individuals who are not on-site at the time they are selected. One commenter asked how they would be folded back into the testing population. The other stated the position that the workers should not be required to return to work solely for the drug test.

Several comments were received requesting changes in the definitions of random and unannounced tests contained in Section 26.3.

5.2 Summary of Responses

The NRC is sensitive to the issues raised in opposition to random testing in general and to random urine testing in particular. Nevertheless, the NRC believes that there is sufficient evidence supporting the effectiveness of random testing in deterring and detecting substance abuse and that a carefully designed chemical testing program covering persons authorized for unescorted access to the protected area of nuclear power facilities is warranted at this time. As indicated below, in response to the sensitive issues of privacy and protection of individual rights, the NRC has taken great care to provide strict specimen collection procedures, chain-of-custody, laboratory certification, test confirmation, and confidentiality requirements within the rule. The NRC is convinced by evidence from the military and from licensees already implementing random testing procedures that random testing is an essential and effective component of the fitness-for-duty program. The NRC has designed the rule to minimize, to the extent possible, the expense and burden of the chemical testing component upon licensees, contractors, vendors, and upon their workers. Stringent quality assurance requirements are imposed upon the licensees, contractors, and vendors as well as upon the laboratories that will be conducting the chemical tests to ensure that test results will be accurate and that false positive results will be essentially eliminated.

Although the NRC believes that behavioral observation and for-cause testing comprise important elements of a substance abuse deterrence and prevention program, and has included them in its rule, it does not believe that, at present, these elements alone are sufficient to provide the level of deterrence and detection necessary. Nevertheless, the NRC appreciates the potential value of developing techniques in behavioral observation and detection of impairment through testing, and intends to monitor progress in these areas. It is prepared to modify the requirements of the fitness-for-duty testing program to incorporate such elements as they become viable, as long as the techniques address the reliability and trustworthiness issue of use as well as the safety issue of current impairment.

The NRC is sensitive to the importance of employee morale to plant safety, and has taken care to provide safeguards in the program to assure the fairness, uniformity, and accuracy of the random testing. The NRC also recognizes the

value of health education and rehabilitation programs in assisting workers and in deterring substance abuse, and notes evidence that random testing programs have been found to be an effective incentive for workers to seek information and assistance. To this end, the NRC has included in the rule, as discussed below, requirements for a licensed physician to review positive test results prior to notification of the licensee, and is requiring that licensee workers have access to an employee assistance program designed to provide assessment, short-term counseling, referral services, and treatment and follow-up monitoring.

The NRC has considered a number of alternative rates and sampling procedures to address the many comments received. The NRC agrees that the high rates of testing needed in the military may not be as essential for the nuclear power industry, as long as adequate coverage and deterrence is assured. In this regard, the NRC notes that the Navy, using a 300 percent per year testing rate, observes about 5 percent positive tests. Commenters in the nuclear industry, with random testing programs, reported less than 1 percent positive tests, with a utility using a 100 percent per year rate reporting 0.5 percent positive. This appears to be reflective of a substantially different workforce population. The approaches considered are:

- ° Alternative A from the proposed rule, which sets the two goals that at least 90 percent of the workforce be tested and that the testing rate for the already-tested population during a year not be set lower than a rate equal to 30 percent of the workforce. The disadvantage of this alternative is its complexity of administration and the provision of a lesser deterrent during part of the year.
- ° Alternative B from the draft rule that requires testing at a rate equal to 300 percent of the workforce. The disadvantage of this alternative is the possible excessive disruption of work activities and the testing of a few individuals at a very high rate which may impact morale. The cost of this rate may be excessive given the reported low number of positive tests for testing rates at 100 percent per year or lower in the nuclear industry.

- ° A method whereby each worker is randomly assigned a day during the next 365 days on which to be tested, and then is randomly reassigned to a day in the following 365-day period. The worker could be tested several times in one year, but is guaranteed at least one test per year. This allows for testing of the entire workforce during any 365-day period and reduces the testing rate in comparison to Alternative B (estimated rate: 200 percent). However, there is a possibility that more workers may be selected for testing on a given day than the licensee has a capacity to test. The disadvantage of this alternative is the need to select testing dates well in advance and the security problems which may result.
- ° A method whereby all workers are subjected to unannounced testing once during the year, and random testing at a low rate (e.g., 25 percent-50 percent) is also used during the year to assure ongoing deterrence.
- ° A method whereby random testing is conducted at a rate equal to approximately 100 percent of the workforce, resulting in about two-thirds of the workers being tested during the course of a given year.

While the NRC has considered a number of alternatives, several of the alternatives proposed by commenters were eliminated. The proposals for testing rates lower than 100 percent per year cannot currently be supported, although the NRC will consider reducing testing rates after several years based on positive experience in the industry. For the time being, however, the NRC believes that testing rates substantially below the 100 percent rate would not assure adequate deterrence. The NRC does not anticipate licensees experiencing significant problems in finding laboratory capacity to support rates in excess of 100 percent. Because of the need to assure an adequate minimum rate of testing, the NRC cannot leave the choice of a testing rate solely to the discretion of the individual licensee.

The proposal that workers not be retested until all other workers are tested and the proposal that there be a specified maximum number of times that workers are tested within a year cannot be supported because they would make the process non-random and would defeat some of the deterrent value of testing. Several of the above alternatives would have the effect of limiting the amount of retesting on particular individuals.

The NRC recognizes that vendor and contractor personnel could be subjected to lower rates of testing to the extent that they are not on-site for the entire year. The NRC believes that there are several strategies available to deal with the implied over-testing of licensee employees. The licensee can divide those being tested into discrete populations (e.g., employees and contractors, or even by contractor). The NRC expects that all categories of workers will be tested in accordance with the alternative rate and procedure selected for the final rule. The NRC will permit the licensee to sample within categories of workers, to sample randomly on at least a weekly basis among those currently on-site, or to employ some other method that satisfies the standards of the selected alternative for all categories of workers covered under this part.

The NRC does not believe that additional guidance is needed on how to deal with workers who are not on-site when they are randomly selected for testing. Current practice is to either test them immediately upon return to the site (with a supporting procedure that prevents disclosure of their selection), place them in a special pool of people to be randomly selected within a few weeks, or to return the person to the testing pool and select someone else. Usually, the licensee assures itself that there is a legitimate reason for the absence, and, if any patterns are evident an investigation is usually conducted along with for-cause tests. Current industry practice is considered adequate on this point.

6.0 RELIABILITY OF TEST RESULTS

6.1 Summary of Comments

The NRC received numerous comments pertaining to the reliability of test results. Several comments in this category expressed concern about the perceived high rate of false positive results and the possible consequences to workers. An official of the Utility Workers Union of America contended that immunoassay screening tests have false positive rates of 5 percent. A private individual cited a Human Relations Institute & Clinic's report claiming that laboratories using initial and confirmatory test procedures have had false positive rates ranging from 4.5 percent to 23.8 percent. Two commenters, a private individual, and an International Brotherhood of Electrical Workers (IBEW) union member asserted that testing laboratories in general have had false positive rates of 30 percent to 60 percent, respectively. The United Brotherhood of Carpenters and Joiners of America and two union locals, one of the IBEW and another of the Coalition of California Utility Workers, cited Center for Disease Control (CDC) study data from the early 1980s to claim that testing technologies are too inaccurate. One set of comments, mostly from the IBEW, wanted the NRC to ensure a 100 percent, or error-free, testing rate. Commenters attributed false positives to low cut-off levels, cross reactivity between drugs, and the varying levels of voided metabolites in the body associated with marijuana use. One commenter, the Utility Workers Union of America, thought that individuals who had received false positives should be awarded monetary compensation. Another commenter, the United Brotherhood of Carpenters and Joiners of America, contended that the EMIT 100 test used in initial screening had too high false negative rates.

Some commenters, mostly NUMARC and 39 licensees supporting the NUMARC comment, thought that the validity of the test results could be challenged either by the generation of true positives from use of over-the-counter drugs and other legal substances or by the mishandling of samples. Four other commenters (Florida Power and Light, the Oil, Chemical and Atomic Workers

Union [OCAW], an IBEW union worker, and a private individual) identified the following as possible challenges to the validity of test results: mislabeling or misidentification of samples; use of improper sample collection techniques; inadequate safeguards against tampering; failure of laboratory equipment; passive inhalation of marijuana; time of day of the sample; and erroneous reading of test results. NUMARC and OCAW recommended adherence to chain-of-custody procedures, in general, while the Wisconsin Electric Power Company and the United Brotherhood of Carpenters and Joiners of America specifically recommended those procedures outlined in the HHS Guidelines. The Duquesne Light Company recommended that chain-of-custody procedures be followed at the site and in the laboratory. Houston Lighting and Power asked the NRC to prohibit personnel from working in the "Fitness-for-Duty Program" (that is, the testing program) who have relatives working at the site.

6.2 SUMMARY OF RESPONSES

The NRC acknowledges the concerns regarding the rate of false positives and specimen collection and handling techniques, and recognizes that these concerns are based upon problems that existed several years ago when drug testing programs were being introduced. The Federal Aviation Administration, in their response to public comments on the same matter (53 FR 47032, November 21, 1988), provided a clear response that we find no reason to improve:

"...In the early years of drug testing and analysis, laboratory security and analytical procedures had not reached today's level of sophistication. False-positive test results occur primarily in analysis of a specimen during an initial screening test, although contemporary screening tests, such as immunoassay tests, have become extremely accurate and approach 99 percent accuracy levels. Despite its increased accuracy, the initial screening test remains a less expensive test used only to yield a preliminary indication of the possible presence of drugs or drug metabolites. In order to ensure the integrity and accuracy of any test result, each positive initial screening test result must be confirmed using GC/MS analysis. The GC/MS confirmation test is an extremely accurate and sophisticated test and is virtually error-free when used in compliance with the DHHS guidelines...The Mandatory Testing Guidelines will provide a system

of checks and balances during collection and analysis of specimens. This system ensures the integrity and accuracy of the tests using appropriate scientific methods and rigid chain-of-custody procedures...Since the mid-1980s, laboratories have become increasingly sophisticated in their analytical methods and chain-of-custody procedures. Many laboratories have compiled extensive records demonstrating scientific accuracy and protection of individual specimens. For example, CompuChem Laboratories, a major drug testing laboratory, has analyzed over 500,000 urine samples, conducting discrete testing for nine different drugs which resulted in nearly five million distinct analyses of these specimens, since 1980. CompuChem also has analyzed approximately 750,000 urine samples for the presence of two different drugs, resulting in nearly 1.5 million analyses of these specimens, pursuant to its contract with the military. None of the over six million analyses performed for DOT, the military, and other private and public entities has resulted in a false-positive test result.

In late 1987, a CompuChem clerical worker incorrectly labeled two samples that belonged to DOT employees. Within hours after the test results were questioned by the Medical Review Officer, CompuChem and the Medical Review Officer had identified and corrected the error. CompuChem was not satisfied with its prompt resolution of the error. As stated in its comment to the NPRM, CompuChem has instituted an additional system of review by CompuChem personnel and computer checks, to ensure that "...this one in a million error will not reoccur."

Another drug testing firm, PharmChem Laboratories, has conducted over eight million nonmilitary drug tests nationwide. In its statement to FAA during the public hearing held in San Francisco on June 9, 1988, PharmChem notes that several courts have determined that the GC/MS confirmation test is "virtually 100 percent accurate, assuming that proper chain-of-custody procedures are followed..."

The NRC has adopted the provisions of the HHS Guidelines with some modifications to further ensure the integrity and accuracy of test results using appropriate scientific methods and rigid chain-of-custody procedures at the site and in the testing laboratory. The confirmatory testing process also

eliminates any false presumptive positive tests resulting from a cross-reacting drug detected during initial screening. As cross-reacting substances are generally prescription or over-the-counter medications, testing procedures in the NRC fitness-for-duty program will include an inquiry on the individual's use of these medications.

Chain-of-custody procedures and a system of reviews, checks, and balances during collection and analysis of specimens outlined in the NRC Guidelines limit and prevent errors and possible subversions. To protect the worker from inappropriate sanction due to any errors in the testing process, cross-reacting substances, or legitimate medical use of controlled substances, a Medical Review Officer (MRO) screens all presumed positive test results and may interview those individuals who have tested positive with the GC/MS confirmatory test. The MRO is trained in prescription and over-the-counter (OTC) drug interaction as well as the physical signs of illicit drug abuse. The worker has an opportunity to identify any ingested licit, prescription, OTC drugs as well as certain food substances that may affect a test result. The chain-of-custody and collection procedures outlined in the NRC Guidelines, along with computer techniques of tracking specimens, limit the probability of mishandling, mislabeling, and misidentification of samples. The NRC Guidelines also outline procedures for the collection of samples to ensure the integrity of the samples and to limit opportunities for sample tampering. To further limit the possibility of subversion of the integrity of the testing process, the NRC Guidelines require licensees to carefully select persons responsible for administering the testing program based upon the highest standards for honesty and integrity and to implement measures appropriate to ensure that these standards are maintained. Background evaluations of testing program personnel would be conducted to verify the integrity of such individuals given the potential misuse of that position. Behavioral observation and periodic re-conduct of the background evaluations would assure continued integrity. Supervisory personnel and an individual's co-workers would be prohibited from performing as collection site personnel and consequently from being involved in the chain-of-custody process.

The NRC does not believe that "passive inhalation" of marijuana smoke will lead to false positives. Studies conducted to simulate conditions that result in passive inhalation have not accurately reflected conditions outside the laboratory often using artificially devised and extremely confined areas with

poor ventilation, followed by immediate testing after prolonged exposure. The cut-off levels in the NRC Guidelines will be set sufficiently high to preclude the possibility of controversy due to chances that a positive test resulted from passive inhalation. The NRC notes that a trustworthiness question may be raised even in the case of passive inhalation. The only effect associated with the time of day of the sample is that urine samples collected earlier in the day contain higher concentrations of drugs or drug metabolites. Samples collected earlier in the day do not generate more false positives as initial positives are still confirmed with the GC/MS test. Erroneous reading of test results would be limited by chain-of-custody procedures and the system of reviews required of testing laboratories.

7.0 TRAINING AND BEHAVIORAL OBSERVATION

7.1 Summary of Comments

The NRC received numerous comments regarding the scope of training required of licensee, contractor, and vendor personnel granted unescorted access to protected areas. Most commenters concurred that training should be provided to all employees covered under the rule to ensure that they understand the licensee's fitness-for-duty program, their responsibilities, the consequences of substance abuse, and the availability of assistance through the Employee Assistance Program (EAP). In accordance with NUMARC, many commenters supported the training of supervisory and managerial personnel in behavioral observation techniques and procedures for initiating appropriate corrective action, including referral of employees for medical assessment or counseling. However, a majority of commenters also expressed strong opposition to the proposed level of training required of non-supervisory personnel assigned escort duties (Section 26.22[b]).

The NRC also received a significant number of comments regarding the requirement that initial training of licensee personnel be completed prior to assignment of duties within the scope of this rule and within three months of initial supervisory assignment, as applicable (Sections 26.21[b] and 26.22[c]). Most of these commenters requested that the NRC revise the proposed rule to allow drug awareness and behavioral observation training to be completed within six months of initial supervisory assignment. Commenters also suggested that refresher training be completed every two years rather than annually.

7.2 Summary of Responses

The NRC has revised the proposed rule to clarify its intent that escort personnel are not required to receive training in supervisory responsibilities. The revised rule requires that all non-supervisory personnel assigned to escort duties must be familiar with techniques for recognizing drugs and indications of the use, sale, or possession of drugs; be familiar with techniques for recognizing aberrant behavior; and be knowledgeable of the proper procedures for reporting incidents of aberrant behavior to the appropriate management authorities.

The NRC received many comments opposing the required completion of drug awareness and behavioral observation training of supervisory and managerial personnel within three months of initial supervisory assignment. However, because of the critical position that supervisory and managerial personnel serve in detecting impaired workers, the NRC has determined that the current provision regarding supervisory training is necessary and will remain as stated in the rule.

The NRC has also determined that the provision requiring licensee personnel to receive annual refresher training in drug awareness and behavioral observation techniques will remain as stipulated in the proposed rule. Because supervisory personnel represent the first line of defense against fitness-for-duty problems, it is critical that they be trained to recognize these problems and handle them appropriately. Therefore, the NRC believes that the training of supervisory and managerial personnel in behavioral observation techniques will provide licensees with an invaluable tool for the detection and deterrence of drug-and alcohol-related impairment and for the detection of impairment from other causes. Because of the significant level of knowledge and training required to accurately detect subtle indications of drug or alcohol impairment and the critical need to identify drug and alcohol abusers before they compromise public safety, the NRC believes it is prudent to require supervisory training on an annual basis, or more frequently when necessary. In addition, the NRC will continue to require annual refresher training of all non-supervisory personnel to ensure that licensee and contractor employees understand the requirements of the licensee's fitness-for-duty program, are aware of their responsibilities, and, in the case of licensee employees, are aware of opportunities for assistance available through EAP services. NRC audits of licensee programs and interviews with contractor and licensee personnel have indicated a need for this level of refresher training.

8.0 FOR-CAUSE TESTING

8.1 Summary of Comments

8.1.1 Suitability of For-Cause Testing

As summarized earlier, many commenters stated that they were in favor of for-cause testing in place of alternative testing methods such as random testing.

8.1.2 Definition of Impairment

Several commenters including NUMARC stated that the current definition of for-cause testing is too broad. Suggestions for improvement included replacing "is impaired" with "may be impaired" or "may have demonstrated aberrant behavior." Finally, commenters stated that most of the examples in paragraph 26.24(a)(3) of when for-cause testing should be required need better definition. Several examples were suggested.

8.1.3 Testing Following an Accident

Several commenters stated that requiring for-cause testing following an accident would inhibit root cause analysis of the accident. One commenter stated that for-cause testing should be required after a serious accident.

8.1.4 Initiation of Testing

Several commenters addressed who should be allowed to initiate for-cause testing. Several commenters stated that "impaired behavior" can only be determined by a physician or other health care professional. Others thought that a minimum of two management officials must document an employee's impairment. One commenter stated that for-cause testing should not be the result of a "discrete expression of concern by a nameless accuser."

8.2 Summary of Responses

The NRC agrees with the commenters that the definition of the circumstances in which "for-cause testing" is appropriate should be clarified. The definition provided in Section 26.3 has been deleted and the language in Section 26.24(a)(3) has been revised. The NRC does not agree that impaired behavior can only be determined by a physician or other health care professional. Supervisors are close to their workers and directly monitor worker performance, often on a daily basis. The NRC also does not agree that a minimum of two managers should be required to document a worker's impaired behavior. In some cases, the impaired behavior may be observed by only one manager during a task that cannot be easily repeated.

9.0 SANCTIONS

9.1 Summary of Comments

9.1.1 Period of Denial of Access

Sections 26.27(b)(1) and (b)(2) stipulate that, as a minimum, the first positive test confirmed by the Medical Review Officer shall result in immediate removal from access for at least 14 days and referral to an EAP for assessment and counseling. Any subsequent confirmed positive test would result in removal from unescorted access for a minimum of three years. A worker who is involved in the sale, use, or possession of illegal drugs while within the protected area of a power plant would be removed from covered activities for a minimum of five years. This section further specifies that the rule does not prohibit the licensee from taking more stringent actions.

This section prompted many and varied comments. Many licensee commenters including NUMARC argued that the entire Section 26.27 should be deleted because licensee management has the responsibility to decide these issues. They believe that establishing sanctions is not within the Commission's statutory authority. Other licensees recommended that the rule should not prescribe any specific time periods for these events because each must be treated on a case-by-case basis. For instance, a licensee commented that some relatively minor situations do not require even fourteen days to assess the worker's drug usage, determine a solution to the problem, and safely return the worker to unescorted access.

There was no particular consensus among those commenters who mentioned specific time periods for removal from access. Local No. 51 of the International Brotherhood of Electrical Workers recommended that a worker be suspended for five days after the first confirmed positive test and for ten days after the second. The System Council U-2 of the IBEW recommended discharge for six months after the second confirmed positive. Local No. 51 also believed that the three-year removal from access is too severe as it would almost certainly lead to dismissal. Permanent dismissal was recommended by

Houston Lighting and Power even for the worker's first confirmed positive test. Carolina Power and Light believed that the 14-day requirement is adequate. Many licensees believed that they should have the option to undertake measures ranging from counseling through discharge following the first positive test result. They stress that they must have the flexibility to do whatever it takes to assure at least a chance at successful rehabilitation of the worker.

There was somewhat less variance in the comments on the appropriate response to a determination that a worker has been involved in the sale, use, or possession of illegal drugs within a protected area. Several licensees stated that the worker should be discharged in such circumstances. NUMARC recommended that the worker be permanently barred from access. Another licensee would discharge the employee but allow the person to be considered for rehire after three years.

9.1.2 Follow-up Tests

Section 26.27(b)(3) of the proposed rule required that workers whose access is reinstated "shall be given unannounced follow-up tests at least once every three months for three years after reemployment to verify continued abstinence from drugs." This requirement prompted a variety of responses. Various union representatives stated that this testing rate and duration would be "excessive, harsh, and punitive" and argued for less frequent testing over a shorter probation period. NUMARC recommended that workers regaining access be tested once every three months but for one year only. On the other side of the spectrum of views, Public Service Electric and Gas stated that the condition of such workers requires "close monitoring, tracking, and continued urine sampling." Rancho Seco's practice in such circumstances requires weekly urinalysis during the first quarter after return to work and monthly testing thereafter. (The length of the probation period was not mentioned.) A third set of commenters indicated that the frequency and duration of such follow-up tests need not be prescribed in the rule but should be left to the employer's determination.

9.2 Summary of Responses

9.2.1 Period of Denial of Access

The Commission's intent in Section 26.27 is that a worker who may pose a threat to safety be removed from safety-sensitive duties as long as he or she remains such a threat. These sanctions are not meant to serve as punishment for substance abuse. Thus, the section allows but does not mandate the permanent denial of unescorted access to protected areas in any of the enumerated drug-related events. The section also recognizes that the severity of threat to safety is a complex matter. Obviously, a long-term heroin addict with an expensive habit would likely be a far more serious threat than a recreational marijuana user. Yet, an effective fitness-for-duty program must be prepared to deal with both types of problems.

It is the NRC's belief that Section 26.27(b)(1) includes an appropriate mix of flexibility and stringency. The 14-day period seems reasonable in that, in almost all cases, it would take at least that long to diagnose a worker's problem, determine a solution, and assure that the problem is addressed before the worker can again be granted access; this may, in some cases, be limited to counseling. Also, the NRC believes that 14 days is needed to conclude that the first confirmed positive test may have resulted from behavior that does not in fact pose a serious safety threat. This minimum period is not meant to constitute punishment. Instead, this period is intended to ensure an adequate time for assessment of the worker's condition and requirements. The NRC does not take a position on whether a worker in this situation should be denied unescorted access longer than 14 days. That is to be decided by the licensee.

Removal from unescorted access for a minimum of three years after a second confirmed positive test is, on the other hand, quite a stringent requirement. Some commenters noted that dismissal may occur in such cases. The NRC believes that this measure is appropriate, however, in light of this rule's goal of assuring that workers are not impaired due to substance abuse. A second positive test would indicate that the person is most likely not able to stop

using the substance in question and could, therefore, pose a threat to safety. The severity of a three-year loss of unescorted access may also provide an incentive for employees to voluntarily enter into rehabilitation programs when they realize the seriousness of the substance abuse problem.

Section 26.27(b)(2) also appears to be well suited to the rule's goal. The tenor of most comments on this section favored more stringent measures than the section would require, and the NRC wishes these commenters to note that the five-year period is intended to be only the minimum removal from unescorted access necessary to protect public health and safety. The five-year period should operate as both a deterrent to the proscribed activities and as a measure that may in fact result in permanent denial of access in most cases where involvement in illegal drugs is detected in protected areas.

9.2.2 Follow-up Tests

The NRC recognizes the need to adjust the frequency of follow-up testing as required in Section 26.27(b)(3). Research indicates that recidivism is most likely during the first 90 days following treatment (Hubbard and Marsden' 1986; Rounsaville. 1986). Most relapses to substance use will take place during that first 90-day period. If a person can remain substance-free during that period, he or she will have a chance to continue to be abstinent.

In light of this research, the Commission has amended this section. Rather than requiring a uniform frequency of testing for the entire three-year probation period, the heightened potential for recidivism during the early stages of that period should be recognized with a rate of testing more frequent than once every three months. Conversely, the reduced chance for using drugs during the rest of the three-year period should be acknowledged by a lower frequency of unannounced tests than this section currently requires.

As amended, this section requires that workers whose access is reinstated be given unannounced follow-up tests at least once every month during the first

four months of restored access. During the next two years and eight months, the worker should be tested at least once every three months to verify continued abstinence. As compared to the proposed rule's requirement, the higher testing rate during the first four months would provide the worker with an increased incentive to remain abstinent as well as create an increased probability of detecting any resumption of substance use that may occur. Thereafter, the lower testing rate would be less onerous for the worker while still providing added assurance that resumption of substance use would be detected.

10.0 IMPAIRMENT FROM OTHER CAUSES

10.1 Summary of Comments

A number of commenters discussed issues pertaining to impairment from causes other than workers' use of illegal drugs.

10.1.1 Identified Additional Sources of Impairment

Workers' use of substances was mentioned most often in these comments, especially the use of alcohol, prescription medications, and over-the-counter medications; the use of caffeine was also mentioned. Comments were also made about the following specific sources of worker impairment: (1) emotional and mental stress in general and stress specifically related to poor attitudes, poor morale, and family problems; (2) fatigue, including fatigue caused by mandatory long hours of duty, rotating shifts, and workers working shifts incompatible with their biological clocks; (3) illness, including allergies; and (4) physical and physiological impairments. One commenter noted that illnesses, particularly colds and flu, are major causes of impairment because both the illness and the medication a worker takes to treat the illness can cause impairment. With regards to fatigue, one commenter objected to the proposed rule because, under the rule, it was his interpretation that workers may be disciplined and possibly terminated due to fatigue caused by work schedules and overtime.

A number of commenters did not specifically address any one of these sources of impairment, but expressed one or more of the following general concerns: (1) the rule should be expanded to address several or all of these potential causes of impairment, regardless of the source of the impairment; (2) it is inappropriate for the rule to focus on illegal drug use and not to also address, in detail, the use of legal drugs, alcohol, or both; and (3) the rule requires licensees to address impairment from sources other than illegal drug use and to provide reasonable assurance that on-duty workers are not impaired from the use of any substance, but it provides no guidelines or direction towards this end.

Some commenters noted that urine testing is an inadequate means of detecting impairment caused by many of these factors, and thought that specific tests for impairment, medical clarification exams, or supervisors' observations should be used to detect impairment.

10.1.2 Legal Drugs

Some commenters thought that the rule should not address legal drugs. One commenter stated that impairment should not be addressed and that the concern should be limited to illegal drug use. Another commenter thought that the language of the rule should be changed to state that the goal of the rule is to achieve a workplace free of illegal drugs and their effects rather than a "drug-free workplace." This commenter also noted that this change should not preclude a licensee from prohibiting on-site use of alcohol. Several commenters stated that expanding the rule to address legal drugs would raise substantial legal concerns (e.g., making the use of legal drugs illegal, forcing a violation of physician/patient confidences) and one commenter thought that these concerns merely highlight the fact that any drug testing is an affront to personal liberty.

NUMARC stated that prescription drugs should be addressed only generally; workers should be required to notify their supervisors of intended use of prescription drugs and care should be taken in response to positive tests that occur as a result of prescription drug use. If prescription drugs are included in the testing program, the response to positive test results should be based on medical advice and workers must not be penalized unless they are abusing the legal/prescription drug. This position was strongly supported, with about half of those commenters who discussed legal drugs supporting the NUMARC position.

Several commenters stated that only the drugs listed in the HHS Guidelines should be the basis for industry testing. The addition of drugs beyond those specified in the HHS Guidelines would create a conflict with HHS restrictions. Further, a number of commenters were concerned that the procedures specifying

how licensees are to identify additional drugs and incorporate them into their programs would defeat the goal of establishing uniformity. Commenters also thought that these procedures were unworkable, burdensome, and open to legal challenges.

A number of commenters stated that the rule should not be expanded to address legal drugs, and that workers should not be denied the use of medications necessary or beneficial to their health and well-being. Several commenters stated that regulation on prescription drugs is outside of the appropriate scope of NRC regulations and that such decisions should be made by physicians and on an individual basis. Other commenters thought that testing for legal drugs is unnecessary, but workers should report the use of those drugs either to their supervisors or to the medical department for an individual decision to be made about what actions should be taken to ensure against on-the-job impairment. One commenter indicated that the prescribing physician could be consulted when making this determination.

Other commenters stated that it was appropriate to expand the testing program to include legal drugs that may cause impairment. Some of these commenters want the rule to specifically state this, while others want the rule to address the testing protocol for these drugs in detail, as has been done for the classes of drugs for which the rule does require testing. The following drugs or drug classes were identified by various commenters as warranting special concern: barbiturates, benzodiazepine, methaqualone, methadone, and propoxyphene. For some of these drugs and drug classes, cut-off levels were proposed.

Commenters also pointed out that some of the classes of drugs currently tested for include drugs that can be used for legitimate medical reasons without creating significant impairment, and the rule should be expanded to ensure such legitimate use of these drugs is protected. Several commenters stated that requiring workers to report the use of prescription drugs to their supervisors adequately addressed the concerns surrounding the use of legal drugs.

10.1.3 Alcohol

Many commenters made statements about whether or not alcohol should be added to the rule. The majority of these commenters, about 60 percent, stated that the rule should be expanded to address alcohol, but that details of how alcohol will be addressed should be published for public comment before the changes are implemented. These commenters include NUMARC, a number of commenters who stated that they support the position stated by NUMARC, and a number of commenters who made this statement without linking it to NUMARC. About 25 percent of the commenters addressing this issue stated that alcohol should be addressed in the rule without such a qualification. About 15 percent of the commenters who addressed this issue stated that alcohol should not be addressed in the rule. Other commenters expressed the concern that the extent to which alcohol is addressed in the rule should not make implementation an insurmountable burden.

The following reasons were given for delaying implementation of an alcohol rule: (1) time should be allowed for the industry to study and develop additional suitable and effective programs to handle alcohol-related problems, much the same as has been provided for drug program development, and (2) prior to final rulemaking, the details of the alcohol requirements should be made available for public comment.

The following reasons were given for including alcohol in the rule: (1) alcohol use and misuse is prevalent, (2) alcohol use can lead to on-duty impairment, (3) alcohol misuse creates fitness-for-duty problems comparable to and perhaps more substantial than the problems caused by illegal drug use, and (4) an NRC regulation requiring testing for alcohol would lend support to established programs.

The following reasons were given for excluding alcohol from the rule: (1) programs already in place and guidance being produced by Edison Electric Institute (EEI) effectively deal with alcohol-related problems, making additional guidance or regulations unnecessary; (2) if additional prescriptive detail is provided, and if that guidance conflicts with established programs,

the rule could result in a less effective approach to dealing with alcohol-related fitness-for-duty problems.

Many specific recommendations were made about the desirable characteristics of an alcohol testing program. A number of commenters recommended using breath tests for blood alcohol concentrations (BACs), although some commenters said that blood tests are more accurate and should therefore be used. Most commenters stated that alcohol should be treated in a manner similar to other drugs, and that testing for alcohol and other drugs should be done on the same occasions. NUMARC, along with about 35 other commenters, stated that tests for alcohol should be done on a random basis, as compared to three commenters who stated that alcohol should only be included in for-cause tests. A few commenters thought that alcohol testing as part of pre-access or preemployment screening was unnecessary. Several commenters addressed BAC cut-off levels by stating the level they recommended, stating the level they were currently using, or urging the NRC to establish a cut-off level. Recommended or currently used cut-off levels ranged from 0.04 percent to 0.10 percent, with the vast majority of commenters citing the 0.04 percent cut-off level. One licensee requested the NRC to establish the 0.04 percent cut-off level, but stated that if the NRC does not establish this level, they would use the 0.10 percent BAC cut-off level used in their local state motor vehicle codes. With regards to sanctions in the event of a violation of alcohol policy, commenters expressed both the opinion that it is appropriate to regard a positive alcohol test the same as a positive drug test, and the opinion that sanctions for violations of the alcohol policy should differ from sanctions for violation of the drug policy and should be left to the discretion of the licensee.

One commenter recommended a rule requiring a period of pre-work abstinence from drinking, such as the eight-hour rule used in the aviation industry.

10.2 Summary of Responses

The NRC agrees that the possible sources of impairment identified by these commenters constitute important fitness-for-duty concerns that should be addressed in licensees' programs. Further, the NRC believes that the rule does address these issues, in that the rule requires licensees to provide reasonable assurance that workers are not impaired from any cause and requires licensees to make EAPs available to workers to assist them with these types of problems.

10.2.1 Additional Sources of Impairment Not Warranting Action at This Time

The NRC does not believe that the health and safety of the public is best served by the NRC providing, at this time, additional prescriptive regulations regarding emotional and mental stress, fatigue, illness, and physical and physiological impairments. The NRC believes that there are a number of ways of effectively addressing these problems, that often the approach used must be tailored to the specific case at hand, and that sound management practices, which are consistent with the licensee's management style, can be expected to be more fruitful than would detailed prescriptive regulations.

Additional Sources of Impairment Warranting Action at This Time

The NRC agrees with the commenters who stated that the rule should be expanded to address impairment that is caused by workers' use of alcohol and legal drugs. The NRC believes that these are especially significant areas of concern because of the negative effects of alcohol and prescription sedatives on vigilance and judgment, which are important components of many jobs within protected areas. The NRC also believes that there is often a relationship between illegal drug abuse and the abuse and misuse of legal drugs and alcohol. The distinction between some types of medication use and drug abuse is not absolute. All use of prescription and over-the-counter drugs lies somewhere in a spectrum that has responsible safe use at one end, dangerous

abuse at the other end, and practices such as irresponsible misuse and accidental misuse somewhere in the middle. For these reasons, the NRC believes that a licensee's policies regarding workers' use of legal drugs and alcohol is as important for ensuring public health and safety as the licensee's policy regarding illegal drug use.

The nexus between illegal drug abuse and the abuse or misuse of legal drugs and alcohol makes it difficult to separate these issues. For example, in some cases the proposed rule addresses classes of drugs that are both abused illegally and used in legal medications (e.g., opiates and amphetamines). Therefore, within a drug testing program adhering to the proposed rule, an overlap between illegal and legal drugs already exists.

Additionally, many of the issues that must be resolved when addressing each of these areas are very similar. For example, if chemical testing is to be used to detect the use of one or more legal drug(s) or alcohol, then the issues pertaining to the testing protocol that must be addressed when testing for illegal drugs--such as chain of custody, establishing cut-off levels, laboratory quality assurance--must all be addressed. Further, all of these issues should be addressed because individual workers may have closely-related substance abuse problems involving illegal drugs, legal drugs, and/or alcohol. Effectively detecting and deterring the abuse of some substances (illegal drugs) while failing to detect and deter the abuse or misuse of others (legal drugs, alcohol, or both) may result in some workers who have drug problems merely substituting one impairing drug with another rather than giving up the unacceptable use of any drugs. This close tie between illegal drug abuse as a fitness-for-duty concern and legal drugs and alcohol as fitness-for-duty concerns, along with the significance of these issues, warrants the NRC addressing all of these issues in a fitness-for-duty rule.

The NRC does not agree that it is beneficial to wait until licensees have studied these problems and attempted to develop their own solutions before taking action. The NRC believes that, as was the case when the NRC delayed rulemaking regarding illegal drug use, such a practice may contribute to

inconsistent policies in the industry and that it is possible that some policies will be developed that prove to be inadequate. Further, such a waiting period would result in an unacceptable delay in the implementation of important components of the NRC's fitness-for-duty rule.

10.2.2 Legal Drugs

The NRC does not think that it is appropriate to publish detailed regulations concerning legal medications at this time. The NRC acknowledges that the task of establishing the panel of drugs for which testing is warranted, and the appropriate testing protocols to be used when performing those tests, is an important and difficult task that warrants careful consideration. Further, the NRC believes that all of the approaches recommended by commenters regarding the regulation of workers' use of legal drugs may prove unacceptable. Some of the recommended approaches can be expected to provide inadequate assurance that a worker's use of legal drugs does not result in on-duty impairment. Other approaches may prove to be unnecessarily intrusive. For example, it may be unnecessary for workers to report to a supervisor or Medical Review Officer their use or intended use of some of prescription drugs.

The NRC believes that requiring workers to report to the Medical Review Officer their use or intended use of some types of drugs is essential, however, and should be considered by licensees. However, the NRC believes that defining these drugs in terms such as "all prescription drugs" or "all drugs that may cause impairment" may be a poor method of developing such a list. There may be over-the-counter drugs, such as over-the-counter stimulants and sedatives, that have significant potential for causing on-duty impairment and thus warrant being reported. Conversely, there may be prescription drugs that have very little potential for causing impairment and do not warrant being reported. Specific policies could be produced that would eliminate the need for workers to report their use of these drugs. For example, it may be possible to assure that some drugs do not create significant problems simply by providing guidance to workers about when the drugs can be used or about the maximum doses of the drugs that can be used by

on-duty workers. The development of such guidance could simplify licensees' fitness-for-duty programs, promote consistency throughout the industry, and reduce the intrusive nature of the fitness-for-duty programs. However, the NRC believes that such guidance should be developed by the industry. Input from the medical community would be especially valuable in this area and should be sought. Should timely progress not be made in this area, the NRC may institute additional rulemaking.

The rule has been modified to require licensees to educate workers about the effects legal drugs may have on job performance. Also, in line with comments, the NRC accepts that chemical testing for some legal drugs is appropriate, and that the testing protocol for these drugs, including proposed cut-off levels, should be included in the final rule. Therefore, the final rule will require that the testing protocol include testing for barbiturates and benzodiazepines, using the testing protocols and cut-off levels established in the rule.

10.2.3. Alcohol

The NRC believes that alcohol is a fitness-for-duty concern. The NRC believes that no on-duty alcohol consumption should be permitted, and that conducting breath tests to determine workers BACs is a necessary step towards detecting and deterring any on-duty use or any unacceptable off-duty use of alcohol.

Breath tests, when conducted following the protocols in the NRC "Mandatory Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs" (Appendix A to Part 26), provide relatively accurate and reliable measures of BACs, and are sufficient for all screening tests. Workers should have the right to have confirmatory tests performed at their request. Because of the improved accuracy obtained when using blood samples, confirmatory tests, may at the option of the individual being tested, be performed using blood samples analyzed with gas chromatographic methods as described in the Federal Register.

-----Begin Option A -----

The NRC believes that the scientific literature strongly demonstrates that BACs can be correlated with impairment, and that a BAC cut-off level of 0.04 percent is appropriate. This cut-off level is low enough to provide reasonable assurance that alcohol-caused impairment will be detected when breath tests are performed, and high enough to eliminate practical and technological problems associated with very low cut-off levels. The NRC therefore requires that blood alcohol concentration cut-off levels be set at 0.04 percent or lower and requires licensees to evaluate the significance of lower BACs. The NRC recognizes that there are practical problems associated with a zero or near-zero cut-off level, and encourages licensees to consider the potential impacts of these problems carefully before using very low cut-off levels.

-----End Option A -----

-----Begin Option B -----

The NRC concurs with those experts on alcohol use who maintain that even very low BACs can indicate some impairment. Further, the NRC recognizes that little is known about the impairing effects of alcohol at very low BACs, because few studies have been done to date examining the effects of alcohol at very low BACs. Therefore the NRC is not prescribing a cut-off level for alcohol tests that is to be associated with the denial of access. Licensees may establish levels that warrant sanctions at their discretion. However, subsequent to any test indicating the presence of alcohol in a worker's blood, the worker shall be evaluated before being allowed unescorted access.

-----End Option B-----

The NRC recognizes the value of a required period of abstinence from drinking that should precede all scheduled tours of work. The NRC therefore is

requiring licensees to include such provisions in their fitness-for-duty programs.

The NRC does not agree with those commenters who state that chemical tests for on-duty alcohol-caused impairment need only be performed on certain drug testing occasions, such as when for-cause testing is performed. The NRC believes that licensees should not indicate to workers that alcohol use that results in on-duty impairment is of less concern than is illicit drug use. Further, the NRC believes that any use of alcohol that results in on-duty impairment poses a significant potential threat to public health and safety.

Finally, the NRC agrees with comments that state that it would be easy for a worker to pass an announced test for alcohol misuse, such as a pre-employment or pre-access authorization screening. However, this is true for many illicit drugs that, like alcohol, are eliminated from the body relatively quickly. As is the case when testing for these illegal drugs, detection of rule violations may be rare, as workers need only abstain for a reasonable period prior to the test to be assured of passing the test. However, it is also very likely that those who are detected through such tests will have a very substantial problem that must be addressed. Some licensees who currently include tests for alcohol in their preemployment screening process have discovered several alcohol abusers who would have gone undetected without the screening process. For these reasons, the NRC requires that chemical tests for the misuse of alcohol should be conducted whenever tests for illegal substance abuse are performed.

With regards to sanctions related to alcohol in the final rule, the NRC agrees that it may not be essential that the actions taken to address alcohol misuse be identical to the actions taken to address illegal substance abuse. However, the NRC does believe that it is essential that licensees test for the misuse of alcohol and that detected impaired workers are removed from duty. Further, sanctions must be adequately severe to deter drinking practices that result in on-duty impairment, and severe enough, as compared to the sanctions associated with illegal drug use, to ensure that workers who abuse illegal drugs are not encouraged to merely switch from a pattern of unacceptable drug taking activity to a pattern of unacceptable alcohol consumption. One way of doing this is to

take actions in the event of a violation of the alcohol policy that are the same as, or similar to, the actions taken when the illicit drug policy is violated. In the absence of such actions, an effective program must provide assurance that a high level of deterrence is present and that workers who are impaired as a result of alcohol misuse are removed from duty.

11.0 CONFIDENTIALITY OF TEST RESULTS

11.1 Summary of Comments

A number of commenters were concerned about the confidentiality of test results and the potential impact of the rule on the privacy of workers. There was concern that test results might be inappropriately released to the detriment of workers. A number of specific suggestions were made to protect workers' rights.

11.1.1 Confidentiality of Results

One commenter favored identifying samples by a number coded to an individual worker rather than by name. Other commenters believed that there should be a protocol defining which licensee's workers should have access to fitness-for-duty records at various stages of the testing process. Several commenters expressed the view that test results should not be releasable to licensees or contractors under 10 CFR 26.27(b) without the written approval of the affected worker. One commenter proposed that all medical personnel involved in the fitness-for-duty process adhere to the American Occupational Medical Association's (AOMA's) "Code of Ethical Conduct for Physicians Providing Occupational Medical Services," and the AOMA "Ethical Guidelines for Drug Screening in the Workplace."

11.1.2 Use of Samples for Other Purposes

A number of commenters were also concerned that specimens taken from workers would be used for purposes beyond the scope of the proposed fitness-for-duty rules and suggested that language be added to the regulations limiting use of the samples to designated purposes.

11.1.3 Tests Conducted by the Licensee

The proposed rule (10 CFR 26.24[d]) would allow licensees to conduct preliminary tests of a sample before forwarding it to a laboratory. Several commenters were concerned that results of such preliminary tests would be inappropriately disclosed and acted upon prior to confirmation by the contract

laboratory. They proposed that access to the results of such preliminary tests should be strictly limited, perhaps to the licensee's laboratory staff only.

11.1.4 Confidentiality for Employee Assistance Programs

One commenter noted the lack of specific confidentiality requirements in the proposed section (26.25) on employee assistance programs and stated that such protections were necessary for the programs to be successful. Another commenter stated that the term "safety considerations," as used in this section, should be defined. A commenter also requested that language be added that employee assistance program EAP counselors would notify management when a belief exists that any worker's condition (self-referred or not) may constitute a hazard to himself or others.

11.1.5 Access to Records

Several commenters suggested that access to the results of chemical testing should be limited to the greatest extent possible, especially given the potential damage to a worker from disclosure of false positive results. In particular, many commenters believed that test results should not be released to law enforcement agencies.

There were a number of comments concerning access to fitness-for-duty records by NRC employees and representatives. Several commenters expressed the view that the NRC has no need for access to individual names and that if such information were provided it might be inappropriately disclosed or made available to the public. It was noted that licensees are expressly directed not to include the names of individuals under the proposed reporting requirements to NRC (26.73[a][3]), but that NRC is eligible to receive names under proposed Section 26.29(b).

Two commenters suggested that the Protection of Information section (26.29) include references to contractors and vendors as well as licensees. They further suggested that the reference to employment decisions be replaced by

access decisions. Another commenter raised the question of whether contractors as well as licensees should be able to obtain fitness-for-duty information under the proposed regulation at Section 26.29(b). An additional commenter suggested that release of fitness-for-duty information under a court order be added to the list of permitted disclosures under Section 26.29(b).

11.2 Summary of Responses

11.2.1 Confidentiality of Results

The NRC believes that further requirements for the protection of worker records at the testing laboratory beyond the requirements of the NRC Guidelines are not needed at this time. Section 2.8 of the Guidelines contains specific protections for such records.

The NRC concurs in the comment that information on a worker denied unescorted access or removed from his position under a fitness-for-duty program shall be provided to licensees and contractors subject to this part but only upon a written release by the affected worker. Appropriate language has been added to Section 26.27(a). The effect of the language is that if the worker elects not to provide such a release to the hiring licensee or contractor, the worker would be denied unescorted access to protected areas.

The comment that Medical Review Officers subscribe to the AOMA Code of Ethical Conduct and their ethical guidelines for drug screening in the workplace has merit. The NRC will continue to study this suggestion. For purposes of the present rulemaking, however, the NRC is satisfied that the statement of qualifications for Medical Review Officers in Section 2.7(b) of the NRC Guidelines is adequate and sufficient.

11.2.2 Use of Samples for Other Purposes

The NRC believes that addition of a specific provision in the rule limiting use of laboratory results to the purpose and scope of the rule is not required. The protections afforded by the NRC Guidelines and Section 26.29(b) are deemed to be

sufficient. Moreover, there should be no incentive for employers to disclose the information to unauthorized persons because of the possibility of liability related to such disclosure.

11.2.3 Tests Conducted by the Licensee

The NRC concurs that there is a potential for abuse of positive test results from preliminary tests conducted by the licensee. These preliminary tests do not have the accuracy of laboratory-conducted confirmatory tests. Consequently, the final rule limits access to the preliminary test results to the licensee's testing personnel.

11.2.4 Confidentiality for Employee Assistance Programs

The EAP requirement at Section 26.25 specifies that such programs are to provide confidential assistance except where safety considerations must prevail. The NRC believes that the plain meaning of these terms is sufficient for this rulemaking and that further clarification in the rule is not required. The NRC concurs in the suggestion that employee assistance program counselors notify management when there is a reasonable belief that any worker's condition may constitute a hazard to himself or herself or others, and the rule's language has been clarified.

11.2.5 Access to Records

The NRC has elected to retain the provisions on entities entitled to access to laboratory records as proposed in Section 26.29(b) with the exception that release of the information under a court order is added. The NRC does not anticipate requesting the results of laboratory tests correlated to individual names. The reporting requirements in Section 26.73(b) in fact specifically state that individual names should not be included in written reports submitted to the NRC. Nevertheless, the NRC wishes to reserve the right to have access to specific results when needed for particular situations involving safety and investigative matters such as malfeasance in the administration or management of the fitness-for-duty program. The NRC also has decided to retain the provision providing access to appropriate law enforcement officials. It is noted

that there is no requirement to routinely provide such officials with laboratory results. Moreover, it is unlikely that such results would be requested because the officials would have no prior knowledge of the results of laboratory tests.

The NRC concurs in the comment that contractors within the scope of the rulemaking should be included in the disclosure and access provisions of Section 26.29(b) and the final rule reflects this addition. The reference to employment decisions in the proposed rule has been replaced by access decisions.

12.0 EMPLOYEE ASSISTANCE PROGRAMS

12.1 Summary of Comments

The NRC received a significant number of comments from licensees regarding employee assistance programs. The majority of commenters agreed that employee assistance programs services are an effective method of combatting the broad spectrum fitness-for-duty problems. However, most of the commenters specified that under the proposed rule the scope of licensee employee assistance program services should be limited to regular, full-time licensee personnel; contractor or vendor personnel should not be covered. Several other commenters indicated that employee assistance program services should not be regulated by the NRC rule in any manner, and would be better addressed by the licensees themselves.

12.2 Summary of Responses

The NRC believes that employee assistance program services provide a valuable tool in combatting fitness-for-duty problems in the nuclear power industry. Therefore, as currently stipulated in the rule, it is the responsibility of each licensee to ensure that all licensee personnel have access to employee assistance programs services and that contractor employee assistance programs meet the criteria of the licensee's employee assistance programs. The NRC has also noted that supervisory personnel should not initiate employee referrals for counseling or treatment. Rather, supervisory personnel should refer employees to an employee assistance program counselor for assistance.

13.0 IMPORTANCE OF HEALTH AND HUMAN SERVICES GUIDELINES

13.1 Summary of Comments

13.1.1 Proposed Alternatives to the HHS Guidelines

Several commenters suggested that an alternative to the HHS Guidelines is the College of American Pathologists (CAP) Forensic Urine Drug Testing (FUDT) program. The commenters contend that the CAP FUDT program is as equally rigorous as the HHS Guidelines but better suited to licensee's needs because: (1) it has an educational component for laboratories, (2) it has accredited 25 laboratories as of October 11, 1988, whereas NIDA has accredited none, (3) the CAP FUDT program allows laboratories to test for additional drugs and at other cut-off levels than those specified in the HHS Guidelines, and (4) the CAP FUDT program does not require approval from the HHS Secretary.

One commenter suggested that an alternative to the HHS Guidelines is the "AFL-CIO Guide for Drug and Alcohol Testing on the Job." Several commenters pointed out that stringent quality controls are required of testing laboratories under state programs; two commenters stated that New York State had a stringent laboratory certification program.

13.1.2 Applicability of HHS Guidelines to the Nuclear Power Industry

A few commenters indicated that the HHS Guidelines should be adopted by the NRC in their entirety. The large majority of commenters stated that, although the HHS Guidelines provide many excellent procedures for ensuring the quality of drug testing programs, the HHS Guidelines contain terminology and provisions that are inappropriate for application to the nuclear power industry. The inappropriate terminology and provisions noted by the commenters include (1) references to "agencies," to Public Law 100-71, to the Privacy Act, and to the HHS Secretary; (2) limitations in the panel of drugs for which certified laboratories can test; (3) cut-off level specifications defined for screening and confirmatory tests; (4) requirements that a licensed physician, as a Medical Review Officer, review all test results; (5) the conflict with on-site

testing created by the requirement that all testing be done by certified laboratories; (6) laboratory certification procedures; and (7) limitations on splitting specimen samples. To ensure that the HHS Guidelines are appropriately adapted to the proposed rule, many commenters recommended that the pertinent sections of the HHS Guidelines be incorporated into the rule itself.

13.1.3 Limitations in the Panel of Drugs for which Certified Laboratories Can Test

A number of commenters specifically supported the intention and value of establishing uniformity across licensees in the panel of drugs, with a smaller number supporting a more flexible approach that allows licensees discretion to deal with local variability in drug use.

A number of commenters objected to the procedures specifying how licensees are to identify additional illegal drugs and incorporate them into their programs, on the grounds that these mechanisms defeat the purpose of uniformity, are unworkable, are burdensome, and open licensees to legal challenges. Some of these same commenters, along with others, recommended that the HHS-specified panel of drugs be expanded to include (for example) alcohol, methadone, barbiturates, benzodiazepine, propoxyphene, methaqualone, and prescription and over-the-counter drugs. Comments made at the public hearing expressed concern about the potential for intrusion into personal medical information if the panel of drugs is not strictly specified and limited.

13.1.4 Cut-off Levels Defined for Screening and Confirmatory Tests

A substantial number of comments were received on the cut-off levels for screening and confirmatory tests, many suggesting specific cut-off levels for particular drugs. An important disagreement among commenters centered around the issue of uniformity in cut-off levels. Some commenters recommended that standard cut-off levels be established and applied by all licensees in order to minimize inconsistency across licensees, maximize the defensibility of the cut-off levels, and avoid conflict with the certified laboratory testing procedures. These commenters thought that discretionary cut-off levels were unworkable because they would be challenged in court and were inconsistent

with certified laboratory procedures specified in the HHS Guidelines. Among these commenters, some supported the existing HHS cut-off levels and some recommended that the HHS levels be modified, generally to be more stringent. A number of commenters suggested standards matching those used by the military. Other commenters, particularly those representing licensees with ongoing drug testing programs, recommended that licensees be allowed discretion to establish cut-off levels more stringent than the minimum specified in the rule. As a compromise, some commenters suggested that laboratory procedures and testing be modified to require them to compile results at both the minimum uniform standard cut-off and the discretionary levels established by the licensees.

These commenters provided different reasons for establishing various cut-off levels, ranging from very stringent to more lenient. A few commenters supported the establishment of cut-off levels based on an objective of establishing a drug-free workplace, recommending essentially zero tolerance and setting cut-off levels just high enough to avoid positives from dietary consumption of legal substances. Others proposed the establishment of cut-off levels that were the lowest (most stringent) levels associated with impairment. Others, sometimes explicitly recognizing that the establishment of cut-off levels involves administrative considerations, recommended the use of "standard" and moderate levels that assist in the establishment of an accepted, widely-used standard and reduce vulnerability to legal challenges. Still others, generally those representing the workers and unions, supported cut-off levels that test for impairment rather than use and that set levels where job performance is probably affected.

A number of licensees commented that they are currently operating drug testing programs which have more stringent (lower) cut-off levels than the HHS Guidelines, especially for marijuana. Commenters were divided in their position regarding adoption of the HHS Guidelines for cut-off levels. Some supported the HHS Guidelines; others supported the more stringent levels proposed by NUMARC. A large number of commenters thought that the HHS cut-off level for marijuana was too lenient, citing experience from ongoing programs that a very high proportion (over 80 percent in Commonwealth Edison's 6-year-old program) of positive marijuana test results fall between 20 and 100 ng/ml. A number of commenters provided specific recommendations for screening and confirmatory cut-off levels for individual drug types.

13.1.5 Regulation of On-Site Screening Test

Although the majority of comments in this category addressed specific aspects of on-site testing, several commenters objected to conducting on-site screening tests by licensees on the grounds that such testing should not be conducted by employers and that it would be more costly, create too high a risk of false results, and result in claims of inequitable treatment. Other commenters, principally representatives of licensees and a health care products manufacturer, supported on-site screening tests as effective, timely, and less costly, particularly if only specimens that tested positive in the on-site aliquot test are sent to the certified laboratory. Some commenters favored modification of the proposed rule (Section 26.24[d]) to allow licensees to establish HHS-certified on-site laboratories and to avoid conflict with the HHS Guidelines. Changes in the specified procedures for on-site testing were also recommended, including enabling certified laboratories to match the cut-off levels established by the on-site program. The need for careful attention to conflicts with specific wording in the HHS Guidelines was noted. (Further discussion of the cut-off level issue is provided elsewhere.)

13.1.6 Requirements for Review of Test Results by a Medical Review Officer

A number of comments were received concerning the qualifications and role of the Medical Review Officer as specified in the HHS Guidelines, paragraph 2.7(b) (53 FR 11985, dated April 11, 1988). Commenters recommended that, should the HHS Guidelines be generally adopted, these specifications should be modified to eliminate the requirement that the MRO be a licensed physician. They recommended broadening the definition to include other licensed medical care providers with training and knowledge in substance abuse disorders and their treatment, identification and use of controlled substances, and prescription practices of pharmacies, and to provide for consultation of the MRO with a licensed physician for resolution of unusual circumstances. One commenter recommended changing the term "Medical Review Officer" to "Medical Review Professionals" to avoid possible confusion with licensee executive officers.

13.1.7 Laboratory Certification Procedures

A number of commenters thought that the number of blind samples was excessive and recommended that the requirement for licensees to submit blind samples be eliminated or substantially reduced. One commenter pointed out the potentially negative effects of having licensees prepare the false documentation associated with blind samples, and others questioned whether a sufficient supply of blind samples would be available on a timely basis. A number of commenters also questioned whether sufficient certified laboratory capacity would be available to implement the proposed rule. Comments both supported and opposed the requirement that laboratories be certified by HHS. Those supporting such certification recommended modification of the proposed rule to specify that licensees are to use HHS-certified laboratories that are directed to conduct drug tests consistent with NRC and licensee requirements. Several other commenters objected to the requirement for HHS certification, noting that it would likely prevent them from using high-quality local laboratories, and would prevent them from testing additional drugs or setting more stringent cut-off levels (unless such modifications are made in the application of the certification process, as discussed above). They recommended that the NRC adopt a provision authorizing licensees to utilize a drug testing laboratory that is either certified via the HHS Guidelines or is certified under a state program that is generally comparable to the HHS program. Other commenters suggested authorization of laboratories certified by The College of American Pathologists Forensic Urine Drug Testing (CAP FUDT) program.

13.1.8 Splitting Specimen Samples

A number of commenters recommended the use of split samples to provide an additional quality control measure and to further protect the rights of the workers by allowing a second check on confirmed positive results. Commenters differed in their specific recommendations concerning the number (2 or 3) and specific procedures for testing the reserved sample(s).

13.2 Summary of Responses

13.2.1 Proposed Alternatives to the HHS Guidelines

The NRC believes that the rigor required by the HHS Guidelines is not matched by any of the proposed alternatives. The NRC Guidelines address many of the concerns expressed by the commenters. The NRC believes that the highest standards are needed to assure that the testing process is accurate, produces valid results, and provides suitable protection for those being tested.

13.2.2 Applicability of HHS Guidelines to the Nuclear Power Industry

The NRC believes that many of the basic requirements of the HHS Guidelines must remain a vital component of the NRC drug testing regulations. However, the NRC is aware that the Guidelines, as written by HHS to apply to testing by Federal agencies, do not perfectly fit the circumstances of the licensees regulated by the NRC. There are many references to legal authorities and other matters that are peculiar to Federal agencies (e.g., references to the Privacy Act; to Executive Order 12564, to the Secretary) and terminology that may be confusing in the NRC-regulated industry context. In addition, the HHS drafted the Guidelines to apply to the physical and organizational circumstances of Federal agencies. Obviously, the circumstances of industries regulated by the NRC are very different from those of Federal agencies. Furthermore, as discussed below, other aspects of the rule, i.e., expansion of the panel of drugs and more stringent cut-off levels, require modification of the HHS Guidelines to maintain consistency and facilitate implementation. Consequently, the NRC agrees with many commenters and is, in its rule, directly implementing in its own regulations revisions to the Guidelines that are applicable to NRC licensee fitness-for-duty programs. These revisions are intended to leave intact the safeguards for accuracy and privacy in drug testing established by the HHS Guidelines while ensuring that the parties regulated by the NRC can practically implement the requirements. Editorial changes have been made in the Guidelines to adapt the terminology to the NRC and its licensees' fitness-for-duty programs.

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13.2.3 Limitations in the Panel of Substances That Certified Laboratories Can Test

Under the HHS Guidelines (2.1[a]), a Federal agency's random drug testing program may test a urine sample only for certain specified drugs. The NRC's proposed rule modifies this requirement by expanding the minimum panel of substances for which samples from the pre-access and random sampling program are to be tested to include alcohol, benzodiazepines, and barbiturates, in addition to marijuana, cocaine, opiate metabolites, phencyclidine, and amphetamines. Furthermore, the rule will allow licensees to include, with specific notification to employees and the NRC, additional drugs found to be prevalent in their geographic area. Licensee would be required to develop appropriate test protocols and cut-off levels. Under Section 26.24(c), a licensee may test the specimen obtained under the NRC rule only for the substances specified in the licensee's fitness-for-duty pre-access and random substance testing program (i.e., the minimum panel plus any additional substances specified by the licensee). For-cause tests are not limited to a specified panel of substances.

In determining which drugs to add to those required in the HHS Guidelines, the Commission assessed evidence regarding the extent of use of the various drugs recommended by commenters and the potential for impairment from the licit use, where appropriate, or abuse of those drugs. The NRC concluded that the panel of drugs in the HHS Guidelines adequately covers the most extensively abused illegal drugs, but does not sufficiently address the major drug class of sedatives (i.e., benzodiazepines and barbiturates). The use and abuse of sedatives by nuclear power plant workers are of significant concern for several reasons.

Although most sedative drugs are obtained legally through prescriptions or in over-the-counter mediations, these drugs are subject to abuse. In fact, some researchers have suggested that sedative abuse is more prevalent than the abuse of opiates in this country. In addition, continued abuse of these substances can lead to dependency and "physician-hopping" or illegal behaviors to obtain supplies of the drugs. Consequently, detection of the use of sedatives and an evaluation by the Medical Review Officer of the manner in which a worker is using sedatives are important to prevent the development of sedative-abuse problems.

Of greater significance is that the use of sedatives while on the job, even at physician-prescribed doses, may result in significant impairment. Although many types of performance are detrimentally affected by the use of sedatives, attention and the ability to maintain vigilance are particularly impaired. And, when combined with alcohol, the impairing effects of sedatives, especially barbiturates, are long-lasting and severe. Therefore, the NRC has concluded that detection and deterrence of the use of these drugs, except under the most carefully controlled and supervised conditions, is as necessary to ensure public health and safety as detecting and deterring the abuse of illegal drugs.

In response to objections by licensees to the requirement that they must consult with local law enforcement authorities and drug counseling services to determine whether other drugs are being used in the geographical locale of the facility and the local workforce and, where appropriate, add these drugs to the list of drugs being tested, the NRC has made this element of the program optional. To address the issue of changing drug use patterns, the NRC may conduct periodic reviews of the minimum drug panel that could result in the inclusion of additional substances.

13.2.4 Cut-off Levels Defined for Screening and Confirmatory Tests

In response to comments concerning the appropriate cut-off levels at which samples will be considered positive, the NRC proposes the screening and confirmatory cut-off levels set forth in the NRC Mandatory Guidelines for Drug and Alcohol Testing. These levels define the standards for establishing presumptive positive and negative results for the minimum panel according to the NRC rule. However, in response to numerous comments by licensees, many of whom have existing drug programs with more stringent cut-off levels for the substances included in the proposed minimum drug panel, the NRC rule establishes minimum standards for the panel of drugs and allows licensees the discretion of setting more stringent cut-off levels for these drugs. For example, instead of using their normal cut-off levels for for-cause and follow-up testing, licensees could obtain data on any trace amounts of drugs for medical evaluation of at-risk

persons. Certified laboratories are authorized to test and report results at these more stringent cut-off levels, if so requested by the licensee. In keeping with the objective of uniformity and the establishment of a comparable database, however, the laboratories are also required to report results for the "standard" cut-off levels established in the rule.

13.2.5. Regulation of On-Site Screening Test

Although the NRC is sensitive to the concerns of workers expressed in the comments, the stringent quality assurance requirements of the rule and the rigor of the HHS certification process have convinced the NRC to retain the option of on-site testing. Under the NRC rule, licensees may perform the breath tests for alcohol and the preliminary screening tests of urine specimens provided that the licensee's staff possess the necessary training and skills for the tasks assigned, their qualifications are documented, and adequate quality controls are implemented. These requirements have been included in the NRC Guidelines. Following preliminary screening, these licensees would submit all positive specimens and a sample of negative specimens to an HHS-certified laboratory for a second screen and for confirmatory testing. This will substantially reduce the number of specimens that must be packaged, sent, and handled at the certified laboratory. The NRC rule does not prohibit licensees from establishing laboratories and seeking HHS certification. Should HHS certification be obtained, the licensee would be allowed to conduct both screening and confirmatory tests at this laboratory.

13.2.6 Requirements for Review of Test Results by a Medical Review Officer

After careful review of the comments received regarding the Medical Review Officer and examination of the Medical Review Officer Manual prepared by the Department of Health and Human Services (September 1988), which describes the role and responsibilities of the MRO, the NRC has concluded that this position does require the qualifications of a licensed physician. To maintain consistency with the HHS program, the NRC has decided to retain the title Medical Review Officer.

13.2.7 Laboratory Certification Procedures

The NRC has given careful consideration to the number of blind samples licensees must submit to the certified laboratory and has determined that the number specified in the NRC Guidelines is necessary to maintain adequate quality control. In addition, licensees which expand their drug panel beyond the NRC specified minimum panel are responsible for submitting a sufficient number of appropriately "spiked" blind samples to meet equivalent laboratory quality control requirements for those additional drugs. The NRC has consulted with personnel of the Office of Workplace Initiatives in the National Institute on Drug Abuse and has been assured that sufficient blind samples and laboratory capacity will be available to implement the proposed rule on a timely basis.

Given the importance of protecting workers from false positive test results and the absence of clear evidence that alternative certification procedures provide an equivalent level of rigor, the NRC rule maintains the requirement for laboratories to obtain HHS certification in order to perform confirmatory chemical tests on specimens submitted for tests under the provision of the NRC rule. In addition to HHS certification, laboratories used by licensees must demonstrate comparable performance and rigor in testing for the additional substances included in the licensee's specified panel of substances (i.e., the NRC minimum panel plus any discretionary additions of the licensee).

13.2.8 Splitting Specimen Samples

The NRC is sensitive to the concerns of nuclear power plant workers regarding the adverse consequences of false positive test results and the advantages of using split samples to provide an additional quality control measure and further protect the rights of workers by allowing a second check on confirmed positive results. The first aliquot, along with appropriate chain-of-custody documentation could be (1) transmitted to the HHS-certified laboratory for screening and confirmatory testing or (2) transmitted to the authorized on-site screening laboratory for preliminary testing. The second aliquot of the split sample, along with appropriate chain-of-custody documentation, could be placed in a secure refrigeration unit or forwarded to a second laboratory for retention. Should the specimen test positive, the second aliquot could be tested by the second HHS-certified laboratory.

In the case of on-site screening, the second aliquot could be discarded if the preliminary test (screen) is negative. If the screening test is conducted off-site, the second aliquot could be discarded immediately upon notification of a negative test result for the specimen. Even though there is a high degree of assurance of the accuracy of the test results provided by the chain-of-custody and HHS-certified laboratory procedures, chain-of-custody concerns by tested workers would remain no matter how precise the process or valid the results. Therefore, the NRC has decided not to mandate nor prohibit split samples; the approach may be used by licensees where additional confidence in the process by the workforce is sought.

14.0 RELATIONSHIP TO ACCESS AUTHORIZATION

14.1 Summary of Comments

This section covers comments relating to the potential overlap of the proposed FFD rule and Industry Guidelines appended to the proposed Access Authorization Policy Statement (AAPS) appearing at 53 FR 7534, March 9, 1988.

14.1.1 What is an Appropriate "Suitable Inquiry"?

A number of commenters raised the issue that the "suitable inquiry" requirement in Section 26.27(a) is too severe and also conflicts with the background investigation elements section of the AAPS. Proposed Section 26.27(a) requires that licensees conduct a suitable inquiry prior to granting unescorted access to determine if a worker has tested positive for drugs in the past. The term "suitable inquiry" as defined in Section 26.3 requires verification of employment history for the previous five years and to determine whether the worker had any positive drug tests. Many commenters pointed out that this requirement will be very difficult and costly to meet in part because prior employers will be reluctant, because of liability concerns, to release records of drug use, even with a signed release form. One commenter pointed out, for example, that under Section 26.29(b) a licensee would not be authorized to release such information to another employer who is not also a licensee.

The commenters noted that the required background investigation in Section 6.2.1 of the Industry Guidelines appended to the AAPS covers similar material to the fitness-for-duty rule, but is not as severe. The investigation contains several elements, one of which is a check on an applicant's character and reputation including prior illegal use or possession of a controlled substance. Information is to be obtained from four references, two supplied by the applicant and two developed by the utility. Employment verification is to be obtained for a minimum of three years. In addition, the evaluation criteria in Section 7.1 of the AAPS require utilities to assess the impact of past illegal use or possession of a controlled substance.

One commenter pointed out that the proposed suitability inquiry requirements will conflict with the required background checks for security personnel in 10 CFR Part 73, Appendix B. These background checks require the licensee to investigate a number of elements related to selection of security personnel including whether an individual has any history of alcoholism or drug addiction. There are no specific time periods associated with the required background checks.

14.1.2 Overlap in Training Requirements

One commenter stated that the training requirements for supervisors and escorts in Section 26.22 already exist in Section 9(c) of the Industry Guidelines and that the requirements in the fitness-for-duty rule could therefore be eliminated.

14.1.3 Relationship of Employee Assistance Programs to the Proposed Access Authorization Policy Statement

One commenter raised the question of whether a voluntary referral to an employee assistance program raises an access authorization issue under the Industry Guidelines appended to the proposed access authorization policy statement. Under the Guidelines, illegal use of drugs is an evaluation criterion for unescorted access (Section 7.1[b]) and an element of the continual behavioral observation program (Section 9[a]).

14.1.4 Temporary Unescorted Access Authorization

One commenter noted the temporary unescorted access authorization in Section 6.4 of the Guidelines and stated that it should be made clear that during the suitable inquiry period, the temporary access authorization would be available.

14.2 Summary of Responses

14.2.1 What is an Appropriate "Suitable Inquiry"?

The NRC recognizes the potential overlap between the required background investigations in the fitness-for-duty rule and the AAPS. The NRC agrees that the background investigation required in the fitness-for-duty rule may be difficult to conduct in some cases and that the desired information may not always be forthcoming. Consequently, the term "suitable inquiry" in Section 26.3 has been modified to provide for the "best effort" provisions of paragraph 6.2.1 of the Industry Guidelines, that is, attempts should be made to obtain information for the entire five year period, but under no circumstances may unescorted access be granted based on an employment check of less than three years. In addition, a requirement has been added to Section 26.27(a) that a suitable inquiry will be conducted only after obtaining a signed release from the worker or prospective worker authorizing the inquiry.

The NRC recognizes the potential additional requirements under the fitness-for-duty rule as compared to currently required background checks for security personnel contained in Appendix B to Part 73. Nevertheless, the required checks with prior employers in the fitness-for-duty rule are considered necessary for the safety and security reasons noted earlier.

14.2.2 Overlap in Training Requirements

The NRC recognizes that there is some overlap in the two training requirements, but does not find any inconsistencies. Moreover, the fitness-for-duty requirements are more comprehensive, to include techniques for recognizing drugs and understanding the role and responsibilities of other fitness-for-program elements such as the employee assistance program. Consequently, no changes were made in the final rule.

14.2.3 Relationship of Employee Assistant Program to the Proposed Access Authorization Policy Statement

The NRC recognizes that there is a connection between the employee assistance program and proposed access authorization policy statement requirements. Under Section 26.25, employee assistance program staff will provide confidential assistance except where safety considerations must prevail and when the employee assistance program counselor believes that a worker's condition poses a hazard to himself or herself or others. Otherwise, voluntary self-referrals to the employee assistance program are treated confidentially and are not reported to management; therefore, that information would not be available for disclosure in response to an inquiry of previous employers. The NRC is satisfied that there is not an inconsistency in the employee assistance program and proposed access authorization policy statement requirements and consequently no changes are made in the final rule.

14.2.4 Temporary Unescorted Access Authorization

NRC agrees that the temporary unescorted access authorization provision in the Industry Guidelines will be applicable to fitness-for-duty background investigations with the added provision that the worker pass a chemical test. Clarifying language has been added to Section 26.27(a).

15.0 REPORTING AND RECORD-KEEPING

15.1 Summary of Comments

15.1.1 Fitness-for-Duty Program Performance Data Form

Many comments on the data form were received. All were severely negative. The consensus was that the stated data requirements are excessive, unnecessary, and expensive and will contribute nothing to the public health and safety. Virtually all respondents asked for deletion of the form and its associated requirements.

15.1.2 Reports to NRC

Section 26.73 directs the licensee to provide information concerning fitness-for-duty events. This was presumed to include identities of violators and a record of the incident and its disposition. Some commenters thought that the NRC is not qualified to ensure the necessary degree of confidentiality demanded for these records, while others pointed out that the NRC handles much sensitive information including classified information and thus is well qualified to receive specific fitness-for-duty data. Among the latter, one commenter went so far as to suggest that the NRC, rather than the licensees, implement and administer the violations tracking system. Public Citizen expressed general support of the reporting requirements and recommended that they be augmented to include additional information.

15.1.3 Reporting Time Requirements

Section 26.73(a)(2) requires detailed reports on all significant fitness-for-duty events and actions to be made to the NRC Operations Center by phone within 24 hours and in writing within 30 days. Many commenters claimed that the 24-hour requirement is excessive. Others pointed out conflicts or potential conflicts between reporting requirements in the fitness-for-duty rule and those cited in 10 CFR 73.71, 10 CFR 50.72, and Reg. Guide 5.62.

15.1.4 Incident Locale

Commenters posed questions as to whether drug or alcohol-related incidents should be reported if they occur outside protected areas--either on-site or off-site.

15.2 Summary of Responses

15.2.1 Fitness-for-Duty Program Performance Data Form

The NRC does not believe that collection of data in a standard format unnecessarily burdens licensees. Collecting data in a standard format would assure that appropriate data is collected, and would facilitate periodic analysis and audits. Certain information is necessary for the NRC to evaluate the effectiveness of the rule and industry programs and a standard data format would provide a tool for the Commission's periodic review program. No specific improvements to the form were suggested by commenters. However, NUMARC has indicated that industry guidelines will be developed which will include data collection elements. The NRC will therefore not, at this time, require a standard set of data to be collected by the licensee. Should the industry guidance not prove adequate, however, the NRC will consider further regulatory action.

15.2.2 Reports to NRC

The NRC sees no reason to change this provision of the rule. The reporting requirements in Section 26.73 are reasonable as stated.

15.2.3 Reporting Time Requirements

The NRC will maintain the 24-hour reporting deadline for fitness-for-duty events involving licensed operators and supervisory personnel. Licensees should note that this provision supersedes and relaxes the 1-hour reporting period required for the fitness-for-duty categories of safeguards events in 10 CFR 73.71. The NRC will publish a revision to Regulatory Guide 5.62 to ensure consistency with this rule.

15.2.4 Incident Locale

Because one of the purposes of the rule is to gauge reliability of staff with unescorted access, incidents indicative of substance abuse are relevant independent of where they occur. The NRC has, therefore, modified the wording of Section 26.73, "Reporting Requirements," to make it clear that incidents occurring off-site or external to protected areas must be reported.

16.0 AUDITS OF FITNESS-FOR-DUTY PROGRAMS

16.1 Summary of Comments

Approximately one-third of the comments received concerning audits of fitness-for-duty programs addressed the frequency requirement for the audits, which is 13 months in the proposed rule. The majority of these commenters stated that the rule should be revised to require an audit every three years, after an initial audit is performed within 13 months of implementation of the program. Most of the other commenters stated that the audit frequency should be once every three or five years. One commenter stated that the audit period should remain on a 13-month cycle.

Two commenters questioned how information that is protected under Section 26.29(b) can be used when sharing audit results of contractors as described in Section 26.80(a). Section 26.29(b) prohibits disclosing some of the information that would be collected during an audit.

Many commenters stated that the word "effectiveness" in Sections 26.80(a) and 26.80(b) is too subjective and that "compliance with the regulations" should be the requirement.

Several commenters stated that the phrase in Section 26.80(b), "individuals qualified in the subjects being audited," should be clarified.

One commenter stated that Section 26.80(a) should be revised to delete the requirement for the licensee to be responsible for the effectiveness of contractor programs and implementation of appropriate corrective action for contractor programs since this should be the contractor's responsibility.

Two commenters stated that Section 26.80(a) should be clarified as to whether or not a licensee may accept audits for contractors conducted by other licensees.

One commenter stated that the requirement in Sections 26.80(a) and 26.80(c) that audit reports be maintained on-site and at corporate headquarters be changed to corporate headquarters only. The basis for this comment is that some utilities have several reactor sites and maintaining the reports at each site would be a redundant effort.

16.2 Summary of Responses

The NRC has maintained the Section 26.80(a) requirement for an audit frequency of nominally every 12 months. This decision is based on the need to assure the reliability and accuracy of chemical testing procedures. As industry experience with fitness-for-duty programs accumulates and is made available to the NRC, the Commission may re-evaluate the frequency of required audits, as warranted.

The NRC agrees that Sections 26.29(b) and 26.80(a) contain a conflict concerning protection of information. Section 26.29(b) has been revised to explicitly allow licensees to have access to personal information that may need to be examined during audits.

The NRC intentionally has used the word "effectiveness" throughout the rule to ensure that all affected parties maintain an overall concern for the rule's objectives rather than focusing on documentation of program compliance with "the letter of the law." Although compliance is important, the Commission's over-riding concern is an answer to the question, "Is the program working?"

The NRC believes that current wording in the rule is adequate to define auditor qualifications. The intent of this section is to ensure that an individual, for example, who is not a licensed physician and has no knowledge of substance abuse is not assigned to evaluate the effectiveness of a particular Medical Review Officer's decision making. Similarly, the NRC

expects that persons who are evaluating testing laboratories will be knowledgeable about the forensic implications of laboratory procedures. Because individuals who possess the requisite skills to conduct these audits are likely to be relatively rare and their services needed only infrequently, licensees will probably find it necessary to contract for appropriate audit staff rather than staffing an entire audit team from the licensee's Quality Assurance program. Current wording in the rule is intended to recognize and encourage such an approach to staffing program audits.

The NRC does not agree with the commenter who suggested that licensees should not be responsible for contractor programs. As noted in the discussion of comments pertaining to the scope of the rule, the licensee is the granting authority for unescorted access to protected areas and so is responsible for the fitness-for-duty and the reliability of any individuals to whom unescorted access is granted, whether contractor or licensee employee. Only by monitoring the effectiveness of contractor programs that the licensee accepts and requiring necessary changes can the licensee be assured that the trust implied by the granting of unescorted access is warranted.

The intent of the wording in the proposed rule is to reduce the burden on licensees by allowing audits of contractors to be shared between licensees and to reduce the burden on contractors who provide personnel to several utilities by reducing the number of required audits. However, each licensee has the ultimate responsibility to ensure that all contractors performing activities within the scope of the rule comply with the rule.

The NRC agrees it is unnecessary to dictate where the licensees should maintain copies of the audit reports as long as a copy is available for NRC inspection. Section 26.80(a) has been changed accordingly.

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17.0 IMPLEMENTATION SCHEDULE

17.1 Summary of Comments

The NRC received numerous comments on the proposed implementation schedule for the rule. Eighteen comments were received from individual licensees. In addition, a number of other licensees submitted letters endorsing the NUMARC position on the rule as a whole, including NUMARC's position on the implementation schedule. Commenters generally agreed that 90 days was insufficient time to implement the provisions of the rule. Problems with the development of training material, modification of existing EAPs, development of administrative procedures, negotiations with unions, and the establishment of contracts with chemical testing laboratories were cited by many of the commenters as reasons for the need for a longer period for implementation. Most commenters suggested that 180 days be allowed for implementation of all provisions of the rule. Some commenters proposed that additional time beyond 180 days be allowed for the implementation of the random testing provisions of the rule.

17.2 Summary of Responses

The NRC places a high priority on the implementation of the fitness-for-duty programs and policies required by the present rule. Many licensees already have in place most of the key program elements. However, because of the complex provisions of the rule, the need for some licensees to establish contractual relations with laboratories, the need to develop implementation procedures, the need to augment existing training materials, and the need to coordinate the provisions of the rule with numerous contractors and negotiate with unions, the NRC is convinced that the quality of the programs will be enhanced by extending the implementation of all provisions of the rule until 180 days following publication of the interim final rule. Because of the importance of the rule, the NRC cannot support the further extension of the implementation of the random testing provision of the rule past the 180-day deadline.

Although licensees need not submit written policies and procedures to the NRC for approval prior to implementing their programs, the Commission has reserved to itself the authority to review the program at any time to assure that the program meets the performance objectives of the rule. If the review or other inspections detect a shortcoming in the program, the Commission can then require corrective action.

18.0 Legal Issues

18.1 Summary of Comments

18.1.1 Constitutionality of Rule

Several commenters noted that significant issues of constitutionality with regard to drug testing in the workplace have been raised under the Fourth Amendment and that these issues are currently being reviewed within the judicial system. Two drug testing cases are on the current calendar of the United States Supreme Court. (National Treasury Employees Union v. Von Raab, 816 F.2d 170 (5th Cir. 1987), cert. granted, 108 S.Ct. 1072 (1988); Railway Labor Executives Association v. Burnley, 839 F.2d 575 (9th Cir. 1988), cert. granted, 108 S.Ct. 2033 (1988)). Generally, commenters representing operators of power reactors support the constitutionality of the rule, while commenters representing labor organizations or individuals challenge the rule's constitutionality. A few of these commenters suggested that the Commission delay its rule until the Supreme Court has acted on the cases before it.

A few commenters stated that the taking of the urine sample for analysis presented a violation of a person's right of privacy under the First Amendment to the Constitution.

A few commenters questioned whether the rule might not violate the self incrimination provision of the Fifth Amendment to the Constitution, in particular with regard to the potential for release of adverse test results to local police.

18.1.2 Federal Rehabilitation Act

A few commenters suggested that the Commission should address the Federal Rehabilitation Act of 1973, as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (29 U.S.C, Sections 701-796) in relation to its fitness-for-duty rule.

18.1.3 Preemption of State and Local Laws

Several commenters noted that some states have enacted laws that appear to conflict with the Commission's rule, and requested clarification whether the Commission's rule would be preemptive of state and local law.

18.1.4 Appeal Procedure

Some commenters questioned the need for and scope of the appeal procedure required by the rule. Reference to due process was seen as importing unnecessarily complicated judicial type procedures, and that fairness was the goal. Reference to collective bargaining procedures was viewed as undesirable because those procedures often incorporate binding arbitration which would also unduly complicate the appeal of denial of unescorted access because of an adverse fitness-for-duty finding. Finally, appeals should be limited to permanent employees of the licensee and not be extended to the employees of contractors.

18.1.5 Protection of Information

Some commenters raised questions about the protection of information, specifically reporting of information to local police, and disclosure of information to arbitrators and the affected individuals. One commenter asked the Commission to address the relationship between protection of information under the Commission's rule and the information protection requirements of 42 CFR Part 2, dealing with drug and alcohol abuse treatment programs.

18.1.6 Collective Bargaining Rights

A commenter raised a question about the relationship of the Commission's rule to the right of workers under the National Labor Relations Act to bargain over conditions of employment and asked that the Commission state its position.

18.1.7 Employee Assistance Program

A commenter asked for the Commission to indicate its legal authority for including employee assistance programs in the rule.

18.1.8 Administrative Procedures for Alcohol

A few commenters questioned whether the notice of proposed rulemaking was adequate to address issues regarding alcohol use and to support the inclusion of alcohol-related provisions in the final rule.

18.2 Summary of Responses

18.2.1 Constitutionality of Rule

It is the Commission's considered opinion at this point that continued assurance of nuclear safety in the operation of power reactors fully justifies the rule being promulgated. The imperatives of safe operation of nuclear power reactors demand a workplace where the reliability, integrity and physical and mental fitness for their assigned duties of all categories of workers with unescorted access to plant vital equipment is unquestioned. The program being mandated by this rule is reasonably related to the achievement of the Commission's safety objective. The Commission has no doubt that the rule will significantly enhance safety of operations at nuclear power reactors. It goes without saying, however, that the Commission will review this rule in light of relevant future Supreme Court decisions, and make whatever revisions those decisions require.

Although decisions and opinions in the two cases cited above would aid the Commission's understanding of the Constitutional limitations on drug testing, neither presents issues to the Court for its consideration in the context of the imperatives of nuclear safety. Thus, questions of the constitutionality of this rule may remain unresolved even after the Court renders its decisions in the two cases. Given this, and the important safety benefits of the rule, the present litigation does not present a sufficient reason for delay in issuing this rule.

It is already well established that persons working in nuclear power plants have diminished expectations of privacy in the workplace with respect to fitness-for-duty issues. For example, control room operators are licensed under rules (10 CFR Part 55) that require medical examination biennially and general good health. Security personnel are subject to medical and mental qualifications, including use of alcohol and drugs (see 10 CFR Part 73, Appendix B). All personnel and their hand-carried items (such as lunch boxes) are subject to search upon entering the protected areas of nuclear power plants, including pat down searches when metal and explosive detectors are not working or when there is suspicion that the person may be attempting to bring proscribed items into the protected area (see 10 CFR 73.55). Most, if not all, licensees of nuclear power plants also are committed through their security plans under 10 CFR Part 73, to conduct background investigations, administer psychological examinations, and observe employees for indications of aberrant behavior. Licensees also have behavioral observation programs that follow Edison Electric Institute guidelines. Finally, all persons with unescorted access to nuclear power plants are, by Federal law, subject to a criminal history records check that requires the taking of fingerprints and the submission of the fingerprints to the Federal Bureau of Investigation (see 10 CFR 73.57). The provision of a urine sample or taking of a breathalyzer test is a small increment in the diminished expectation of privacy under which persons work in a nuclear power plant. Accordingly, the Commission concludes that its rule does not constitute an unconstitutional invasion of the right of privacy. Indeed, persons working in nuclear power plants may already be considered to be highly regulated, and, in regard to Fourth Amendment issues, within the ambit of Shoemaker v. Handel, 795 F.2d 1136 (3rd Cir. 1986), cert. denied, 479 U.S. 986 (1986).

On the assumption that the rule being promulgated is within the Constitution in other respects, the rule's provisions on protection of information do not infringe upon the right of a person to not incriminate himself. In the Commission's view, the case of Schmerber v. California, 384 U.S. 757 (1966) controls the issue. In that case, the Court upheld the taking of a blood sample for alcohol analysis against a Fifth Amendment challenge. A urine sample is no more incriminating.

18.2.2 Federal Rehabilitation Act

The Federal Rehabilitation Act of 1973, as amended, does not include, within the concept of "handicapped person", an individual who is an alcohol or drug abuser whose current use of alcohol or drugs prevents that individual from performing the duties of the job in question or whose employment, by reason of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others (see 10 CFR 4.101(a) and 29 U.S.C. 706(7)(B)).

An individual whose urine or breath sample tests positive for drugs or alcohol is obviously a current user whose continued unescorted access to plant vital equipment constitutes a direct threat to nuclear safety. However, a person who enters into an employee assistance program and whose subsequent tests are negative is not a current user and would be entitled to the protection of the Federal Rehabilitation Act if it were applicable to his place of work because of his employer's receipt of or benefit from Federal financial assistance. Federal financial assistance is defined at 10 CFR 4.4(d) and means essentially the provision by the Federal Government of any funds or personnel or property free of charge or at reduced rates. The Commission does not provide any Federal financial assistance to nuclear power reactor licensees. On the contrary, the Commission charges power reactor licensees for the regulatory services it renders (see 10 CFR Parts 170 and 171). Whether or not other Federal agencies provide such assistance is not known to the Commission. Each licensee implementing the Commission's fitness-for-duty rule will need to determine for itself whether it is receiving such assistance.

18.2.3 Preemption of State and Local Laws

The Atomic Energy Act of 1954, as amended, preempts to the Federal Government the field of regulation of nuclear power reactors in all matters pertaining to radiological safety of operation. See 10 CFR 8.4, Pacific Gas and Electric Co., v. State Energy Resources Conservation and Development Comm., 461 U.S. 190 (1983). However, State laws on possession, sale or use of controlled substances and alcohol were enacted with broad social goals in mind rather than radiological safety. Thus, such laws would not be preempted. There would be preemption in the rare case where a state sought to control fitness-for-duty of nuclear plant employees for radiological safety purposes or a state law made compliance with NRC's fitness-for-duty rule different or impossible.

18.2.4 Appeal Procedure

The Commission believes that an appeal or review procedure with respect to the results of tests is needed because elementary fairness to the adversely affected individual will help assure employee cooperation in the implementation of the licensee's program. Such cooperation should contribute to successful implementation of the rule. Fairness is represented in the rule by the employee assistance program, the appeal procedure, and the protection of information. Therefore, the appeal procedure is retained, but modified to replace reference to due process with reference to impartiality and objectivity and removal of reference to collective bargaining agreements. Because the focus of the rule is on fitness for unescorted access and not directed at an employment relationship, and because the licensee will be making the access determination based on fitness-for-duty for all persons needing unescorted access, whether they are permanent employees, temporary employees or contractor employees, the procedure is not being limited to permanent employees of the licensee. The Commission notes, however, that in union plants the review procedure covers drug and alcohol issues subject to collective bargaining and that the removal of the reference to collective bargaining agreements in the rule does not preclude bargained for procedures, including binding arbitration, from being employed in resolving disputes over fitness-for-duty determinations. The allowance of an internal management review is discretionary only, and not mandatory except in the absence of any other procedure.

18.2.5 Protection of Information

It is not the Commission's intention that results of testing be routinely available to local law enforcement agencies except under court order since the test result does not, in and of itself, demonstrate whether the use of the drug or alcohol was on-site or off-site, legal or illegal. The Commission is, however, firmly convinced that on-site criminal conduct, such as sale or possession of illegal substances, not be protected by the Commission's rule. The Commission agrees that the individual to whom the information pertains should be able to see the records in which the information is contained. The Commission also agrees that such records should be available to an arbitrator, or other adjudicator who is being asked to resolve a fitness-for-duty dispute, provided the records are relevant to the particular dispute. Section 26.29 has been modified to clarify its application accordingly.

With regard to 42 CFR Part 2, it is the Commission's conclusion that it has no relationship to the Commission's rule. 42 CFR Part 2 comprises the regulations of the Department of Health and Human Services implementing Section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (42 U.S.C. 290 et. seq.). It states the rules for maintaining confidentiality of patient records for persons in drug or alcohol abuse prevention and treatment programs regulated by or receiving assistance from the United States Government. First, the Commission is providing no assistance to any such program in the private sector. Second, it is not regulating such a program. The requirement for an employee assistance program does not mandate a treatment program that would fall under the regulations in 42 CFR Part 2. As noted in the response to the issue of preemption, the employee assistance program is not a preempted area. Its content is open to bargaining and the application of other nonconflicting State laws. Further, licensees are not precluded from referring employees to treatment programs to which the HHS rules might apply as long as the minimum program required by Section 26.25 is provided by the licensee. In that case outside patient records would be totally separate from records required by 10 CFR Part 26 and would be protected according to other applicable rules.

18.2.6 Collective Bargaining Rights

According to Memorandum GC 87-5, issued by the General Counsel of the National Labor Relations Board on September 8, 1987, drug or alcohol testing for current employees and job applicants is a mandatory subject of collective bargaining and that the implementation of a drug or alcohol testing program is a substantial change in working conditions. Although the Commission's rule requires a drug and alcohol testing program and sets certain standards for it, the rule is not one directed at labor relations, but rather at nuclear safety. The Commission's rule applies equally to union and nonunion workers. It does not affect, even indirectly, the right of self-organization provided by the National Labor Relations Act. The rule does not preclude collective bargaining over issues in drug or alcohol testing programs that are not addressed by it. In the Commission's view, its rule and the opinion of the NLRB General Counsel are compatible documents. See, Metropolitan Life Insurance Co. v. Massachusetts, 471 U.S. 724, 755 (1985).

18.2.7 Employee Assistance Program

The authority statement for the rule states that it is promulgated under Section 161, among others, of the Atomic Energy Act. Included within Section 161 is section 161i(3) which gives the Commission authority to promulgate rules to govern any activity authorized pursuant to the Atomic Energy Act, including operation of facilities, to protect health and safety. The employee assistance program required by the rule is an incremental addition to safety by giving persons with fitness-for-duty problems a nonthreatening avenue to resolve those problems, thus removing a potential for compromising the safety of operation of a nuclear power reactor. In the Commission's view the employee assistance program can be incorporated in a Commission rule under the broad scope of Section 161 of the Atomic Energy Act.

18.2.8 Administrative Procedures for Alcohol

Under the Administrative Procedure Act (5 U.S.C. 553) the Commission is obligated to provide in its notice of proposed rulemaking either the terms or substance of the proposed rule or a description of the subject and issues involved. With respect to alcohol, the proposed rule specifically included it in the scope of the licensees' fitness-for-duty programs (Section 26.20). The performance objectives are applicable to any substance, legal or illegal, that can adversely affect a person's ability to perform. There is no doubt that alcohol is such a substance. The rule text did not, however, include prescriptive requirements for alcohol. However, the Commission expressly asked for comment on the extent to which guidance should be given as to alcohol and prescription drugs. Standards for blood alcohol content were extensively discussed in the Statement of Considerations along with a Commission request for comment on whether the Commission should prescribe a cutoff level for alcohol. Thus, the notice of proposed rulemaking clearly covered alcohol both in the terms of the proposed rule and in describing in some detail the subject and issues involved. The public was well advised that alcohol testing was a subject within the rulemaking and that the Commission expected to resolve basic issues regarding testing for alcohol in the comment period on the proposed rule. Therefore, the inclusion in the final rule of basic additional requirements for alcohol testing is, in the Commission's view, well within the scope of the proposal. There is no requirement that the additional rule text dealing with alcohol testing be published for separate comment, and not as part of the final rule.

19.0 Costs/Benefits

19.1 Summary of Comments

Several commenters stated that the NRC should justify the rulemaking under the provisions of 50.109(a)(3), however, no commenters supported the alternative that a backfitting analysis is not necessary under the provisions of 50.109(a)(ii).

Several commenters said that the estimated costs in the Backfit Analysis were substantially under-estimated in the following cost element areas: costs to administer the testing and training programs, particularly the estimate of the numbers of additional staff that would be necessary to administer the program; length of time estimated for individual employee training, both initial and refresher; time to take a test between leaving and returning to work area; added cost of using HHS certified laboratories and quality control measures; and, costs to conduct background checks.

In addition to these comments, one person, whose comments were included as enclosures by two respondents from one union, contended that: the number of persons that would be tested is under-estimated and did not include contractor personnel; incremental costs are incorrect because not all plants have fully developed programs; average life of plants should be 40 years rather than 25; use of 10 percent discount rate is unrealistic; and, costs associated with alcohol, legal drug use, and other kinds of performance impairment were ignored.

This commenter also contends that: written policies and procedures and labor contract modifications involve recurring as well as initial costs; employee turnover needs to be factored into training and testing; costs of employee assistance programs do not include medical and counseling staff, training materials, and medical testing and treatment; costs of legal challenges resulting from the program omitted awards of back pay and/or damages and underestimated volume of appeals; and, indirect costs to workers from false positives (lost jobs or wages, humiliation, etc.) are not included.

In addition to these cost comments, one person, whose comments were included as enclosures by two respondents from one union, contended that benefits are over-estimated and not documented. In particular, the commenter challenged: benefits of reduction in lost productivity due to employees being unfit for duty; the nexus between use of illegal drugs and impairment of work performance; and, reduction in insurance rates resulting from more comprehensive drug testing.

19.2 Summary of Responses

The NRC agrees with the comments that the rulemaking should be justified under the provisions of 10 CFR 50.109 (a)(3). The Backfit Analysis has been modified based on consideration of the above cost comments as follows:

19.2.1 Cost to Administer the Testing and Training Programs

Staff agrees and has adjusted the cost estimate to include the costs of:

- a. additional personnel to administer the testing and training programs;
- b. one person for program administration and record keeping;
- c. one person for collection and processing of specimens; and
- d. a Medical Review Officer.

Miscellaneous costs have also been increased to better reflect the costs of forms and record development, and the costs of protected storage for records.

19.2.2 Length of Time for Individual Training

Based on the comments, the estimate of training costs has been adjusted to reflect the following:

- a) at least one hour of initial training for all employees;

- b) at least four additional hours of initial training for supervisors.

19.2.3 Time to Take a Test

Several commenters noted that the estimate of 30 minutes of an employee's lost productive time is too low. Lost productive time can include time to secure and restart work in progress and travel between the employee's work station and the specimen collection station. The Backfit Analysis estimate was based on an assumption of 15 minutes for travel to and from the collection site and 15 minutes at the collection station. This was based on the assumption that the majority of employees tested would have work stations within the protected area, and that at most sites the collection station would be efficiently located in or near the protected area to accommodate the large number of tests to be conducted. Also, the staff had assumed that after selecting an individual for testing on a given day, selection of when the test will be conducted that day would take into account holding down lost production time. Staff discussed these assumptions with licensees who have been conducting testing. Some suggested 90 minutes might be appropriate. Other licensees questioned said that 30 minutes is adequate, but that longer times could result from administrative inefficiencies. Based on the comments and the further discussions the estimated time has been increased to 60 minutes.

19.2.4 Added Cost of Using HHS-Certified Laboratories and Quality Control Measures

Staff reexamined the cost estimates of initial and confirmatory tests by contacting three laboratories to determine their charges for initial screening and confirmatory tests. Prices quoted were \$16, \$17, \$20, and \$25 per initial test, and \$50, \$65, and \$75 per confirmatory test. The lab that was on the high end for initial test cost was on the low end for confirmatory test cost, and had two prices, which depended on the number of samples in the contract. No laboratories have been certified under the HHS guidelines. It is speculative to assess whether the labs contacted would have to undergo any additional expenditures to be so certified and whether they would pass such costs on to their customers or would absorb those costs to remain competitive. Costs could

go down due to economies of scale, but could go up initially due to increased demand for certified labs exceeding the supply. Staff sees no compelling reason to change the Backfit Analysis cost estimates of \$20 per initial screening and \$75 per confirmatory test.

An additional cost of quality control is the blind samples to be included along with the employee specimens. The Backfit Analysis included a cost to the utilities of \$50 per blind performance test specimen. This cost is in addition to the cost of initial screening and confirmatory tests on these specimens. Staff believes that this is a reasonable representation of the quality control costs that will be incurred, and has made no change to this cost.

19.2.5 Costs to Conduct Background Checks

The staff disagrees that there is a need to include the costs of conducting background checks in the incremental cost estimate. Industry has already committed to these background checks through NUMARC in its Access Authorization Program, and thus costs associated with background checks would be expended regardless of whether or not they were required by the Fitness-for-Duty rule.

19.2.6 Number of Persons to be Tested

The Backfit Analysis assumed an average of 1500 employees and contractors would be tested randomly at each plant. This estimate was based on experience with the fingerprint cards submitted to the NRC in compliance with 10 CFR 73.57, which requires these cards to be submitted for all persons granted unescorted access to the protected area. This is the same population as would be covered by the Fitness-for-Duty rule. After receiving the comments, staff checked these estimates with several licensees and was satisfied that the estimate is appropriate. Staff disagrees that any change is needed to this element of the cost estimate.

19.2.7 Incremental Costs

The comment that not all plants have fully developed programs would be inconsistent with full implementation of industry commitments to follow the EEI

guidelines. Any costs incurred because commitments have not been met are considered costs for corrective action and not an impact of the present rule-making.

19.2.8 Average Life of Plants

The NRC issues licenses with a 40 year limit. For many plants this time starts at the date of the construction permit, resulting in 30 years remaining for operation. Some plants are being licensed for 40 years from the date of the operating license, resulting in a longer operating period. Some plants are just beginning their operations while others have already been operating under license for many years. Whether the useful life of some will be extended through license renewal is somewhat speculative and has not been considered. However, the effect on the total cost will be small in any event because costs beyond 25 years contribute little to the total cost in the present worth approach the NRC is using for its cost estimates.

19.2.9 Use of 10 Percent Discount Rate

The NRC uses a 10 percent discount rate in its regulatory impact analyses to be consistent with applicable OMB guidance. Because of concerns that this rate may be unrealistic at the present time, the NRC also shows the costs associated with a perhaps more realistic 5 percent discount rate.

19.2.10 Costs Associated with Other Performance Impairments

Staff disagrees that any change to the Backfit Analysis is needed for these costs. Activities associated with preventing alcohol abuse, legal drug use, and other kinds of performance impairment consist of training, testing and employee assistance programs. The costs assumed for these cost elements already cover these activities.

19.2.11 Recurring Costs

The staff disagrees that any change to the Backfit Analysis is needed for recurring costs of written procedures and contract modifications. Staff agrees

that licensees incur recurring costs for periodic revision to these documents, but sees no significant difference to these recurring costs attributable to the Fitness-for-duty rule. Costs of periodic revisions would accrue even without the Fitness-for-duty rule. Furthermore, only the costs for compliance with the rule need be considered, not costs of elective changes. The Backfit Analysis contains only the one time cost to modify these documents to meet the rule requirements.

19.2.12 Employee Turnover

One commenter noted that the NRC seemed to assume an employee turnover rate of zero. Staff recognizes that newly hired workers also would need orientation training, but considers this to not add to the incremental costs because such training is already part of the industry's existing fitness-for-duty programs. Staff considers the one time cost for current employees to be an additional cost beyond the current industry fitness-for-duty costs because the revisions to the industry program at many plants will require retraining of existing staff in these new procedures and rules of employment insofar as they differ from existing fitness-for-duty procedures and rules of employment. Staff disagrees that any change to the incremental costs is needed for employee turnover.

19.2.13 Costs of Employee Assistance Programs

Staff agrees that the costs of medical and counseling staff, training materials, and medical testing and treatment were underestimated, and has revised the Backfit Analysis to include additional personnel to administer the testing and training programs, in addition to the additional employee assistance program staff provided for in the draft analysis.

19.2.14 Costs of Legal Challenges

Staff agrees that there may be some costs associated with these legal challenges, but has no basis for assessing these costs. Attention to quality controls, whose costs were included, should serve to minimize these legal costs.

19.2.15 Indirect Costs to Workers from False Positives

The program has been designed to essentially eliminate false positives by use of diverse state of the art testing procedures and quality controls, including the use of certified laboratories, blind samples, chains of custody, and retention of portions of specimens for retesting. The staff agrees that the costs to an individual could be substantial should such an event occur but has not included these indirect costs in a quantitative manner for lack of a means for estimating them fairly. The NRC has considered these indirect costs in a qualitative sense, and has determined that the benefits warrant any such indirect costs (which are highly unlikely) in addition to the quantified direct costs.

19.2.16 Benefits Overestimated

Benefits are described in Items 3 and 4 of the Backfit Analysis. The latter included the statement that, in addition to the more important benefits of preventing unacceptable risk to the public from radiological releases, benefits will likely accrue to licensees from the potential reduction in absenteeism, lost worker productivity, medical and insurance costs, and plant downtime. Staff agrees that these claimed benefits have not been quantified or documented. Staff did not intend to imply that the cost reductions associated with these benefits would outweigh the costs of implementation of the Fitness-for-duty program, only that these benefits would exist and would serve to somewhat offset the expenses of the program. Lack of quantification of these benefits tends to make the Backfit Analysis cost increase estimates conservative.

With respect to the relationship of illegal drugs and impairment of work performance, see discussion under Item 3, Impairment vs Reliability, above, and NUREG/CR 5227, "Fitness-for-duty in the Nuclear Power Industry: A Review of the Technical Issues."

SUMMARY OF SIGNIFICANT CHANGES FROM THE PROPOSED RULE

The NRC amended several sections of the proposed rule in response to comments received from the public on the issues and in response to questions raised in the Notice of Proposed Rulemaking. The following is a summary of the significant changes.

The scope of the rule was amended to include power reactors under construction and to extend the date for implementation of all requirements to 180 days after publication of the rule.

The definition of "confirmed positive test" was amended to clarify that the test is not a confirmed positive until the Medical Review Officer has reviewed the test results. The Medical Review Officer's review must be completed and licensee management notified within 10 days of the initial presumptive positive screening test.

The definition of "suitable inquiry" was amended to clarify that a best-effort verification of employment history is intended to be consistent with paragraph 6.2.1 of the "Industry Guidelines for Nuclear Power Plant Access Authorization Programs" (53FR7534). A conforming amendment was made to the management actions section that required the inquiry.

The general performance objectives were amended to clearly show that the reliability and trustworthiness of nuclear power plant personnel must also be assured.

The requirements for written policies and procedures were amended to include a prohibition against the consumption of alcohol prior to and during work, and the requirement to address situations where a person has been called in to perform unscheduled work.

The requirements for training of escorts have been amended to clarify NRC's intent that escorts need not be trained as supervisors.

The period in which a test must be performed prior to the initial granting of unescorted access was specified as 60 days.

The random testing rate was established as 100 percent per year.

The basis for for-cause tests was clarified.

NRC testing guidelines modeled after the HHS Guidelines, have been developed as the standards for the collection, protection, and testing of specimens for drugs and alcohol. These NRC Guidelines, to obtain higher confidence of detection of use (which bears on the potential for impairment and reliability and trustworthiness), will set lower cutoff levels for marijuana and other substances than set by the HHS Guidelines. In addition, the NRC Guidelines will add three substances to the required testing protocol.

Licensees will be required to certify to the NRC that their fitness-for-duty programs have been implemented.

Testing laboratories shall be laboratories certified by the Department of Health and Human Services.

A requirement has been added to limit access to the results of preliminary tests.

Tests for alcohol are required to be performed in conjunction with other substance tests. Tests are to be administered by a breath analysis. A confirmatory test may be done with another breath measurement instrument, or if demanded by the person being tested, by gas chromatography analysis of blood.

The requirements for management actions were revised to add the use of alcohol which resulted in on-duty impairment as a subject of the inquiry to previous employers.

The requirement for making available information concerning prior violations of a fitness-for-duty program was amended to include a requirement that the inquiry be supported by a signed release from the individual being investigated.

The frequency of unannounced tests following reinstatement was amended to require more frequent testing for the first four months.

A requirement was added to the section on management actions for licensees to impose sufficient sanctions for alcohol, prescription drugs and over-the-counter drugs to deter substance substitution.

The appeals process requirements were clarified.

The requirements to protect information have been amended to clarify that personal information can be disclosed to persons deciding matters on review or appeal, to persons pursuant to a court order, and to auditors (in addition to those listed in the proposed rule).

Records retention periods have been changed to five years.

Reporting requirements have been amended to include abuse of alcohol onsite by a licensed reactor operator or supervisory personnel.

The requirement to maintain a copy of the audit report onsite has been deleted.

MODIFICATION OF ENFORCEMENT POLICY

The Commission is modifying its General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C (Enforcement Policy) to reflect the Commission's new rule on Fitness-for-Duty, 10 CFR Part 26. The changes to the Enforcement Policy are being published concurrently with the new rule.

The modifications to the Enforcement Policy are being made in Supplement VII "Miscellaneous Matters" to provide examples of violations of fitness-for-duty requirements. The examples are A.6, B.6, B.7, B.8, C.6, C.7, C.8, C.9, D.4, D.5, and E.4. As with the examples in the other Supplements to the Enforcement Policy, the new examples are neither controlling nor exhaustive nor do they establish new requirements. The examples are to be used as guidance in considering the severity levels of violations of requirements.

In developing the examples, the Commission notes that it is not the unfit person that establishes the violation but rather the licensee's failures, including those of its contractors and vendors, that create violation. For example, if the licensee has effectively implemented its fitness-for-duty program meeting NRC requirements and, based on behavior observation, identifies and removes a person not fit for duty, there may not be a regulatory violation.

The example for Severity Level I is of very significant concern because it represents the failure to implement a fitness-for-duty program. This example would be applicable to a situation where essentially the licensee does not have a program in place.

The examples for Severity Level II are also very significant because they involve the failure to take action when there is the potential to have a direct impact on safety-related activities.

The examples for Severity Level III are significant because they represent significant individual violations or significant breakdowns in basic elements of a fitness-for-duty program. Basic elements include important aspects of the program, such as: training, appeals, records, testing integrity, randomness in testing, audits, prescreening, management response, contractor oversight, and employee assistance. A breakdown in the program categorized at a Severity Level III will normally involve more than one significant failure of a single element or single failures of a number of elements.

Severity Level IV and V violations are matters which, while requiring correction, are less significant to the overall fitness-for-duty program.

FINDING OF NO SIGNIFICANT
ENVIRONMENTAL IMPACT: AVAILABILITY

An environmental assessment was included in the notice of the proposed rulemaking at 53 FR 36822. The Commission has determined under the

National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required.

PAPERWORK REDUCTION ACT STATEMENT

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements. Public reporting burden for this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch, Division of Information Support Services/IRM, Office of Administration and Resources Management, U. S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

REGULATORY ANALYSIS

An analysis of the costs and benefits of the final rule is included in the backfit analysis described below.

BACKFIT ANALYSIS

Several commenters stated that the NRC should justify the rulemaking under the provisions of 50.109(a)(3). The NRC agrees, and finds that the rule will provide a substantial increase in the overall protection of public health and safety, and that the direct and indirect costs of implementation are justified in view of the increased protection.

The backfit analysis is available for inspection and copying for a fee at the NRC Public Document Room at 2120 L Street, NW, Washington, D.C. 20555. Single copies may be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

REGULATORY FLEXIBILITY ACT CERTIFICATION

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This new 10 CFR Part 26 applies to certain owners and operators of civilian nuclear power reactors and their contractors. The companies that own power reactor facilities do not fall within the scope of "small entities" set forth in the Regulatory Flexibility Act or the small business size standards set out in regulations issued by the Small Business Administration in 13 CFR Part 121. Any costs to the minor number of small entities affected, i.e., contractors, will apply only to those contractor employees working at the nuclear power reactors, and would probably be reimbursed through the contract.

LIST OF SUBJECTS IN 10 CFR PART 2 AND 26

Part 2 - Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Civil penalty, Enforcement, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Violations, Waste treatment and disposal.

Part 26 - Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

For the reasons set in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C 553, the NRC is adopting a new 10 CFR Part 26, and amending 10 CFR Part 2.

PART 2 - RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read in part as follows:

AUTHORITY: SEC. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. Appendix C, Supplement VII, is amended by adding example 6 to paragraph A, examples 6, 7, and 8 to paragraph B, examples 6, 7, 8 and 9 to paragraph C, examples 4 and 5 to paragraph D, and example 4 to paragraph E to read as follows:

Appendix C -- General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * *

Supplement VII -- Severity Categories

A. Severity I. * * *

6. Failure to substantially implement the required fitness-for-duty program. ^{18/}

B. Severity II. * * *

6. Failure to remove an individual from unescorted access who has been involved in the sale, use, or possession of illegal drugs within

^{18/} The examples for violations for fitness-for-duty relate to violations of 10 CFR Part 26.

- the protected area or to take action for on duty misuse of alcohol, prescription drugs, or over-the-counter drugs;
7. Failure to test for cause when observed behavior within the protected area or credible information concerning activities within the protected area indicates possible unfitness for duty based on drug or alcohol use; or
 8. Deliberate failure of the licensee's Employee Assistance Program to notify licensee's management when EAP's staff is aware that an individual's condition may adversely affect safety related activities.
- C. Severity III. * * *
6. Failure to complete a suitable inquiry on the basis of 10 CFR Part 26, keep records concerning the denial of access, or respond to inquiries concerning such denials such that, as a result of the failure, a person previously denied access for fitness for duty reasons was improperly granted access;
 7. Failure to take the required action for a person confirmed to have been tested positive for illegal drug use or take action for onsite alcohol use; not amounting to a Severity Level II violation;
 8. Failure to assure, as required, that contractors or vendors have an effective fitness-for-duty program; or
 9. Breakdown in the fitness-for-duty program involving a number of violations of the basic elements of the fitness-for-duty program that collectively reflect a significant lack of attention or carelessness towards meeting the objectives of 10 CFR 26.10.
- D. Severity IV. * * *
4. Isolated failures to meet basic elements of the fitness-for-duty program not involving a Severity Level I, II, or III violation.
 5. Failure to report acts of licensed operators or supervisors pursuant to 10 CFR 26.73.
- E. Severity V. * * *
4. Minor violations of fitness for duty requirements.

3. Part 26 is added to 10 CFR Chapter I to read as follows:

Part 26 -- Fitness for Duty Programs

Sec.

- 26.1 Purpose.
- 26.2 Scope.
- 26.3 Definitions.
- 26.4 Interpretations.
- 26.6 Exemptions.
- 26.8 Information collection requirements: OMB approval.

General Performance Objectives

- 26.10 General performance objectives.

Program Elements and Procedures

- 26.20 Written policy and procedures.
- 26.21 Policy communication and awareness training.
- 26.22 Training of supervisors and escorts.
- 26.23 Contractors and vendors.
- 26.24 Chemical testing.
- 26.24a Construction site program.
- 26.25 Employee assistance programs.
- 26.27 Management actions and sanctions to be imposed.
- 26.28 Appeals.
- 26.29 Protection of information.

Inspections, Records and Reports

- 26.70 Inspections.
- 26.71 Record keeping requirements.
- 26.73 Reporting requirements.

Audits

26.80 Audits.

Enforcement

26.90 Violations.

Appendix A - Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs.

Authority: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273) §§ 26.20, 26.21, 26.22, 26.23, 26.24, 26.25, 26.27, 26.28, 26.29 and 26.80 are issued under secs. 161b and i, 68 Stat. 948, and 949 as amended [42 U.S.C. 2201(b) and (i)]; §§ 26.70, 26.71, and 26.73 are issued under sec. 161o, 68 Stat. 950, as amended [42 U.S.C. 2201(o)].

General Provisions

§ 26.1 Purpose.

This Part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty programs and procedures by the licensed nuclear power industry.

§ 26.2 Scope.

(a) The regulations in this Part apply to licensees authorized to operate a nuclear power reactor. Each licensee shall implement a fitness-for-duty program which complies with this Part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to protected areas, and to licensee, vendor, or contractor personnel required to physically report

to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures. The regulations in this Part do not apply to NRC employees, or to law enforcement personnel or offsite emergency fire and medical response personnel while responding on-site.

(b) Certain regulations in this Part apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with the following sections of this Part: 26.10; 26.20; 26.23; 26.24a; 26.70; and 26.73.

(c) The requirements in this Part must be implemented by each licensee authorized to construct or operate a nuclear power reactor no later than (insert date 180 days after the effective date of the final rule).

§ 26.3 Definitions.

"Aliquot" means a portion of a specimen used for testing.

"Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

"Confirmatory test" means a second analytical procedure to identify the presence of a specific drug, drug metabolite or alcohol which is independent of the initial screening test and which uses a different technique and chemical principle from that of the initial screening test in order to ensure reliability and accuracy.

"Confirmed positive test" means the result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen at or above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation.

"Contractor" means any company or individual with which the licensee has contracted for work or service to be performed inside the protected area boundary, either by contract, purchase order, or verbal agreement.

"Cut-off level" means the value set for designating a test result as positive.

"Follow-up testing" means chemical testing at unannounced intervals, to ensure that an employee is maintaining abstinence from the abuse of drugs or alcohol.

"Illegal drugs" means those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

"Initial or screening tests" means an immunosay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or a breathalyzer test for alcohol. Initial screening may be performed at the licensee's testing facility; a second screen and confirmation testing must be conducted by a HHS-certified laboratory.

"Medical Review Officer" means a licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

"Protected area" has the same meaning as in §73.2(g) of this chapter, an area encompassed by physical barriers and to which access is controlled.

"Random test" means a system of unannounced drug testing administered in a statistically random manner to a group so that all persons within that group have an equal probability of selection.

"Suitable inquiry" means best-effort verification of employment history for the past five years, but in no case less than three years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating substance abuse, removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy.

"Vendor" means any company or individual, not under contract to a licensee, providing services in protected areas.

§ 26.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this Part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 26.6 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

§ 26.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this Part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this Part under control number_____.

(b) The approved information collection requirements contained in this Part appear in §§ 26.20, 26.21, 26.22, 26.23, 26.24, 26.29, 26.71, 26.73, and 26.80.

(c) The total burden for these record keeping requirements is estimated to be 313 hours per site per year. In implementing the record keeping requirements the affected licensee shall report to the Commission any comments concerning the accuracy of the estimate and any suggestions for reducing the burden.

General Performance Objectives

§ 26.10 General performance objectives.

Fitness-for-duty programs must:

(a) Provide reasonable assurance that nuclear power plant personnel will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(b) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this Part; and

(c) Have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances.

Program Elements and Procedures

§ 26.20 Written policy and procedures.

Each licensee subject to this Part shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of this Part. Each licensee shall retain a copy of the current written policy and procedures as a record until the Commission terminates each license for which the policy and procedures were developed and, if any portion of the policies and procedures are superseded, retain the superseded material for three years after each change. As a minimum, written policies and procedures must address fitness for duty through the following:

(a) An overall description of licensee policy on fitness for duty. The policy must address use of illegal drugs and abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs). Written policy documents must be in sufficient detail to provide affected individuals with information on what is expected of them, and what consequences may result from lack of adherence to the policy. As a minimum, the written policy must prohibit the consumption of alcohol (1) within a specified time period preceding any scheduled working tour, and (2) during the period of any working tour. Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue and illness.

(b) A description of programs which are available to personnel desiring assistance in dealing with drug, alcohol, or other problems that could adversely affect the performance of activities within the scope of this Part.

(c) Procedures to be utilized in testing for drugs and alcohol, including procedures for protecting the employee and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.

(d) A description of immediate and follow-on actions which will be taken, and the procedures to be utilized, in those cases where employees, vendors, or contractors assigned to duties within the scope of this Part are determined to have been involved in the use, sale, or possession of illegal drugs; or to have consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess prior to reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration.

(e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure must --

(1) Require a statement to be made by a called-in person as to whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;

(2) If alcohol has been consumed within this period, require a determination of fitness for duty by breath analysis or other means; and

(3) Require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed.

(f) The Commission may at any time review the licensee's written policy and procedures to assure that they meet the performance objectives of this Part.

§ 26.21 Policy communications and awareness training.

(a) Persons assigned to activities within the scope of this Part shall be provided with appropriate training to ensure they understand --

(1) Licensee policy and procedures, including the methods that will be used to implement the policy;

(2) The personal and public health and safety hazards associated with abuse of drugs and misuse of alcohol;

(3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the Medical Review Officer;

(4) Employee assistance programs provided by the licensee; and

(5) What is expected of them and what consequences may result from lack of adherence to the policy,

(b) Initial training must be completed prior to assignment to activities within the scope of this Part. Refresher training must be completed on a nominal 12 month frequency or more frequently where the need is indicated. A record of the training must be retained for a period of at least three years.

§ 26.22 Training of supervisors and escorts.

(a) Managers and supervisors of activities within the scope of this Part must be provided appropriate training to ensure they understand --

- (1) Their role and responsibilities in implementing the program;
- (2) The roles and responsibilities of others, such as the personnel, medical, and employee assistance program staffs;
- (3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;
- (4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in employee behavior and
- (5) Procedures for initiating appropriate corrective action, to include referral to the employee assistance program.

(b) Persons assigned to escort duties shall be provided appropriate training in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel.

(c) Initial training must be completed prior to assignment of duties within the scope of this Part and within 3 months after initial supervisory assignment, as applicable. Refresher training must be completed on a nominal 12 month frequency, or more frequently where the need is indicated. A record of the training must be retained for a period of at least three years.

§ 26.23 Contractors and vendors.

(a) All contractor and vendor personnel performing activities within the scope of this Part for a licensee must be subject to either the licensee's program relating to fitness for duty, or to a program, formally reviewed and approved by the licensee, which meets the requirements of this Part. Written agreements between licensees and contractors or vendors for activities within the scope of this Part must be retained for the life of the contract and will clearly show that --

(1) The contractor or vendor is responsible to the licensee for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program which meets the standards of this Part; and

(2) Personnel having been denied access or removed from activities within the scope of this Part at any nuclear power plant for violations of a fitness-for-duty policy will not be assigned to work within the scope of this Part without the knowledge and consent of the licensee.

(b) Each licensee subject to this Part shall assure that contractors whose own fitness-for-duty programs are relied on by the licensee adhere to an effective program, which meets the requirements of this Part, and shall conduct audits pursuant to § 26.80 for this purpose.

§ 26.24 Chemical testing.

(a) To provide a means to deter and detect substance abuse, the licensee shall implement the following chemical testing programs for persons subject to this Part:

(1) Testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this Part.

(2) Unannounced tests imposed in a random manner. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test. As a minimum, tests must be administered on a nominal weekly frequency.

- ° Alternative A: The tests must be conducted in a manner that assures that at least 90 percent of the individuals within the scope of the rule are tested each year, that testing is performed throughout the year and that testing rates for individuals already tested with negative results not be lower than 30 percent per year (2 1/2 percent per month) for the remainder of the testing year.

- ° Alternative B: The tests must be administered throughout the year at an annual rate equivalent to 300 percent of the population subject to testing.

- ° Alternative C: Each worker shall be randomly assigned a day during the next 365 days on which to be tested, and then shall be randomly reassigned to a day in the following 365 day period.

- ° Alternative D: Each worker shall be subjected to an unannounced test on an individual rather than work unit basis once during the year. In addition, random testing at a rate of 50 percent shall be used during the year to assure ongoing deterrence.

- ° Alternative E: Random testing shall be conducted at a rate equal to at least 100 percent of the workforce.

(3) Testing for-cause, i.e., as soon as possible following any observed behavior indicating possible substance abuse; after accidents involving a failure in individual performance resulting in personal injury, in a radiation exposure or release of radioactivity in excess of regulatory limits, or actual or potential substantial degradations of the level of safety of the plant if there is reasonable suspicion that the worker's behavior contributed to the event; or after receiving credible information that an individual is abusing drugs or alcohol.

(4) Follow-up testing on an unannounced basis to verify continued abstention from the use of substances covered under this Part.

(b) Testing for drugs and alcohol must at a minimum, conform to the "Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs," issued by the Nuclear Regulatory Commission and appearing in Appendix A to this rule, hereinafter referred to as the NRC Guidelines. Licensees, at their discretion, may implement programs with more stringent standards (e.g., lower cutoff levels, broader panel of drugs). Management actions with respect to persons who fail a more stringent standard, but do not test positive under the NRC Guidelines must be the same as if the individual failed the NRC standards.

(c) Licensees shall test for all eight substances described in paragraph 2.1(a) of the NRC Guidelines. In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances with abuse potential are being used in the geographical locale of the facility and the local workforce. When appropriate, other substances so identified may be added to the panel of substances for testing. Appropriate cutoff limits must be established by the licensee for these substances.

(d) Licensees may conduct initial screening tests of an aliquot prior to forwarding selected specimens to a laboratory certified by the Department of Health and Human Services, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, their qualifications are documented, and adequate quality controls are implemented. Quality control procedures for initial screening tests by a licensee's testing facility must include the processing of blind performance test specimens and the submission to the HHS-certified laboratory of a sampling of specimens initially tested as negative. Access to the results of preliminary tests must be limited to the licensee's testing staff, the Medical Review Officer, the Fitness-for-duty Program Manager, and employee assistance program staff when appropriate.

(e) The Medical Review Officer's review of the test results must be completed and licensee management notified within 10 days of the initial presumptive positive screening test.

(f) Quality controls and procedures for HHS-certified laboratories shall be consistent with the Department of Health and Human Services standards for "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies." (53 FR 11970, 11986 - 11989, dated April 11, 1988). HHS-certified laboratories shall conduct initial screening tests on all specimens forwarded for testing and shall perform confirmation tests on all specimens that are screened as presumptive positive. Licensees shall submit blind performance test specimens to HHS-certified laboratories in accordance with the NRC Guidelines (Appendix A).

(g) Tests for alcohol must be administered by a breath analysis. A breath alcohol content indicating a blood alcohol concentration of 0.04 percent must be a positive test result. Any alcohol concentration below this level must also be evaluated to determine whether the licensee's policy on alcohol has been violated.

-----OR-----

(g) Tests for alcohol must be administered by a breath analysis, with any alcohol concentration evaluated to determine whether the licensee's policy on alcohol use has been violated.

If a confirmatory test is requested by the person being tested, the confirmatory test may be done with another breath measurement instrument that meets evidential standards described in Section 2.7(0)(3) of Appendix A. Should the person demand further confirmation, the test must be a gas chromatography analysis of blood.

§ 26.24a Construction site program.

Construction permit licensees shall implement a chemical testing program, including random tests, and shall make provisions for employee assistance programs, imposition of sanctions, appeal procedures, the protection of information, and record keeping.

§ 26.25 Employee assistance programs (EAP).

Each licensee subject to this Part shall maintain an employee assistance program to strengthen fitness-for-duty programs by offering assessment, short-

term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the scope of this Part. Employee assistance programs should be designed to achieve early intervention and provide for confidential assistance. The employee assistance program staff shall inform licensee management when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others (including those who have self-referred).

§ 26.27 Management actions and sanctions to be imposed.

(a) Prior to the initial granting of unescorted access to a protected area or the assignment to activities within the scope of this Part to any person, the licensee shall obtain a written statement from the individual as to whether activities within the scope of this Part were ever denied the individual. The licensee shall complete a suitable inquiry on a best-efforts basis to determine if that person was, in the past, tested positive for drugs or use of alcohol that resulted in on-duty impairment, subject to a plan for treating substance abuse (except for self-referral for treatment), or removed from activities within the scope of this Part, or denied unescorted access at any other nuclear power plant in accordance with a fitness-for-duty policy. If such a record is established, the new assignment to activities within the scope of this Part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, provided the restrictions of paragraph (b) of this section are observed. To meet this requirement, the identity of persons denied unescorted access or removed under the provisions of this Part and the circumstances for such denial or removal, including test results, will be made available in response to a licensee's, contractor's, or vendor's inquiry supported by a signed release from the individual. Failure to list reasons for removal or revocation of unescorted access shall be sufficient cause for denial of unescorted access. The temporary access provision in Section 6.4 of the "Industry Guidelines for Nuclear Power Plant Access Authorization Programs" shall be applicable to this Part with the added provision that the prospective worker must pass a chemical test conducted according to the requirements of § 26.24(a)(1).

(b) Each licensee subject to this Part shall, as a minimum, take the following actions. Nothing herein shall prohibit the licensee from taking more stringent action.

(1) Impaired workers, or those whose fitness may be questionable, shall be removed from activities within the scope of this Part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this Part.

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs onsite, a confirmed positive test result must be presumed to be an indication of offsite drug use. The first confirmed positive test must, as a minimum, result in immediate removal from activities within the scope of this Part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment must be developed, and any rehabilitation program deemed appropriate must be initiated during such suspension period. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this Part must be obtained before permitting the individual to be returned to these activities. Any subsequent confirmed positive test must result in removal from unescorted access to protected areas and activities within the scope of this Part for a minimum of three years from the date of removal.

(3) Any individual determined to have been involved in the sale, use, or possession of illegal drugs while within a protected area of any nuclear power plant must be removed from activities within the scope of this Part. The individual may not be granted unescorted access to protected areas or assigned to activities within the scope of this Part for a minimum of five years from the date of removal.

(4) Persons removed for periods of three years or more under the provisions of paragraphs (b)(2) and (3) of this section for the illegal sale, use or possession of drugs and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this Part by a licensee subject to this Part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from drugs for at least three years. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this Part must be obtained before permitting the individual to perform activities within the scope of this Part. Any person granted unescorted access or whose access is reinstated under these

provisions must be given unannounced follow-up tests at least once every month for four months and at least once every three months for the next two years and eight months after unescorted access is reinstated to verify continued abstinence from proscribed substances. Any confirmed use of drugs through this process or any other determination of subsequent involvement in the sale, use or possession of illegal substances must result in permanent denial of unescorted access.

(5) Paragraphs (b) (2), (3), and (4) of this section do not apply to alcohol, valid prescriptions, or over-the-counter drugs. Licensee sanctions for confirmed misuse of alcohol, valid prescription, and over-the-counter drugs as determined by the Medical Review Officer shall be sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs.

(c) Refusal to provide a specimen for testing and resignation prior to removal for violation of company fitness-for-duty policy concerning drugs must be recorded as removals for cause. These records must be retained for the purpose of meeting the requirements of § 26.27(a).

(d) If a licensee has a reasonable belief that an NRC employee may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but shall escort the individual. In any instance of this occurrence, the appropriate Regional Administrator must be notified immediately by telephone. During other than normal working hours, the NRC Operations Center must be notified.

§ 26.28 Appeals.

Each licensee subject to this Part, and each contractor implementing a fitness-for-duty program under the provisions of § 26.23, shall establish a procedure for licensee and contractor employees to appeal the results of an alcohol or drug test. The procedure must provide notice and an opportunity to respond and may be an impartial internal management review. A licensee review procedure need not be provided to employees of contractors when the contractor is administering his own alcohol and drug testing.

§ 26.29 Protection of Information.

(a) Each licensee subject to this Part, who collects personal information on an individual for the purpose of complying with this Part, shall establish and maintain a system of files and procedures for the protection of the personal information. This system must be maintained until the Commission terminates each license for which the system was developed.

(b) Licensees and contractors shall not disclose the personal information collected and maintained to persons other than assigned Medical Review Officers, other licensees or their authorized representatives legitimately seeking the information as required by this Part for unescorted access decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials under court order, the subject individual or his or her representative, or to those licensee representatives who have a need to have access to the information in performing assigned duties, including audits of licensee's and contractor's programs, to persons deciding matters on review or appeal, and to other persons pursuant to court order. This section does not authorize the licensee to withhold evidence of criminal conduct from law enforcement officials.

Inspections, Records, and Reports

§ 26.70 Inspections.

(a) Each licensee subject to this Part shall permit duly authorized representatives of the Commission to inspect, copy, or take away copies of its records and inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of this Part.

(b) Written agreements between licensees and their contractors and vendors must clearly show that the --

(1) Licensee is responsible to the Commission for maintaining an effective fitness-for-duty program in accordance with this Part; and

(2) Duly authorized representatives of the Commission may inspect, copy, or take away copies of any licensee, contractor, or vendor's documents, records, and reports related to implementation of the licensee's, contractor's, or vendor's fitness-for-duty program under the scope of the contracted activities.

§ 26.71 Record keeping requirements.

Each licensee subject to this Part and each contractor implementing a licensee approved program under the provisions of § 26.23 shall --

(a) Retain records of inquiries conducted in accordance with § 26.27(a), that result in the granting of unescorted access to protected areas, until five years following termination of such access authorizations;

(b) Retain records of confirmed positive test results which are concurred in by the Medical Review Officer, and the related personnel actions for a period of at least five years;

(c) Retain records of persons made ineligible for three years or longer for assignment to activities within the scope of this Part under the provisions of § 26.27(b)(2), (3), (4) or (c), until the Commission terminates each license under which the records were created; and

(d) Collect and compile fitness-for-duty program performance data. The data must be analyzed and appropriate actions taken to correct program weaknesses. The data and analysis must be retained for three years.

§ 26.73 Reporting requirements.

(a) Each licensee subject to this Part shall inform the Commission of significant fitness-for-duty events including:

(1) Sale, use, or possession of illegal drugs within the protected area and,

(2) Any acts by any person licensed under 10 CFR Part 55 to operate a power reactor or by any supervisory personnel assigned to perform duties within the scope of this Part, (i) involving the sale, use, or possession of a controlled substance, (ii) resulting in confirmed positive tests on such persons, (iii) involving use of alcohol within the protected area, or (iv) resulting in a determination of unfitness for scheduled work due to the consumption of alcohol.

(b) Notifications must be made to the NRC Operations Center by telephone within 24 hours of the discovery of the event by the licensee.

(c) Fitness-for-duty events shall be reported under this section rather than reported under the provisions of § 73.71.

(d) By (insert date 180 days after the effective date of the final rule) each licensee shall certify to the NRC that its fitness-for-duty program is implemented. The certification shall describe any licensee cut-off levels more stringent than those imposed by this Part.

Audits

§ 26.80 Audits.

(a) Each licensee subject to this Part shall audit the fitness-for-duty program nominally every 12 months. In addition, audits must be conducted, nominally every 12 months, of those portions of fitness-for-duty programs implemented by contractors. Licensees may accept audits of contractors conducted by other licensees and need not re-audit the same contractor for the same period of time. Each sharing utility shall maintain a copy of the audit report, to include findings, recommendations and corrective actions. Licensees retain responsibility for the effectiveness of contractor programs and the implementation of appropriate corrective action.

(b) Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both fitness-for-duty program management and personnel directly responsible for implementation of the fitness-for-duty program.

(c) The result of the audit, along with recommendations, if any, must be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions must be documented. These documents must be retained for three years. NRC Guidelines require licensee audits of HHS-certified laboratories as described in Appendix A.

Enforcement

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of --

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974; or
- (3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of--

- (1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;
- (2) Section 206 of the Energy Reorganization Act of 1974;
- (3) Any rule, regulation, or order issued under these Sections.
- (4) Any term, condition, or limitation of any license issued under these Sections; or
- (5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any regulation or order issued under the requirements of the Act, include regulations under this Part, may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

GUIDELINES FOR NUCLEAR POWER PLANT DRUG AND ALCOHOL TESTING PROGRAMS

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Subpart A - General

1.1 Applicability.

(1) These guidelines apply to licensees authorized to operate nuclear power reactors.

(2) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein.

(3) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

1.2 Definitions.

For the purposes of this part, the following definitions apply:

"Aliquot." A portion of a specimen used for testing.

"BAC." Blood alcohol concentration (BAC), which can be measured directly from blood or derived from a measure of the concentration of alcohol in a breath specimen, is a measure of the mass of alcohol in a volume of blood such that an individual with 100 mg of alcohol per 100 ml of blood has a BAC of 0.10 percent.

"Commission." The U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Chain-of-custody." Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

"Collection site." A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

"Collection site person." A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) a collection is observed or (b) collection is monitored by nonmedical personnel, the collection site person must be a person of the same gender as the donor.

"Confirmatory test." A second analytical procedure to identify the presence of a specific drug, drug metabolite, or alcohol which is independent of the screening test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry [GC/MS] is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, phencyclidine, alcohol, benzodiazepines, and barbiturates).

"Confirmed positive test." The result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation.

"HHS-certified laboratory." A urine and blood testing laboratory that maintains certification to perform drug testing under the Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 FR 11970).

"Illegal drugs." Those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

"Initial or screening test." An immunoassay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or a breathalyzer test for alcohol.

"Licensee's testing facility." A drug testing facility operated by the licensee or one of its vendors or contractors to perform the initial testing of urine samples and to perform initial breath tests for alcohol. Such a testing facility is optional and not required to maintain HHS certification under this part.

"Medical Review Officer". A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

"Permanent record book." A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

"Reason to believe." Reason to believe that a particular individual may alter or substitute the urine specimen.

"Split sample." A portion of a urine specimen that may be stored by the licensee to be tested in the event of appeal.

Subpart B - Scientific and Technical Requirements

2.1 The Substances.

(a) Licensees shall, as a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, benzodiazepines, barbiturates, and alcohol for pre-access, for-cause and random tests.

(b) Licensees may test for any illegal drugs during a for-cause test.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH on tests for specific gravity, creatinine concentration, or presence of adulterants).

2.2 General Administration of Testing.

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. Such procedures shall include, as a minimum, the following:

(a) Use of a chain-of-custody form. The original shall accompany the specimen to the HHS-certified laboratory. A copy shall accompany any split sample. The form shall be a permanent record on which identity data (or codes) on the employee and on the specimen collection process and all transfer of custody of the specimen is retained.

(b) Use of a tamperproof sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the chain-of-custody form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement

assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions, and training shall be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in 2.2(3) and performs collections in accordance with those instructions.

(3) Collection site persons shall be provided with detailed, clearly-illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for confirmatory analysis following a positive breath test shall be specified in the written instructions provided to individuals tested. The instructions shall also state that failure to request a confirmatory blood test indicates that the individual accepts the breath test results.

2.3 Preventing Subversion of Testing.

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, laboratory technicians, specimen couriers, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. At a minimum, these measures shall ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

As a minimum:

(1) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(2) Appropriate background checks and psychological evaluations shall be completed prior to assignment of any tasks associated with the administration of the program, and shall be conducted at least once every three years.

(3) Persons responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

2.4 Specimen Collection Procedures.

(a) "Designation of Collection Site." Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) "Collection Site Person." A collection site person shall have successfully completed training to carry out this function. In any case where the collection of urine is observed, the collection site person must be a person of the same gender as the donor. Persons drawing blood shall be qualified to perform that task.

(c) "Security." The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility cannot be dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories.

(d) "Chain-of-Custody." Licensee chain-of-custody forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another shall always be accomplished through chain-of-custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(e) "Access to Authorized Personnel Only." No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a

collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the individual has departed the collection site.

(f) "Privacy." Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (g)(14) of this appendix, or the oral temperature does not equal or exceed that of the specimen.

(2) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below .2 g/L.

(3) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

(4) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) "Integrity and Identity of Specimens." Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure, that a blood sample or breath exhalant tube cannot be substituted or tampered with, and that the information on the specimen container and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form and to list all of the prescription medications and over-the-counter preparations that he or she can remember using within the last three weeks.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine, breath, or blood specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the blood, breath, or urine sample is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(8) The individual may provide his/her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance on the specimen custody and control form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or on-site rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(13) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(14) If the temperature of a urine specimen is outside the range of 32.5° - 37.7°C/90.5° - 99.8°F, that is a reason to believe that the individual may have

altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(15) Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(16) All urine specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(18) Alcohol breath tests shall be conducted after the urine specimen has been collected, and shall be delayed if any source of mouth alcohol or any other substances are ingested during this period (e.g., eating, smoking, use of breath fresheners, regurgitation of stomach contents from vomiting or burping). The collection site person shall ensure that each breath specimen taken comes from the end, rather than the beginning, of the breath expiration. Two breath specimens shall be collected from each individual no less than two minutes apart and no more than 10 minutes apart. The test results shall be considered accurate if the result of each measurement is within plus or minus ten percent of the average of the two measurements. If the two tests do not agree, the breath tests shall be repeated on another evidential-grade breath analysis machine.

(19) If the alcohol screening breath test indicates that the individual is positive for a BAC at or above the 0.04 percent cut-off level, the individual may request a confirmatory blood test, at his or her discretion. All vacuum tube and needle assemblies used for blood collection shall be factory-sterilized. The collection site person shall ensure that they remain properly sealed until used. Antiseptic swabbing of the skin shall be performed with a nonethanol antiseptic. Sterile procedures shall be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

(20) Both the individual being tested and the collection site person shall keep urine and blood specimens in view at all times prior to their being sealed and labeled. If a urine specimen is split (as described in Section 2.7(j)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine sample or the transfer of the specimen and the placement of the tamperproof seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamperproof seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen containers for the purpose of certifying that it is the specimen collected from him or her.

(i) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimens identified as having been collected from him or her are in fact the specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine custody and control form information concerning medications taken or administered in the past 30 days.

(24) The collection site person shall enter in the permanent record book all information identifying the specimens. The collection site person shall sign the permanent record book next to the identifying information.

(25) A higher level supervisor in the drug testing program shall review and concur in advance with any decision by a collection site person to obtain a urine specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(26) The collection site person shall complete the chain-of-custody forms for both the aliquot and the split sample, if collected, and shall certify proper completion of the collection.

(27) The specimens and chain-of-custody forms are now ready for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(28) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person shall not leave the collection site in the interval between presentation of the specimen by the individual and securement of the samples with identifying labels bearing the individual's specimen identification numbers and seals initialled by the individual. If the involved collection site person leaves his or her work station momentarily, the specimens and custody forms shall be taken with him or her or shall be secured. If the collection site person is leaving for an extended period of time, the specimens shall be packaged for transfer to the laboratory before he or she leaves the site.

(h) "Collection Control." To the maximum extent possible, collection site personnel shall keep the individual's specimen containers within sight both before and after the individual has urinated or provided a breath or blood sample. After the specimen is collected and whenever urine specimens are split, they shall be properly sealed and labeled. A chain-of-custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(i) "Transportation to Laboratory or Testing Facility." Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To transfer specimens off-site for initial screening and for a second screen and confirmatory analysis of presumptive positive specimens, the specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes or padded mailers) and those containers shall be securely sealed to

eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(j) "Failure to Cooperate." If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the Medical Review Officer and shall document the non-cooperation on the specimen custody and control form. The provision of blood specimens for use to confirm a positive breath test for alcohol shall be entirely voluntary, at the individual's discretion. In the absence of a voluntary blood test the positive breath test shall be considered a confirmed positive.

2.5 HHS-certified Laboratory Personnel.

(a) "Day-to-Day Management of the HHS-certified Laboratories."

(1) The HHS-certified laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratories' drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A PhD in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a PhD in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology, and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of their testing laboratories. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures

are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in Section 2.7(0) of this appendix).

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) "Test Validation." The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) "Day-to-Day Operations and Supervision of Analysts." The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain-of-custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) "Training." The laboratory's testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) "Files." Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

2.6 Licensee Testing Facility Personnel.

(a) "Day-to-Day Management of Operations." Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and

practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

(b) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) "Files." Licensees' testing facility personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate and appropriate data to support determinations of honesty and integrity conducted in accordance with Section 2.3 of this appendix.

2.7 Laboratory and Testing Facility Analysis Procedures.

(a) "Security and Chain-of-Custody."

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split samples are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee's testing facility. Documentation of individuals accessing these areas, dates, and times of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain-of-custody forms for those specimens or aliquots as they are received.

(b) "Receiving."

(1) When a shipment of specimens is received, laboratory and licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying chain-of-custody forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's chain-of-custody forms attached to the shipment shall be reported within 24 hours to the licensee, in the case of HHS-certified laboratories, and shall be noted on the laboratory's chain-of-custody form which shall accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee shall be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's

or testing facility's accession area until all analyses have been completed. Aliquots and the chain-of-custody forms shall be used by laboratory or testing facility personnel for conducting initial and confirmatory tests, as appropriate.

(c) "Short-Term Refrigerated Storage." Specimens that do not receive an initial test within 7 days of arrival at the laboratory or are not shipped within 6 hours from the licensee's testing facility and any retained split samples shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) "Specimen Processing." Urine specimens identified as presumptive positive by a licensee's testing facility shall be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) "Preliminary Initial Test."

(1) For the analysis of urine specimens, any preliminary test performed by a licensee's testing facility and the initial screening test performed by a HHS-certified laboratory shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The initial test of breath for alcohol performed at the collection site shall use a breath analysis technique which meets the requirements of the National Bureau of Standards. The following initial cut-off levels shall be used when screening specimens to determine whether they are negative for these eight substances:

Initial test
level (ng/ml)

Marijuana metabolites.....	100
Cocaine metabolites.....	300
Opiate metabolites.....	300*
Phencyclidine.....	25
Amphetamines.....	1,000
Benzodiazepine metabolite (Oxazepam).....	50
Barbiturates.....	100

Alcohol.....(1) 0.04% BAC
or (2) BAC to be determined by licensee

In addition, licensee's may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

*25 ng/ml is immunoassay specific for free morphine.

(2) These test levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines by the Department of

Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(f) "Confirmatory Test."

(1) Specimens which test negative as a result of this second screening shall be reported as negative to the licensee and will not be subject to any further testing.

(2) All urine samples identified as positive on the screening test performed by a HHS-certified laboratory shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, and at the cut-off values required by the licensee's unique program, where differences exist. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

Confirmatory test
level (ng/ml)

Marijuana metabolite.....	15*
Cocaine metabolite.....	150**
Opiates:	
Morphine.....	300
Codeine.....	300
Phencyclidine.....	25
Amphetamines:	
Amphetamine.....	500
Methamphetamine.....	500
Benzodiazepine metabolite.....	10***
Barbiturates:	
Phenobarbital.....	100
Thiopental.....	100
Pentobarbital.....	100
Secobarbital.....	100
Amobarbital.....	100
Aprobarbital.....	100
Hexobarbital.....	100
Butobarbital.....	100

Alcohol.....0.04% BAC

or (2) BAC to be determined by licensee

* Delta-9-tetrahydrocannabinol-9-carboxylic acid.

** Benzoyllecgonine.

*** Oxazepam

In addition, licensees may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

(3) The analytic procedure for confirmatory analysis of blood samples voluntarily provided by individuals testing positive for alcohol on a breath test shall comply with State standards controlling the testing of blood for alcohol concentrations.

(4) These test levels and the panel of drugs for testing are subject to change by the NRC in response to licensee experience and changes by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(g) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's Medical Review Officer within 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report shall identify the substances tested for, whether positive or negative, and the cut-off(s) for each, the specimen number assigned by the licensee, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens testing positive on the confirmatory analysis shall be reported positive for a specific substance. Specimens which test positive during the preliminary testing at the licensee's testing facility will not be reported to licensee management or to the Medical Review Officer and will not be forwarded to the HHS-certified laboratory for further testing, except as a performance check of the licensee's testing facility's procedures.

(3) The Medical Review Officer may request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of test results. The Medical Review Officer may only disclose quantitation of test results to the licensee for tests if required in an appeals process. Quantitation of negative tests for urine specimens shall not be disclosed. Alcohol quantitation for a blood specimen shall be provided to the licensee with the Medical Review Officer's evaluation.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the Medical Review Officer. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain-of-custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports and attached to which shall be a copy of the test report.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the fitness-for-duty program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Initial test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories shall be included for test results reported within that month. Normally this summary shall be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

(A) Number of specimens received;

(B) Number of specimens reported out;
and

(C) Number of specimens screened
positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines
Benzodiazepine metabolites
Barbiturates
Alcohol

(ii) Confirmatory Testing:

(A) Number of specimens received for confirmation:

(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine
Benzodiazepine metabolites
Barbiturates
Alcohol

(7) The statistics shall be presented for both the cutoff levels in these guidelines and any more stringent cutoff levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available analytical results for licensee drug testing programs when requested by the NRC or the licensee for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.

(h) "Long-Term Storage." Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time, but if no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period. Any split samples retained by the licensee shall be transferred into long-term storage upon determination by the Medical Review Officer that the specimen has a confirmed positive test.

(i) "Retesting Specimens." Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) "Split Samples." Urine specimens may be split, at the licensee's

discretion, into two parts at the collection site. One half of such samples (hereafter called the aliquot) shall be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the sample (hereafter called the split sample) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until the aliquot has been determined to be negative or until the positive result of a screening test has been confirmed. As soon as the aliquot has tested negative, the split sample in storage may be destroyed. If the aliquot tests positive by confirmatory testing, then, at the tested individual's request, the split sample may be forwarded on that day to another HHS-certified laboratory that did not test the aliquot. The chain-of-custody and testing procedures to which the split sample is subject, including cut-off levels, shall be the same as those used to test the initial aliquot. The results of any second testing process shall be made available to the Medical Review Officer and to the individual tested.

(k) "Subcontracting." HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of performing testing of the seven classes of drugs (marijuana, cocaine, opiates, phencyclidine, amphetamines, benzodiazepines, and barbiturates) and of whole breath, and confirmatory GC/MS methods specified in these guidelines.

(1) "Laboratory Facilities."

(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.

(2) HHS-certified laboratories shall have the capability, at the same laboratory premises, of performing initial tests for each drug and drug metabolite for which service is offered, and for performing confirmatory tests for alcohol and for each drug and drug metabolite for which service is offered. Any licensee testing facilities shall have the capability, at the same premises, of performing initial screening tests for each drug and drug metabolite for which testing is conducted. Initial breath tests for alcohol may be performed at the collection site.

(m) "Inspections." The NRC and any licensee utilizing an HHS-certified laboratory shall reserve the right to inspect the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, shall permit the NRC and the licensee to conduct unannounced inspections. In addition, prior to the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. The NRC shall reserve the right to inspect a licensee's testing facility at any time.

(n) "Documentation." HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under

legal challenge for an indefinite period.

(o) "Additional Requirements for HHS-certified Laboratories and Licensee's Testing Facilities."

(1) "Procedure manual." Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cut-off values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) "Standards and controls." HHS-certified laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in services; and expiration date.

(3) "Instruments and equipment."

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment shall be an evidential-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards (49 FR 48855) and to any applicable State statutes.

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) "Remedial actions." There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) "Personnel available to testify at proceedings." The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

2.8 Quality Assurance and Quality Control.

(a) "General." HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain-of-custody, security and reporting results, initial and confirmatory testing,

and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) "Licensee's Testing Facility Quality Control Requirements for Initial Tests." Because all positive preliminary tests for drugs are forwarded to an HHS-certified laboratory for a screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facility's false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall process blind performance test specimens and submit a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. In addition, the manufacturer-required performance tests of the breath analysis equipment used by the licensee shall be conducted as set forth in the manufacturer's specifications.

(c) "Laboratory Quality Control Requirements for Initial Tests at HHS-Certified Laboratories." Each analytical run of specimens to be screened shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

In addition, with each batch of samples, a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration, shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(d) "Laboratory Quality Control Requirements for Confirmation Tests." Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) "Licensee Blind Performance Test Procedures."

(1) Licensees shall purchase chemical testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the HHS Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each licensee shall submit blind performance test specimens to each HHS-certified laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the licensee is testing.

(4) The licensee shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result, and based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the HHS-certified laboratory. Then the licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the licensee shall promptly notify the NRC. The licensee shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the licensee shall instruct the laboratory to submit to them all quality control data from the batch of specimens which included the false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an on-site review of the laboratory which may be conducted un-announced during any hours of operation of the laboratory. Based on information provided by the NRC, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.9 Reporting and Review of Results.

(a) "Medical Review Officer shall review results." An essential part of the licensees' testing programs is the final review of results. A positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to licensee management officials.

(b) "Medical Review Officer --qualifications and responsibilities." The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be a licensee or contract employee. The role

of the Medical Review Officer is to review and interpret positive test results obtained through the licensee's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally pre-scribed medication. The Medical Review Officer shall not consider the results of tests that are not obtained or processed in accordance with these Guidelines, although he or she may consider the results of tests on split samples in making his or her determination, as long as those split samples have been stored and tested in accordance with the procedures described in these Guidelines.

(c) "Positive Test Results." Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the licensee's policy, notify the applicable employee assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent).

(d) "Verification for opiates; review for prescription medication." Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence--in addition to the urine test--of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the licensee's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.) For other drugs that are commonly prescribed or commonly included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and that are listed in the licensee's panel of substances to be tested, the Medical Review Officer shall also determine that there is clinical evidence--in addition to the urine test--of unauthorized use of any of these substances or their derivatives.

(e) "Reanalysis authorized." Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original aliquot on timely request of the individual tested, and shall also authorize an analysis of any sample stored by the licensee.

(f) "Results consistent with responsible substance use." If the Medical Review Officer determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment, the Medical Review Officer shall report the test result to the licensee as negative.

(g) "Result scientifically insufficient." Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory

or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines.) The licensee's testing facility and the HHS-certified laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual(s) responsible for day-to-day management of the licensee's test facility, of the HHS-certified laboratory or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the licensee. The licensee shall maintain records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in such reports.

Subpart C - Employee Protection

3.1 Protection of Employee Records

Licensee contracts with HHS certified laboratories and procedures for the licensee's testing facility shall require that test records be maintained in confidence, as provided in 10 CFR 26.29. Records shall be maintained and used with the highest regard for individual privacy.

3.2 Individual Access to Test and Laboratory Certification Results.

Any individual who is the subject of a drug or alcohol test under this part shall, upon written request, have access to any records relating to his or her tests and any records relating to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings.

Subpart D - Certification of Laboratories Engaged in Chemical Testing

4.1 Use of DHHS-certified laboratories.

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Subpart C - "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (53 FR 11970, 11986-11989) dated April 11, 1988, and subsequent amendments thereto for screening and confirmatory testing except for initial screening tests at a licensee's testing facility conducted in accordance with 10 CFR 26.24(d). Information concerning the current certification status of laboratories is available from: The Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels as may be specified by licensees for the five classes of drugs identified in the HHS Guidelines or when testing for benzodiazepines, barbiturates, and for any

other substances included in licensees' drug panels, and for conducting alcohol confirmatory tests as are followed when testing for the five classes of drugs identified in the HHS Guidelines.

Dated at Rockville, MD this _____ day of _____, 1989.

For The Nuclear Regulatory Commission.

Samuel J. Chilk
Secretary of the Commission

Enclosure 4

Annotated Copy of Rule Changes

PART 26—FITNESS FOR DUTY PROGRAMS

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 - 26.28 Appeals.
 - 26.29 Protection of information.
- Inspections, Records and Reports
- 26.70 Inspections.
 - 26.71 Recordkeeping requirements.

Sec.

- 26.73 Reporting requirements.

Audits

- 26.80 Audits.

Enforcement

- 26.90 Violations. ←

Authority: Secs. 53, 81, 103, 104, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.

Appendix A - Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs

General Provisions

§ 26.1 Purpose.

This part prescribes requirements and standards for the establishment and maintenance of certain aspects of fitness-for-duty programs and procedures by the licensed nuclear power industry.

§ 26.2 Scope.

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor. Each licensee shall implement a fitness-for-duty program which complies with all sections of this part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to protected areas, and to licensee or contractor personnel required to respond to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures. The regulations in this part do not apply to NRC representatives, employees, or to law enforcement personnel and offsite emergency fire and medical response personnel while on official duty or responding on-site.

(b) The requirements in this part must be implemented by each licensee authorized to operate a nuclear power reactor no later than (insert date 90 days after publication of final rule), except for the requirements to implement random drug testing contained in § 26.24, which must be implemented no later than (insert date 180 days after publication of final rule).

(b) Certain regulations in this part also apply to licensees holding permits to construct a nuclear power plant. Each construction permit holder, with a plant under active construction, shall comply with the following sections of this part: 26.10; 26.20; 26.23; 26.24a; 26.70; and 26.73

§ 26.3 Definitions.

"Aliquot" means a portion of a specimen used for testing.

"Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

"Confirmatory test" means a second analytical procedure to identify the

presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy.

drug, drug metabolite or alcohol screening

screening

~~"Confirmed positive test" means the result of a confirmatory test that has confirmed the presence of concentrations of drugs or metabolites in a specimen above the "cutoff level."~~

result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation.

~~"Cutoff level" means the value set for designating a test result as positive.~~

~~"Drug abuse" means the use of a psychoactive substance for other than medical purposes which impairs the physical, mental, emotional or social well-being of the user.~~

~~"Follow-up testing" means chemical testing at unannounced intervals, during or as follow-up to treatment, to ensure that an employee is maintaining abstinence from the previously identified abuse of drugs.~~

means or alcohol.

~~"For-cause testing" means chemical testing at the request of a supervisor, or other responsible management official, based upon reasonable suspicion that a person is impaired or may have used drugs.~~

"Contractor" means any company or individual with which the licensee has contracted for work/or service to be performed inside the protected area boundary, either by contract, purchase order, or verbal agreement.

~~"Illegal drugs" means a controlled substance included in Schedule I or II of the Controlled Substances Act, as amended, 21 U.S.C. 801, et seq. The term "illegal drugs" does not mean the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.~~

~~"Impairment" means deficient or diminishing on-the-job performance resulting from physical or psychological stressors that may include abuse of drugs or other substances.~~

drugs" means those drugs included in Schedule I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

~~"Initial screening test" means an immunoassay screen to eliminate "negative" urine specimens from further consideration.~~

"Initial or screening tests" means an immunoassay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or a breathalyzer test for alcohol. Initial screening may be performed at the licensee's testing facility; a second screen and confirmation testing must be conducted by a HHS-certified laboratory.

~~"Protected area" has the same meaning as in § 73.2(g) of this chapter, an area encompassed by physical barriers and to which access is controlled.~~

~~"Random test" means a system of administered unannounced drug testing imposed in a statistically random manner to a group so that all persons within that group have an equal probability of selection.~~

~~"Suitable inquiry" means verification of employment history for a minimum of the past five years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating drug abuse,~~

best-effort biomedical information.

~~removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other~~

but in no case less than three years.

substance

employment in accordance with a fitness-for-duty policy.

~~"Unannounced testing" means unannounced random tests.~~

"Vendor" means any company or individual, not under contract to a licensee, providing services in protected areas.

§ 26.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 26.6 Exemptions.

The ~~Committee~~ may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Commission

§ 26.7 Information collection requirements: OMB approval.

The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part of the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number: _____

(b) The approved information collection requirements contained in this part appear in: §§ 26.20, 26.21, 26.22, 26.23, 26.29, 26.71, 26.73, and 26.80.

26.24

(c) The total burden for these record keeping requirements is estimated to be 313 hours per site per year. In implementing the record keeping requirements the affected licensee shall report to the Commission any comments concerning the accuracy of the estimate and any suggestions for reducing the burden.

General Performance Objectives

§ 26.10 General performance objectives.

~~Fitness-for-duty programs shall~~

(a) ~~Provide reasonable assurance that nuclear power plant personnel are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;~~

(b) ~~Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part; and~~

(c) ~~Have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances.~~

"shall" changed to "must" throughout rule (not further indicated herein)

will perform their tasks in a reliable and trustworthy manner and

Program Elements and Procedures

§ 26.20 Written policy and procedures.

Each licensee subject to this part shall establish and implement written policies

and procedures designed to meet the general performance objectives and specific requirements of this part. Each licensee shall retain a copy of the current written policy and procedures as a record until the Commission terminates each license for which the policy and procedures were developed and, if any portion of the policies and procedures are superseded, retain the superseded material for three years after each change. As a minimum, written policies and procedures shall address fitness for duty through the following:

(a) ~~An overall description of licensee policy on fitness for duty. The policy shall address abuse of illegal drugs and legal drugs (e.g., alcohol, prescription and over-the-counter drugs). Licensee policy shall also address other factors that could affect fitness for duty such as mental stress, fatigue and illness.~~

Written policy documents shall be in sufficient detail to provide affected individuals with information on what is expected of them, and what consequences may result from lack of adherence to the policy.

use
abuse of

As a minimum, the written policy shall prohibit the consumption of alcohol (1) within a specified time period preceding any scheduled working tour, and (2) during the period of any working tour.

Licensee policy should also address other factors that could affect fitness for duty such as mental stress, fatigue and illness.

(b) A description of programs which are available to personnel desiring assistance in dealing with drug or other problems that could adversely affect the performance of activities within the scope of this part. , alcohol,

(c) Procedures to be utilized in testing for drugs including procedures for protecting the employee and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual. and alcohol,

(d) A description of immediate and follow-on actions which will be taken, and the procedures to be utilized, in those cases where employees or contractors assigned to duties within the scope of this part are determined to have been involved in the use, sale, or possession of illegal drugs, vendors,

or to have consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess prior to reporting to duty as demonstrated with a test that can be used to determine blood alcohol concentration.

(e) A procedure that will ensure that persons called in to perform an unscheduled working tour are fit to perform the task assigned. As a minimum, this procedure shall--

§ 26.21 Policy communications and awareness training

(a) Persons assigned to activities within the scope of this part shall be provided with appropriate training to ensure they understand--

(1) Licensee policy and procedures, including the methods that will be used to implement the policy;

(2) The personal and public health and safety hazards associated with abuse of drugs and misuse of alcohol;

(3) The effect of prescription and over-the-counter drugs and dietary conditions on drug test results, and the role of the Medical Review Officer on job performance and chemical

(4) Employee assistance programs provided by the licensee, and

(1) require a statement to be made by a called-in person as to whether he or she has consumed alcohol within the length of time stated in the pre-duty abstinence policy;

(2) if alcohol has been consumed within this period, require a determination of fitness for duty by breath analysis or other means; *AND*

(3) require the establishment of controls and conditions under which a person who has been called-in can perform work, if necessary, although alcohol has been consumed.

(f) The Commission may at any time review the licensee's written policy and procedures to assure that they meet the performance objectives of this Part.

(5) What is expected of them and what consequences may result from lack of adherence to the policy.

(b) Initial training must be completed prior to assignment to activities within the scope of this part. Refresher training must be completed on an annual basis, or more frequently where the need is indicated. A record of the training shall be retained for a period of at least three years.

a nominal 12 month frequency

§ 26.22 Training of supervisors and escorts.

(a) Managers and supervisors of activities within the scope of this part shall be provided appropriate training to ensure they understand—

(1) Their role and responsibilities in implementing the program;

(2) The roles and responsibilities of others, such as the personnel, medical, and Employee Assistance Program (EAP) staffs;

(3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;

(4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in employee behavior (in the case of escorts, the behavioral observation techniques shall cover detection of impairment); and

(5) Procedures for initiating appropriate corrective action, to include referral of employees for counseling or treatment (in the case of escorts, this shall cover reporting to appropriate management).

to the EAP.

(b) Persons assigned to escort duties shall be provided appropriate training to ensure they understand the matters contained in § 26.22(e)(3), (4), and (5).

in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel.

(c) Initial training must be completed prior to assignment of duties within the scope of this part and within 3 months of initial supervisory assignment, as applicable. Refresher training must be completed on an annual basis, or more frequently where the need is indicated. A record of the training shall be retained for a period of at least three years.

a nominal 12 month frequency

§ 26.23 Contractors

(a)

and Vendors.

→ All contractor personnel performing activities within the scope of this part for a licensee must be subject to either the licensee's program relating to fitness for duty, or to a program formally reviewed and approved by the licensee, which meets the standards of this part. Written agreements between licensees and contractors for activities within the scope of this part shall be retained for the life of the contract and will clearly show that—

and vendor

requirements

or vendors

(1)

(d) The contractor is responsible to the licensee for adhering to the

or vendor
adhering

licensee's fitness-for-duty policy, or maintaining and ~~adhering~~ to an effective fitness-for-duty program which meets the standards of this part; and (2)

adhering

~~Personnel having been denied access or removed from nuclear safety activities at any nuclear power plant for violations of fitness-for-duty policy will not be assigned to contracted work~~ within the scope of this Part without the knowledge and consent of the licensee. within the scope of this Part

§ 26.24 Chemical testing.

(a) To provide a means to deter and detect ~~and~~ abuse, the licensee shall implement the following chemical testing programs for persons subject to this part:

(1) Testing ~~immediately before~~ the initial granting of unescorted access to protected areas or assignment to activities within the scope of this part.

(2) Unannounced tests imposed in a random manner. The tests must be administered so that a person completing a test is immediately eligible for another unannounced test.

(i) Alternative A: The tests must be conducted in a manner that assures that at least 90 percent of the individuals within the scope of the rule are tested each year, that testing is performed throughout the year and that testing rates for individuals already tested with negative results not be lower than 30 percent per year (2½ percent per month) for the remainder of the testing year.

(ii) Alternative B: The tests must be administered throughout the year at an annual rate equivalent to 300 percent of the population subject to such testing.

(b) Each licensee subject to this Part shall assure that contractors whose own fitness-for-duty programs are relied on by the licensee adhere to an effective program, which meets the requirements of this Part, and shall conduct audits pursuant to § 26.80 for this purpose.

within 60 days
prior to

Substance

As a minimum, tests must be administered on a nominal weekly frequency.

(iii) Alternative C: Each worker shall be randomly assigned a day during the next 365 days on which to be tested, and then shall be randomly re-assigned to a day in the following 365-day period.

(iv) Alternative D: Each worker shall be subjected to an unannounced test on an individual rather than work unit basis once during the year. In addition, random testing at a rate of 50% shall be used during the year to assure ongoing deterrence.

(v) Alternative E: Random testing shall be conducted at a rate equal to at least 100% of the workforce.

(3) Testing for-cause, i.e., immediately following any observed behavior indicating possible ~~drug~~ abuse: after accidents involving a failure in individual performance resulting in personal injury, in a radiation exposure or release of radioactivity in excess of regulatory limits, or actual or potential substantial degradations of the level of safety of the plant; or after receiving credible information that an individual is abusing drugs

as soon as possible

substance

if there is a reasonable suspicion that the worker's behavior contributed to the accident;

or alcohol.

(4) Follow-up testing on a random basis to verify continued abstention from the use of ~~drugs~~

an unannounced

substances covered under this part.

and alcohol

(b) Testing for drugs shall, at a minimum, conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" issued by the Alcohol, Drug Abuse, and Mental Health Administration of the Department of Health and Human Services (these guidelines are available for review at the Public Document Room, 2100 L St., NW, Washington, DC 20535, and will be published with the final regulations), hereinafter referred to as the ~~MWS~~

"Guidelines for Nuclear Power Plant Drug and Alcohol Testing Programs," issued by the Nuclear Regulatory Commission and appearing in Appendix A to this rule.

NRC

discretion, may implement programs with more stringent standards (e.g., lower cutoff levels). Management actions with respect to persons who fail a more stringent standard, but do not test positive under the HHS Guidelines incorporated in this rule, would also be at the discretion of the licensee.

NRC

[shall be consistent with the requirement of this rule.]

(c) Licensees shall test for all ~~five~~ ~~drugs or classes of drugs~~ described in paragraph 2.1(a) (1) and (2) of the HHS Guidelines. In addition, licensees shall consult with local law enforcement authorities and drug counseling services to determine whether other ~~drugs~~ are being used in the geographical locale of the facility and the local workforce. Where appropriate, other drugs so identified must be added to the list of ~~drugs being tested~~. Conservative cutoff limits must be established by the licensee for these ~~drugs~~.

eight substances

NRC

may

[substances with abuse potential]

[Where appropriate, other substances so identified may be added to the panel of substances for testing.]

substances

(d) Licensees may conduct preliminary tests of an aliquot prior to forwarding selected specimens to a contract laboratory meeting the requirements of paragraph (e) of this section, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, their qualifications are documented, and adequate quality controls are implemented. Quality control procedures for preliminary tests shall include the processing of blind performance test specimens and the submission to the contract laboratory of a sampling of specimens initially tested as negative.

[initial screening]

[certified by the Department of Health and Human Services,

initial screening

HHS-certified

[Access to the results of preliminary tests shall be limited to the licensee's testing staff, the Medical Review Officer, and the FFD Program Manager.]

(e) The Medical Review Officer's review of the test results must be completed and licensee management notified within 10 days of the initial presumptive positive screening test.

(f) Quality controls and procedures for contract laboratories shall be consistent with the HHS standards for "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies." (these guidelines are available for review at the Public Document Room, 2120 L St. NW., Washington, DC 20535, and will be published with the final regulations). HHS-certified Department of Health and Human Services (53FR11970, 11986-11987, dated April 11, 1988).

Contract laboratories shall conduct initial screening tests and confirmatory tests on all specimens forwarded for testing. Licensees shall submit blind performance test specimens to contract laboratories in accordance with paragraph 2.5(d)(2) and (3) of the HHS Guidelines. HHS-certified NRC (Appendix A)

(g) Tests for alcohol shall be administered by a breath analysis. A breath alcohol content indicating a blood alcohol concentration of 0.04% shall be a positive test result. Any alcohol concentration below this level shall also be evaluated to determine whether the licensee's policy on alcohol has been violated.

~~If a confirmatory test is demanded by the person being tested, the confirmatory test shall be a gas chromatography analysis of blood.~~

--OR--

(g) Tests for alcohol shall be administered by a breath analysis, with any alcohol concentration evaluated to determine whether the licensee's policy on alcohol use has been violated. If a confirmatory test is requested by the person being tested, the confirmatory test shall be a gas chromatography analysis of blood.

may be done with another breath measurement instrument that meets evidential standards described in Section 2.7(0)(3) of Appendix A. Should the person demand further confirmation, the test

26.23 Employee Assistance Programs (EAP).

Each licensee subject to this part shall maintain an Employee Assistance Program to strengthen fitness-for-duty programs by offering assessment, short-term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the

26.24a "Construction Site Program Construction permit licensees shall implement a chemical testing program, including random tests, and shall make provisions for employee assistance programs, appeal procedures, the protection of information, and recordkeeping.

imposition of sanctions,

scope of this part. EAPs should be designed to achieve early intervention and provide for confidential assistance ~~(except where safety considerations must prevail)~~ EAP staff shall inform licensee management when a determination has been made that ~~any self-referring individual's condition~~ constitutes a hazard to himself or herself or others ~~(including those who have self-referred)~~

§ 26.27 Management actions and sanctions to be imposed.

(a) Prior to the initial granting of unescorted access to a protected area or the assignment to activities within the scope of this part to any person, the licensee shall obtain a written statement from the individual as to whether activities within the scope of this part were ever denied the individual and shall complete a suitable inquiry to determine if that person was, in the past, tested positive for illegal drugs, subject to a plan for treating drug abuse, or removed from activities within the scope of this part, or denied unescorted access at any other nuclear power plant in accordance with a fitness-for-duty policy. If such a record is established, the new assignment to activities within the scope of this part or granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program, provided the restrictions of paragraph (b) of this section are observed. To meet this requirement, the identity of persons denied unescorted access or removed under the provisions of this part and the circumstances for such denial or removal, including test results, will be made available in response to an inquiry by any company or its contractor falling under the scope of this part. Failure to list all previous employers and reasons for removal or revocation of unescorted access shall be cause for denial of unescorted access.

The licensee on a best-efforts basis or use of alcohol which resulted in on-duty impairment, substance (except for self-referral for treatment).

are to a licensee's, contractor's, or vendor's inquiry supported by a signed release form from the individual.

sufficient

(b) Each licensee subject to this part shall, as a minimum, take the following actions. Nothing herein shall prohibit the licensee from taking more stringent action.

The temporary access provision in Section 6.4 of the "Industry Guidelines for Nuclear Power Plant Access Authorization Programs" shall be applicable to this part with the added provision that the prospective worker must pass a chemical test conducted according to the requirements of Section 26.24(a)(1).

(1) Impaired workers, or those whose fitness may be questionable, shall be removed from activities within the scope of this Part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this Part.

(2) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs onsite, a confirmed positive test result shall be presumed to be an indication of offsite drug use. The first confirmed positive test shall, as a minimum, result in immediate removal from activities within the scope of this part for at least 14 days and referral to the EAP for assessment and counseling during any suspension period. Plans for treatment, follow-up, and future employment shall be developed, and any rehabilitation program deemed

(no comma)

appropriate must be initiated as appropriate, during such suspension period. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this part shall be obtained before permitting the individual to be returned to these activities. Any subsequent confirmed positive test shall result in removal from unescorted access to protected areas and activities within the scope of this part for a minimum of three years from the date of removal.

(3)

(2) Any individual determined to have been involved in the sale, use, or possession of illegal drugs while within a protected area of any nuclear power plant shall be removed from activities within the scope of this Part. The individual may not be granted unescorted access to protected areas or assigned to activities within the scope of this part for a minimum of five years from the date of removal.

(4)

(3) Persons removed for periods of three years or more under the provisions of the above paragraphs for the illegal sale, use or possession of drugs and who would have been removed under the current standards of a hiring licensee, may be granted unescorted access and assigned duties within the scope of this part by a licensee subject to this Part only when the hiring licensee receives satisfactory medical assurance that the person has abstained from drugs for at least three years. Satisfactory management and medical assurance of the individual's fitness to adequately perform activities within the scope of this part shall be obtained before permitting the individual to perform activities within the scope of this part.

(b)(2) and (3) of this section

Any person granted unescorted access or whose access is reinstated under these provisions, shall be given unannounced follow-up tests at least once every three months for three years after reemployment to verify continued abstinence from drugs. Any confirmed use of drugs through this process or any other determination of subsequent involvement in the sale, use or possession of illegal drugs shall result in permanent denial of unescorted access.

month for four months and at least once every three months for the next two years and eight months after unescorted access is reinstated

proscribed substances.

substances

(c) Refusal to provide a specimen for testing and resignation prior to removal for violation of company policy concerning drugs shall be recorded as removal for cause. Such records shall be retained for the purpose of meeting the requirements of § 26.27(a).

fitness-for-duty

removals

(d) If a licensee has reasonable belief that an NRC employee may be under the influence of any substance, or otherwise unfit for duty, the licensee may not deny access but may escort the individual. In

(5), Paragraph (b)(2), (3), and (4) of this section do not apply to alcohol, valid prescriptions, or over-the-counter drugs. Licensee sanctions for confirmed misuse of alcohol, valid prescriptions and over-the-counter drugs as determined by the Medical Review Officer shall be sufficient to deter abuse of legally obtainable substances as a substitute for abuse of proscribed drugs.

any instance of this occurrence, the appropriate Regional Administrator shall be notified immediately by telephone. During other than normal working hours, the NRC Operations Center shall be notified.

§ 26.28 Appeals.

licensee and contractor

Each licensee subject to this part shall establish a procedure for employees and contractor/vendor employees to appeal fitness-for-duty determinations that could have an adverse effect on the individual's employment. The procedure must provide notice and an opportunity to respond and be consistent with fundamental principles of due process. Where applicable, grievance review procedures contained in collective bargaining agreements covering the bargaining unit of which the employee is a member will normally meet this requirement, and they may be used for this purpose whether or not the administrative action taken is a grievable action under the contract.

and each contractor implementing a fitness-for-duty program under the provisions of section 26.23.

the results of an alcohol or drug test.

and may be an impartial management review.

A licensee review procedure need not be provided to employees of contractors when the contractor is administering his own alcohol and drug testing.

§ 26.29 Protection of Information.

(a) Each licensee subject to this part, who collects personal information on an individual employee for the purpose of complying with this part, shall establish and maintain a system of files and procedures for the protection of the personal information. Such system shall be maintained until the Commission terminates each license for which the system was developed.

(b) The licensee shall not disclose the personal information collected and maintained to persons other than assigned medical review officers, other licensees legitimately seeking the information as required by this part for employment decisions and who have obtained a release from current or prospective employees or contractor personnel, NRC representatives, appropriate law enforcement officials, the subject individual or his or her representative, or to those licensee personnel who have a need to have access to the information in performing assigned duties.

Inspections, Records and Reports

§ 26.70 Inspections.

(a) Each licensee subject to this part shall permit duly authorized representatives of the Commission to inspect its records, premises, activities, and personnel as may be necessary to accomplish the purposes of this part.

(b) Written agreements between licensees and their contractors will clearly show that the—

(c) Licensee is responsible to the Commission for maintaining an effective

Licensees and contractors

officers

or their authorized representatives

unescorted access

under court order,

representatives

including audits of licensee and contractors programs, to persons deciding matters on review or appeal, and to other persons pursuant to court order. This section does not authorize the licensee to withhold evidence of criminal conduct from law enforcement officials.

and vendors

copy, or take away copies of

and inspect its

Duly authorized representatives of
the Commission

fitness-for-duty program in accordance
with this part; and

(2) ~~NRC~~ may inspect, copy, or take
away copies of any ~~licensee's~~ licensee,
contractor documents, records, and , or vendor
reports related to implementation of the
licensee's ~~contractor's~~ fitness-for-duty , contractor's, or vendor's
program under the scope of the
contracted activities.

§ 26.71 Recordkeeping requirements.

Each licensee subject to this part
shall—

(a) Retain records of inquiries
conducted in accordance with § 26.27(a),
that result in the granting of unescorted
access to protected areas, until ~~three~~ five
years following termination of such
access authorizations;

(b) Retain records of confirmed
positive test results which are concurred
in by the Medical Review Officer, and related
the subsequent personnel actions for a
period of at least three years; and five

(c) Retain records of persons made
ineligible for three years or longer for
assignment to activities within the scope
of this part under the provisions of
§ 26.27(b)(1), (2), (3) or (c), until the (2)(3)(4)
Commission terminates each license
under which the records were created.

(d) Collect and compile fitness-for-
duty program performance data as
described in NRC Form. The
data shall be analyzed and appropriate
actions taken to correct program
weaknesses. Such data and analysis
shall be retained for three years and
made available for inspection by the
NRC

§ 26.73 Reporting requirements.

(a) Each licensee subject to this part shall inform the Commission of significant fitness-for-duty events including:

~~(1) Sale, use, or possession of illegal drugs within the protected area and~~

(1)

~~(iii) Any acts involving the illegal sale, use or possession of a controlled substance by any person licensed under 10 CFR Part 55 to operate a power reactor or by any supervisory personnel assigned to perform duties within the scope of this part. This includes the results of confirmed positive tests on such persons.~~

(2) Any acts by any person licensed under 10 CFR Part 55 to operate a power reactor or by any supervisory personnel assigned to perform duties within the scope of this part, (i) involving the sale, use, or possession of a controlled substance, (ii) resulting in confirmed positive tests on such persons, (iii) involving use of alcohol within the protected area, or (iv) determination of unfitness for scheduled work due to the consumption of alcohol.

~~(b) Such notifications shall be made to the NRC Operations Center by telephone within 24 hours of the discovery of the event.~~

(b)

~~(3) Written reports documenting such notifications and specifying actions taken shall be submitted within 30 days to the U.S. Nuclear Regulatory Commission Document Control Desk.~~

by the licensee.

Washington, DC 20555. The licensee shall also submit one copy to the appropriate NRC Regional Office.

Written reports shall not include the names of the individuals.

(b) Fitness-for-duty events shall be reported under this section rather than reported under the provisions of § 73.71.

Audits

§ 26.80 Audits.

(a) Each licensee subject to this part shall ~~under the fitness-for-duty program~~ audit to be audited at least once every 12 months. In addition, audits shall be conducted, at least once every 12 months, of those portions of fitness-for-duty programs implemented by contractors. Licensees may accept audits of contractors conducted by other licensees and need not re-audit the same contractor for the same period of time. *

Each sharing utility must maintain a copy of the audit report, to include findings, recommendations and corrective action must be provided to each sharing utility and made available on-site for NRC inspection. Licensees retain responsibility for the effectiveness of contractor programs and the implementation of appropriate corrective action.

(b) Audits shall focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited, and independent of both program management and personnel directly responsible for implementation of the fitness-for-duty program.

(c) The result of the audit, along with recommendations, if any, shall be documented and reported to senior corporate and site management. The resolution of the audit findings and corrective actions shall be documented. These documents shall be retained for three years and made available for NRC inspection.

(d) By (insert date 180 days after effective date of rule), each licensee shall certify to the NRC that its fitness-for-duty program is implemented. The certification shall describe any licensee cut-off levels more stringent than those imposed by this Part.

licensee audits

NRC Guidelines require ~~additional inspection~~ of HHS-certified laboratories as described in Appendix A.

Enforcement

§ 26.90 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of—

(1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these sections, ~~or under section 161 of the Act;~~

(4) Any term, condition, or limitation of any license issued under these sections; or

(5) Any provisions for which a license may be revoked under section 166 of the Atomic Energy Act of 1954.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any regulation or order issued under the requirements of the Act, include regulations under this part, may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

Dated at Rockville, Maryland, this 15th day of September, 1988.

For the Nuclear Regulatory Commission.

Samuel J. Chilk.

Secretary of the Commission.

Enclosure 5

NRC Guidelines (Comparative Text)

**MANDATORY GUIDELINES FOR
FEDERAL WORKPLACE DRUG
TESTING PROGRAMS**

Subpart A—General

- 1.1 Applicability.
- 1.2 Definitions.
- 1.3 Future Revisions

**Subpart B—Scientific and Technical
Requirements**

- 2.1 The Drugs.
- 2.2 Specimen Collection Procedures.
- 2.3 Laboratory Personnel.
- 2.4 Laboratory Analysis Procedures.
- 2.5 Quality Assurance and Quality Control.
- 2.6 Interim Certification Procedures.
- 2.7 Reporting and Review of Results.
- 2.8 Protection of Employee Records.
- 2.9 Individual Access to Test and Laboratory Certification Results.

**Subpart C—Certification of Laboratories
Engaged in Urine Drug Testing for Federal
Agencies**

- 3.1 Introduction.
- 3.2 Goals and Objectives of Certification.
- 3.3 General Certification Requirements.
- 3.4 Capability to Test for Five Classes of Drugs.
- 3.5 Initial and Confirmatory Capability at Same Site.
- 3.6 Personnel.
- 3.7 Quality Assurance and Quality Control.
- 3.8 Security and Chain of Custody.
- 3.9 One-Year Storage for Confirmed Positives.
- 3.10 Documentation.
- 3.11 Reports.
- 3.12 Certification.
- 3.13 Revocation.
- 3.14 Suspension.
- 3.15 Notice: Opportunity for Review.
- 3.16 Recertification.
- 3.17 Performance Test Requirement for Certification.
- 3.18 Performance Test Specimen Composition.
- 3.19 Evaluation of Performance Testing.
- 3.20 Inspections.
- 3.21 Results of Inadequate Performance.

Authority: E.O. 12564 and sec. 503 of Pub. L. 100-71.

Subpart A—General

1.1 Applicability.

(a) These mandatory guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101 (3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) And any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(b) Any agency or component of an agency with a drug testing program in existence as of September 15, 1986, and the Departments of Transportation and Energy shall take such action as may be necessary to ensure that the agency is brought into compliance with these Guidelines no later than 90 days after they take effect, except that any judicial challenge that affects these Guidelines shall not affect drug testing programs subject to this paragraph.

**PART 40—PROCEDURES FOR
TRANSPORTATION WORKPLACE
DRUG TESTING PROGRAMS**

Subpart A—General

- Sec
- 40.1 Applicability.
- 40.2 Definitions.

**Subpart B—Scientific and Technical
Requirements**

- 40.21 The drugs.
- 40.23 Preparation for testing.
- 40.25 Specimen collection procedures.
- 40.27 Laboratory personnel.
- 40.29 Laboratory analysis procedures.
- 40.31 Quality assurance and quality control.
- 40.33 Reporting and review of results.
- 40.35 Protection of employee records.
- 40.37 Individual access to test and laboratory certification results.

**Subpart C—Certification of Laboratories
Engaged in Urine Drug Testing**

- 40.41 Use of DHHS-certified laboratories.

**Appendix A to Part 40—DHHS Certification
Standards**

**Appendix B to Part 40—Urine Custody and
Control Form**

Authority: 49 U.S.C. 102, 301.

Subpart A—General

§ 40.1 Applicability.

This part applies to transportation employers (including self-employed individuals) conducting drug urine testing programs pursuant to regulations issued by agencies of the Department of Transportation and to such transportation employers' officers, employees, agents and contractors, to the extent and in the manner provided in DOT agency regulations.

**GUIDELINES FOR NUCLEAR POWER
PLANT DRUG AND ALCOHOL
TESTING PROGRAMS**

Subpart A - General

- 1.1 Applicability
- 1.2 Definitions

**Subpart B - Scientific and Technical
Requirements**

- 2.1 The Substances
- 2.2 General Administration of Testing
- 2.3 Preventing Subversion of Testing
- 2.4 Specimen Collection Procedures
- 2.5 HHS-Certified Laboratory Personnel
- 2.6 Licensee Testing Facility Personnel
- 2.7 Laboratory and Testing Facility Analysis Procedures
- 2.8 Quality Assurance and Quality Control
- 2.9 Reporting and Review of Results

Subpart C - Employee Protection

- 3.1 Protection of Employee Records
- 3.2 Individual Access to Test and Laboratory Certification Results

**Subpart D - Certification of Laboratories
Engaged in Chemical Testing**

- 4.1 Use of HHS-Certified Laboratories

Subpart A - General

1.1 Applicability.

(1) These guidelines apply to licensees authorized to operate nuclear power reactors.

(2) Licensees may set more stringent cut-off levels than specified herein or test for substances other than specified herein.

(3) Only laboratories which are HHS-certified are authorized to perform urine drug testing for NRC licensees, vendors, and licensee contractors.

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(c) Except as provided in 2.6, Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(d) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(e) These Guidelines do not apply to drug testing conducted under legal authority other than E.O. 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

(f) Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

1.2 Definitions.

For purposes of these Guidelines the following definitions are adopted:

Aliquot. A portion of a specimen used for testing.

Chain of Custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved agency chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt of the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody.

§ 40.2 Definitions.

For purposes of this part the following definitions apply:

Aliquot. A portion of a specimen used for testing.

Chain of custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody. Two forms of chain of custody documents are utilized under this part. An external chain of custody form or "urine custody and control form" (described in § 40.23) is used to document chain of custody to the laboratory. An internal chain of custody form is utilized to document handling and transfer of the original sample container and aliquots within the laboratory.

1.2 Definitions.

For the purposes of this part, the following definitions apply:

"Aliquot." A portion of a specimen used for testing.

"BAC." Blood alcohol concentration (BAC), which can be measured directly from blood or derived from a measure of the concentration of alcohol in a breath specimen, is a measure of the mass of alcohol in a volume of blood such that an individual with 100 mg of alcohol per 100 ml of blood has a BAC of 0.10 percent.

"Commission." The U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Chain-of-custody." Procedures to account for the integrity of each specimen by tracking its handling and storage from the point of specimen collection to final disposition of the specimen.

HHS

Collection Site A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection Site Person A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function.

Confirmatory Test A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability

and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

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Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) A collection is observed or (b) collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

Confirmatory test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency of the United States Department of Transportation administering regulations requiring compliance with this part, including the United States Coast Guard, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Urban Mass Transportation Administration, and the Research and Special Programs Administration.

Employee. An individual designated in a DOT agency regulation as subject to drug urine testing and the donor of a specimen under this part. As used in this part "employee" includes a final applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, "employer" is inclusive of a industry consortium or joint enterprise comprised of two or more employing entities, but no single employing entity is relieved of its responsibility for compliance with this part by virtue of participation in such a consortium or joint enterprise.

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"Collection site." A place designated by the licensee where individuals present themselves for the purpose of providing a specimen of their urine, breath, and/or blood to be analyzed for the presence of drugs or alcohol.

"Collection site person." A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) a collection is observed or (b) collection is monitored by nonmedical personnel, the collection site person must be a person of the same gender as the donor.

"Confirmatory test." A second analytical procedure to identify the presence of a specific drug, drug metabolite, or alcohol which is independent of the screening test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry [GC/MS] is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, phencyclidine, alcohol, benzodiazepines, and barbiturates).

"Confirmed positive test." The result of a confirmatory test that has established the presence of drugs, drug metabolites, or alcohol in a specimen above the cut-off level, and that has been deemed positive by the Medical Review Officer (MRO) after evaluation.

"HHS-certified laboratory." A urine and blood testing laboratory that maintains certification to perform drug testing under the Department of Health and Human Services (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 FR 11970).

"Illegal drugs." Those drugs included in Schedules I through V of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Initial test (also known as screening test). An immunoassay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer. A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Permanent Record Book. A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

Reason to Believe. Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of E.O. 12564.

Secretary. The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

1.3 Future Revisions.

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the Federal Register.

Subpart B—Scientific and Technical Requirements

2.1 The Drugs.

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

(1) Federal agency applicant and random drug testing programs shall at a minimum test for marijuana and cocaine:

(2) Federal agency applicant and random drug testing programs are also authorized to test for opiates, amphetamines, and phencyclidine; and

(3) When conducting reasonable suspicion, accident, or unsafe practice testing, a Federal agency may test for any drug listed in Schedule I or II of the CSA

Initial test (also known as screening test). An immunoassay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer. A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Permanent Record Book. A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection. May be used in conjunction with a modified urine custody and control form to document collection.

Reason to believe. Reason to believe that a particular individual may alter or substitute the urine specimen.

Secretary. The Secretary of Transportation or the Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing this part.

Subpart B—Scientific and Technical Requirements

§ 40.21 The drugs.

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

"Initial or screening test." An immunoassay screen for drugs or drug metabolites to eliminate "negative" urine specimens from further consideration or a breathalyzer test for alcohol.

"Licensee's testing facility." A drug testing facility operated by the licensee or one of its vendors or contractors to perform the initial testing of urine samples and to perform initial breath tests for alcohol. Such a testing facility is optional and not required to maintain HHS certification under this part.

"Medical Review Officer." A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse.

"Permanent record book." A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

"Reason to believe." Reason to believe that a particular individual may alter or substitute the urine specimen.

"Split sample." A portion of a urine specimen that may be stored by the licensee to be tested in the event of appeal.

Subpart B - Scientific and Technical Requirements

2.1 The Substances.

(a) Licensees shall, as a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, benzodiazepines, barbiturates, and alcohol for pre-access, for-cause and random tests.

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12584, Pub. L. 100-71, and these Guidelines shall be used only to test for those drugs included in agency drug-free workplace plans and may not be used to conduct any other analysis or test unless otherwise authorized by law.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval. If testing for those substances is authorized under agency regulations and if the Department of Health and Human Services has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

(b) Licensees may test for any illegal drugs during a for-cause test.

(c) Licensees shall establish rigorous testing procedures that are consistent with the intent of these guidelines for any other drugs not specified in these guidelines for which testing is authorized under 10 CFR 26, so that the appropriateness of the use of these substances can be evaluated by the Medical Review Officer to ensure that individuals granted unescorted access are fit for maintaining access to and for performing duties in protected areas.

(d) Specimens collected under NRC regulations requiring compliance with this part may only be designated or approved for testing as described in this part and shall not be used to conduct any other analysis or test without the permission of the tested individual.

(e) This section does not prohibit procedures reasonably incident to analysis of a specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration, or presence of adulterants).

§ 40.23 Preparation for testing

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a) Utilization of a standard urine custody and control form (carbonless manifold). The form shall be a multiple-part, carbonless record form with an original (part 1) that shall accompany the specimen to the laboratory. Copies shall be provided for the Medical Review Officer (part 2, to go directly to the MRO), the employee (part 3), the collection site (part 4) (if distinct from the employer), and the employer representative (part 5). The form should be a permanent record on which identifying data on the employee and on the specimen collection and transfer process is retained. The form shall be constructed to display, at a minimum, the following elements, which shall appear on its respective parts as indicated:

(1) The following information shall appear on all parts of the form:

(i) A preprinted specimen identification number, which shall be unique to the particular collection.

(ii) The employee's Social Security or employee identification number, which shall be entered by the employee.

(iii) Specification of the type of test conducted (pre-employment, random, etc.), which shall be entered by the employer representative or collector (acting for the employer).

(iv) A block providing that "Collector must note temperature of specimen has been read and record here if not within the range of 32.5—37.7C/90.5—99.8F:" with an area for the required notation.

2.2 General Administration of Testing.

The licensee testing facilities and HHS-certified laboratories described in this part shall develop and maintain clear and well-documented procedures for collection, shipment, and accession of urine and blood specimens under this part. Such procedures shall include, as a minimum, the following:

(a) Use of a chain-of-custody form. The original shall accompany the specimen to the HHS-certified laboratory. A copy shall accompany any split sample. The form shall be a permanent record on which identity data (or codes) on the employee and on the specimen collection process and all transfer of custody of the specimen is retained.

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(v) A chain-of-custody block providing areas to enter the following information for each transfer of possession: purpose of change; released by (signature/print name); received by (signature/print name); date. The words "Provide specimen for testing" and "DONOR" shall be preprinted in the initial spaces.

(vi) Information to be completed by the collection site person, identifying that person and providing the date of collection, the collection site and the telephone number (if any) of the collection site; a space for remarks at which unusual circumstances may be described; and a certification statement as set forth below and a signature block with date which shall be completed by the collection site person:

I certify that the specimen identified on this form is the specimen presented to me by the employee providing the certification below, that I have verified that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as required by the instructions provided.

(vii) A block to be completed by the laboratory after analysis of the specimen, providing a space for entry of the laboratory accession number and a certification to read as follows, together with spaces to enter the printed name and signature of the certifying laboratory official and date:

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results attached are for that specimen.

(2) Information to be provided by the employee, which shall appear on parts 2 through 5 of the form only: Employee name (printed); duty location; job title; date of birth; and a certification statement as set forth below, together with a signature block with date which shall be completed by the employee:

I certify that the urine specimen identified on this form is my own; that it is fresh and has not been adulterated in any manner; and that the identification information provided on this form and on the collection bottle is correct. I consent to the submission of this specimen to the certified laboratory designated by my employer, to the analysis of the specimen for controlled substances as provided by Federal requirements, and to the release of test results from that analysis to the Medical Review Officer designated by my employer.

(3) A block to be completed by the employee, which shall appear only on parts 2 and 3 of the form, containing a statement as follows: "If you wish to have prescription or over-the-counter medications you may have taken or been administered within the past 30 days considered as your test results are reviewed, you may list them here:" followed by an adequate writing area to list such substances.

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A form meeting the requirements of this paragraph is displayed at Appendix B to this part. The urine custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information (other than the employee identification number) may not be provided to the laboratory and employee medical information may appear only on the copies provided to the employee and to the Medical Review Officer. In lieu of a form meeting the above-described criteria, an employer may choose to use a multiple-sample chain of custody form together with a permanent record book maintained at the site of collection to document collection and transfer of specimens under this part, so long as the data elements set forth above are documented, personal identifying information is not disclosed to the laboratory, and the record system is designed in such a manner as to maintain the confidentiality of medical information.

(b) Use of a tamperproof sealing system designed in a manner such that the specimen bottle top can be sealed against undetected opening, the bottle can be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space has been provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the employee, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(b) Use of a tamperproof sealing system designed in a manner such that the specimen container top can be sealed against undetected opening, the container can be identified with a unique identifying number identical to that appearing on the chain-of-custody form, and space has been provided to initial the container affirming its identity. For purposes of clarity, this requirement assumes use of a system made up of one or more pre-printed labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which one or more specimens and associated paperwork may be transferred and which can be sealed and initialed to prevent undetected tampering.

(d) Written procedures, instructions, and training shall be provided as follows:

(1) Licensee collection site procedures and training of collection site personnel shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the individual tested, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A non-medical collection site person shall receive training in compliance with this appendix and shall demonstrate proficiency in the application of this appendix prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which collection occurs may serve as a collection site person if that person is provided the instructions described in 2.2(3) and performs collections in accordance with those instructions.

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(3) Collection site persons shall be provided with detailed, clearly illustrated written instructions on the collection of specimens in compliance with this part. Employer representatives and employees subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(3) Collection site persons shall be provided with detailed, clearly illustrated, written instructions on the collection of specimens in compliance with this part. Individuals subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(4) The option to provide a blood specimen for confirmatory analysis following a positive breath test shall be specified in the written instructions provided to individuals tested. The instructions shall also state that failure to request a confirmatory blood test indicates that the individual accepts the breath test results.

2.3 Preventing Subversion of Testing.

Licensees shall carefully select and monitor persons responsible for administering the testing program (e.g., collection site persons, laboratory technicians, specimen couriers, and those selecting and notifying personnel to be tested), based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. At a minimum, these measures shall ensure that the integrity of such persons is not compromised or subject to efforts to compromise due to personal relationships with any individuals subject to testing.

As a minimum:

(1) Supervisors, co-workers, and relatives of the individual being tested shall not perform any collection, assessment, or evaluation procedures.

(2) Appropriate background checks and psychological evaluations shall be completed prior to assignment of any tasks associated with the administration of the program, and shall be conducted at least once every three years.

(3) Persons responsible for administering the testing program shall be subjected to a behavioral observation program designed to assure that they continue to meet the highest standards for honesty and integrity.

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2.2 Specimen Collection Procedures.

(a) **Designation of Collection Site.** Each agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) **Security Procedures** shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

1.4.25 Specimen collection procedures.

(a) **Designation of collection site.** (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory. An independent medical facility may also be utilized as a collection site provided the other applicable requirements of this part are met.

(2) A designated collection site may be any suitable location where a specimen can be collected under conditions set forth in this part, including a properly equipped mobile facility. A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination (unless a single-use collector is used with sufficient capacity to contain the void), and a suitable clean surface for urinals. The site must also have a source of water for washing hands, which, if practicable, should be external to the enclosure where urination occurs.

(b) **Security.** The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen.

(1) Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(2) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the employee or distraction of the collection site person.

2.4 Specimen Collection Procedures.

(a) "Designation of Collection Site." Each drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine or blood specimens to a drug testing laboratory. A properly equipped mobile facility that meets the requirements of this part is an acceptable collection site.

(b) "Collection site person." A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the specimen(s) provided by those individuals. A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required herein. In any case where: (a) a collection is observed or (b) collection is monitored by non-medical personnel, the collection site person must be a person of the same gender as the donor.

(c) "Security." The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen. Security procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to drug and alcohol testing, the portion of the facility used for testing shall be secured during that testing.

(1) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present, and that undetected access (e.g., through a rear door not in the view of the collection site person) is impossible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the individual or distraction of the collection site person.

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(c) **Chain of Custody.** Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) **Access to Authorized Personnel Only.** No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) **Privacy Procedures for collecting urine specimens** shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided.

(3) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person.

(c) **Chain of custody.** The chain of custody block of the urine custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) **Access to authorized personnel only.** No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialed, the urine custody and control form has been executed, and the employee has departed the site.

(f) **Privacy.** (1) Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided, as further described in this paragraph.

(2) For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

(i) The employee has presented a urine specimen that falls outside the normal temperature range, and the employee declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (f)(23) of this part, or the oral temperature does not equal or exceed that of the specimen.

(ii) The last urine specimen provided by the employee (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below 2 g/L.

(iii) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye

(2) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply: The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person. These minimum procedures shall apply to the mailing of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the mailing of specimens to HHS-certified laboratories.

(d) **"Chain of Custody."** Licensee chain-of-custody forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another shall always be accomplished through chain-of-custody procedures. Every effort shall be made to minimize the number of persons handling the specimens.

(e) **"Access to Authorized Personnel Only."** No unauthorized personnel shall be permitted in any part of the designated collection site where specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person, and ensure against any confusion in the identification of specimens, a collection site person shall conduct only one collection procedure at any given time. For this purpose, a collection procedure is complete when the specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the individual has departed the collection site.

(f) **"Privacy."** Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. For purposes of this appendix the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute a urine specimen:

(1) The individual has presented a urine specimen that falls outside the normal temperature range, and the individual declines to provide a measurement of oral body temperature by sterile thermometer, as provided in paragraph (g)(14) of this appendix, or the oral temperature does not equal or exceed that of the specimen.

(2) The last urine specimen provided by the individual (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below 2 g/L.

(3) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.).

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(iv) The employee has previously been determined to have used a controlled substance without medical authorization and the particular test is being conducted as a part of a rehabilitation program, on return to service after any required rehabilitation, or under a DOT agency regulation providing for follow-up testing after return to service.

(f) Integrity and identity of specimen.

Employers shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. Where practicable, there shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site, the collection site person shall ensure that the individual is positively identified as the employee selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(4) The individual has previously been determined to have used a substance inappropriately or without medical authorization and the particular test is being conducted as a part of a rehabilitation program or on return to service after evaluation and/or treatment for a confirmed positive test result.

(g) "Integrity and Identity of Specimens." Licensees shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure, that a blood sample or breath exhalant tube cannot be substituted or tampered with, and that the information on the specimen container and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that authentic specimens are obtained and correctly identified:

(1) To deter the dilution of urine specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure, it shall be effectively secured or monitored to ensure it is not used (undetected) as a source for diluting the specimen.

(2) When an individual arrives at the collection site for a urine or breath test, the collection site person shall ensure that the individual is positively identified as the person selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive for a urine or breath test at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) After the individual has been positively identified, the collection site person shall ask the individual to sign a consent-to-testing form and to list all of the prescription medications and over-the-counter preparations that he or she can remember using within the last three weeks.

(5) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine, breath, or blood specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room in which the blood, breath, or urine sample is collected. The individual may retain his or her wallet.

(6) The individual shall be instructed to wash and dry his or her hands prior to urination.

(7) After washing hands prior to urination, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the urine specimen.

(f) Integrity and identity of Specimen

Agencies shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other agency official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

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(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance in the permanent record book.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the urine custody and control form.

(9) In the exceptional event that an employer-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measure is critical and in no case shall exceed 4 minutes.

(8) The individual may provide his/her urine specimen in the privacy of a stall or otherwise partitioned areas that allows for individual privacy.

(9) The collection site person shall note any unusual behavior or appearance on the specimen custody and control form.

(10) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement for urine specimen collection (e.g., an accident investigation), a public or on-site rest room may be used according to the following procedures. A collection site person of the same gender as the individual shall accompany the individual into the rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain-of-custody procedures.

(11) Upon receiving a urine specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(13) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(12) After the urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(13) Immediately after the urine specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of a specimen is outside the range of 32.5°-37.7°C/ 90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual may alter or substitute the specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(13) If the temperature of a specimen is outside the range of 32.5°-37.7°C/ 90.5°-99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the urine custody and control form.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual has altered or substituted the specimen as described in paragraph (e)(2)(i) and (iii) of this section, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(14) If the temperature of a urine specimen is outside the range of 32.5° - 37.7°C/90.5° - 99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(15) Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(16) All urine specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(17) Whenever there is reason to believe that a particular individual may alter or substitute the urine specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Alcohol breath tests shall be conducted after the urine specimen has been collected, and shall be delayed if any source of mouth alcohol or any other substances are ingested during this period (e.g., eating, smoking, use of breath fresheners, regurgitation of stomach contents from vomiting or burping).

(18) Alcohol breath tests shall be conducted after the urine specimen has been collected, and shall be delayed if any source of mouth alcohol or any other substances are ingested during this period (e.g., eating, smoking, use of breath fresheners, regurgitation of stomach contents from vomiting or burping). The collection site person shall ensure that each breath specimen taken comes from the end, rather than the beginning, of the breath expiration. Two breath specimens shall be collected from each individual no less than two minutes apart and no more than 10 minutes apart. The test results shall be considered accurate if the result of each measurement is within plus or minus ten percent of the average of the two measurements. If the two tests do not agree, the breath tests shall be repeated on another evidential-grade breath analysis machine.

(19) If the alcohol screening breath test indicates that the individual is positive for a BAC at or above the 0.04 percent cut-off level, the individual may request a confirmatory blood test, at his or her discretion. All vacuum tube and needle assemblies used for blood collection shall be factory-sterilized. The collection site person shall ensure that they remain properly sealed until used. Antiseptic swabbing of the skin shall be performed with a nonethanol antiseptic. Sterile procedures shall be followed when drawing blood and transferring the blood to a storage container; in addition, the container must be sterile and sealed.

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(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19)-(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the agency.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter in the permanent record book all information identifying the specimen. The collection site person shall sign the permanent record book next to the identifying information.

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(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. As provided below, the specimen shall be sealed (by placement of a tamperproof seal over the bottle cap and down the sides of the bottle) and labeled in the presence of the employee. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19)-(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the employer. If separate from the label, the tamperproof seal shall also be applied.

(20) Both the individual being tested and the collection site person shall keep urine and blood-specimens in view at all times prior to their being sealed and labeled. If a urine specimen is split (as described in Section 2.7(j)) and if any specimen is transferred to a second container, the collection site person shall request the individual to observe the splitting of the urine sample or the transfer of the specimen and the placement of the tamperproof seal over the container caps and down the sides of the containers.

(21) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (h) through (j) of this section.

(22) The collection site person shall place securely on each container an identification label which contains the date, the individual's specimen number, and any other identification information provided or required by the drug testing program. If separate from the labels, the tamperproof seals shall also be applied.

(23) The individual shall initial the identification labels on the specimen containers for the purpose of certifying that it is the specimen collected from him or her.

(i) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimens identified as having been collected from him or her are in fact the specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine custody and control form information concerning medications taken or administered in the past 30 days.

(24) The collection site person shall enter in the permanent record book all information identifying the specimens. The collection site person shall sign the permanent record book next to the identifying information.

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(22) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(23) A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(24) The collection site person shall complete the chain of custody form.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and custody form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

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(22) (i) The individual shall be asked to read and sign a statement on the urine custody and control form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(ii) The individual shall be provided an opportunity to set forth on the urine custody and control form information concerning medications taken or administered in the past 30 days.

(iii) When specified by DOT agency regulation or required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee may not be required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others.

(23) A higher level supervisor of the collection site person, or a designated employer representative, shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based upon the circumstances described paragraph (e)(2) of this section.

(24) The collection site person shall complete the chain of custody portion of the urine custody and control form to indicate receipt from the employee and shall certify proper completion of the collection.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26)(i) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the specimen and urine custody and control form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

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(25) A higher level supervisor in the drug testing program shall review and concur in advance with any decision by a collection site person to obtain a urine specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(26) The collection site person shall complete the chain-of-custody forms for both the aliquot and the split sample, if collected, and shall certify proper completion of the collection.

(27) The specimens and chain of custody forms are now ready for transfer to the laboratory or the licensee's testing facility. If the specimens are not immediately prepared for shipment, they shall be appropriately safeguarded during temporary storage.

(28) While any part of the above chain-of-custody procedures is being performed, it is essential that the specimens and custody documents be under the control of the involved collection site person. The collection site person shall not leave the collection site in the interval between presentation of the specimen by the individual and securement of the samples with identifying labels bearing the individual's specimen identification numbers and seals initialled by the individual. If the involved collection site person leaves his or her work station momentarily, the specimens and custody forms shall be taken with him or her or shall be secured. If the collection site person is leaving for an extended period of time, the specimens shall be packaged for transfer to the laboratory before he or she leaves the site.

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(ii) The collection site person shall not leave the collection site in the interval between presentation of the specimen by the employee and securement of the sample with an identifying label bearing the employee's specimen identification number (shown on the urine custody and control form) and seal initialed by the employee. If it becomes necessary for the collection site person to leave the site during this interval, the collection shall be nullified and for the collection of

(g) **Collection Control.** To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(g) **Collection control.** To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. The urine custody and control form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approval chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) **"Collection Control."** To the maximum extent possible, collection site personnel shall keep the individual's specimen containers within sight both before and after the individual has urinated or provided a breath or blood sample. After the specimen is collected and whenever urine specimens are split, they shall be properly sealed and labeled. A chain-of-custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

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(h) Transportation to Laboratory.

Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site supervisor shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(h) Transportation to laboratory.

Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site person shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(i) **Failure to cooperate.** If the employee refuses to cooperate with the collection process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen) the collection site person shall inform the employer representative and shall document the non-cooperation on the urine custody and control form.

(i) "Transportation to Laboratory or Testing Facility." Collection site personnel shall arrange to transfer the collected specimens to the drug testing laboratory or licensee testing facility. To transfer specimens off-site for initial screening and for a second screen and confirmatory analysis of presumptive positive specimens, the specimens shall be placed in containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes or padded mailers) and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain-of-custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

(j) "Failure to Cooperate." If the individual refuses to cooperate with the urine collection or breath analysis process (e.g., refusal to provide a complete specimen, complete paperwork, initial specimen), then the collection site person shall inform the Medical Review Officer and shall document the non-cooperation on the specimen custody and control form. The provision of blood specimens for use to confirm a positive breath test for alcohol shall be entirely voluntary, at the individual's discretion. In the absence of a voluntary blood test the positive breath test shall be considered a confirmed positive.

2.3 Laboratory Personnel**(a) Day-to-Day Management.**

(1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in

§ 40.27 Laboratory personnel

(a) **Day-to-day management.** (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

2.5 HHS-certified Laboratory Personnel.

(a) "Day-to-Day Management of the HHS-certified Laboratories."

(1) The HHS-certified laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratories' drug testing facilities.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the appropriate State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology, and

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(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in 2.4(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), and (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of their testing laboratories. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in Section 2.7(0) of this appendix).

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test Validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-Day Operations and Supervision of Analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality

control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other Personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) "Test Validation." The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) "Day-to-Day Operations and Supervision of Analysts." The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) "Training." The laboratory's testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) "Files." Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

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2.6 Licensee Testing Facility Personnel.

(a) "Day-to-Day Management of Operations." Any licensee testing facility shall have an individual to be responsible for day-to-day operations and to supervise the testing technicians. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the licensee testing facility, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; and proper remedial actions to be taken in response to detecting aberrant test or quality control results.

(b) "Other Personnel." Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(c) "Files." Licensees' testing facility personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate and appropriate data to support determinations of honesty and integrity conducted in accordance with Section 2.3 of this appendix.

2.4 Laboratory Analysis Procedures.

(a) *Security and Chain of Custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

§ 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

2.7 Laboratory and Testing Facility Analysis Procedures.

(a) "Security and Chain of Custody."

(1) HHS-certified drug testing laboratories and any licensee testing facility shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records and split samples are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times in the HHS-certified laboratory and in the licensee's testing facility. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

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(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the agency's chain of custody forms attached to the shipment shall be immediately reported to the agency and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) *Short-Term Refrigerated Storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

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(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

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(2) Laboratories shall use chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain-of-custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain-of-custody forms for those specimens or aliquots as they are received.

(b) "Receiving."

(1) When a shipment of specimens is received, laboratory and licensee's testing facility personnel shall inspect each package for evidence of possible tampering and compare information on specimen containers within each package to the information on the accompanying chain-of-custody forms. Any direct evidence of tampering or discrepancies in the information on specimen containers and the licensee's chain-of-custody forms attached to the shipment shall be reported within 24 hours to the licensee, in the case of HHS-certified laboratories, and shall be noted on the laboratory's chain-of-custody form which shall accompany the specimens while they are in the laboratory's possession. Indications of tampering with specimens at a testing facility operated by a licensee shall be reported within 8 hours to senior licensee management.

(2) Specimen containers will normally be retained within the laboratory's or testing facility's accession area until all analyses have been completed. Aliquots and the chain-of-custody forms shall be used by laboratory or testing facility personnel for conducting initial and confirmatory tests, as appropriate.

(c) "Short-Term Refrigerated Storage." Specimens that do not receive an initial test within 7 days of arrival at the laboratory or are not shipped within 6 hours from the licensee's testing facility and any retained split samples shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

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(d) **Specimen Processing.** Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) **Initial Test.** (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test level (ng/ml)
Marijuana metabolites.....	100
Cocaine metabolites.....	300
Opiate metabolites.....	300
Phencyclidine.....	25
Amphetamines.....	1,000

* 25ng/ml if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(d) **Specimen processing.** Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) **Initial test.** (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test level (ng/ml)
Marijuana metabolites.....	100
Cocaine metabolites.....	300
Opiate metabolites.....	* 300
Phencyclidine.....	25
Amphetamines.....	1,000

* 25ng/ml if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT Agency under that agency's regulations.

(d) "Specimen Processing." Urine specimens identified as presumptive positive by a licensee's testing facility shall be shipped to an HHS-certified laboratory for testing. Laboratory facilities for drug testing will normally process urine specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests at either the licensee's testing facility or an HHS-certified laboratory, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) "Preliminary Initial Test."

(1) For the analysis of urine specimens, any preliminary test performed by a licensee's testing facility and the initial screening test performed by a HHS-certified laboratory shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The initial test of breath for alcohol performed at the collection site shall use a breath analysis technique which meets the requirements of the National Bureau of Standards. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these eight substances:

	Initial test level (ng/ml)
Marijuana metabolites.....	100
Cocaine metabolites.....	300
Opiate metabolites.....	300*
Phencyclidine.....	25
Amphetamines.....	1,000
Benzodiazepine metabolite (Oxazepam).....	50
Barbiturates.....	100

Alcohol.....(1) 0.04% BAC or (2) BAC to be determined by licensee

In addition, licensee's may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

*25 ng/ml is immunoassay specific for free morphine.

(2) These test levels are subject to change by the NRC in response to industry experience and changes to the HHS Guidelines by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(f) **Confirmatory Test.** (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

(f) **Confirmatory test.** (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

(f) **"Confirmatory Test."**
(1) Specimens which test negative as a result of this second screening shall be reported as negative to the licensee and will not be subject to any further testing.
(2) All urine samples identified as positive on the screening test performed by a MHS-certified laboratory shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cut-off values listed in this paragraph for each drug, and at the cut-off values required by the licensee's unique program, where differences exist. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

	Confirma- tory test level (ng/ ml)
Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opates:	
Morphine.....	* 300
Codeine.....	* 300
Phencyclidine.....	25
Amphetamines:	
Amphetamine.....	500
Methamphetamine.....	500

¹ Delta-9-tetrahydrocannabinol-9-carboxylic acid.
² Benzoylcegonine.

	Confirma- tory test level (ng/ ml)
Marijuana metabolite ¹	15
Cocaine metabolite ²	150
Opates:	
Morphine.....	300
Codeine.....	300
Phencyclidine.....	25
Amphetamines:	
Amphetamine.....	500
Methamphetamine.....	500

¹ Delta-9-tetrahydrocannabinol-9-carboxylic acid.
² Benzoylcegonine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the employer for the written approval of the DOT agency as provided in that agency's regulations.

	Confirmatory test level (ng/ml)
Marijuana metabolite.....	15*
Cocaine metabolite.....	150**
Opates:	
Morphine.....	300
Codeine.....	300
Phencyclidine.....	25
Amphetamines:	
Amphetamine.....	500
Methamphetamine.....	500
Benzodiazepine metabolite.....	10***
Barbiturates:	
Phenobarbital.....	100
Thiopental.....	100
Pentobarbital.....	100
Secobarbital.....	100
Amobarbital.....	100
Aprobarbital.....	100
Hexobarbital.....	100
Butobarbital.....	100

Alcohol.....0.04% BAC
or (2) BAC to be determined by licensee
* Delta-9-tetrahydrocannabinol-9-carboxylic acid.
** Benzoylcegonine.
*** Oxazepam In addition, licensees may specify more stringent cutoff levels. Results shall be reported for both levels in such cases.

(3) The analytic procedure for confirmatory analysis of blood samples voluntarily provided by individuals testing positive for alcohol on a breath test shall comply with State standards controlling the testing of blood for alcohol concentrations.

(g) **Reporting Results.** (1) The laboratory shall report test results to the agency's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the agency, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory shall report as *negative* all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the agency but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain of custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports.

(g) **Reporting results.** (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the employer, and the drug testing laboratory specimen identification number (accession number). The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory shall report as *negative* all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the employer but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the urine custody and control form (part 1), which shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(g) "Reporting Results."

(1) The HHS-certified laboratory shall report test results to the licensee's Medical Review Officer within 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual at the laboratory. The report shall identify the substances tested for, whether positive or negative, and the cut-off(s) for each, the specimen number assigned by the licensee, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The HHS-certified laboratory and any licensee testing facility shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens testing positive on the confirmatory analysis shall be reported positive for a specific substance. Specimens which test positive during the preliminary testing at the licensee's testing facility will not be reported to licensee management or to the Medical Review Officer and will not be forwarded to the HHS-certified laboratory for further testing, except as a performance check of the licensee's testing facility's procedures.

(3) The Medical Review Officer may request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of test results. The Medical Review Officer may only disclose quantitation of test results to the licensee for tests if required in an appeals process. Quantitation of negative tests for urine specimens shall not be disclosed. Alcohol quantitation for a blood specimen shall be provided to the licensee with the Medical Review Officer's evaluation.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone from HHS-certified laboratory personnel to the Medical Review Officer. The HHS-certified laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain-of-custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports and attached to which shall be a copy of the test report.

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(6) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

- (A) Number of specimens received;
 - (B) Number of specimens reported out;
- and
- (C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

(ii) Confirmatory Testing:

- (A) Number of specimens received for confirmation;
- (B) Number of specimens confirmed positive for:

Marijuana metabolite

Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by DHHS or any Federal agency for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(6) The laboratory shall provide to the employer official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of the employer's employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial testing:

- (A) Number of specimens received;
 - (B) Number of specimens reported out;
- and
- (C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

(ii) Confirmatory testing:

- (A) Number of specimens received for confirmation;
- (B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(6) The HHS-certified laboratory and the licensee's testing facility shall provide to the licensee official responsible for coordination of the fitness-for-duty program a monthly statistical summary of urinalysis and blood testing and shall not include in the summary any personal identifying information. Initial test data from the licensee's testing facility and the HHS-certified laboratory, and confirmation data from HHS-certified laboratories shall be included for test results reported within that month. Normally this summary shall be forwarded from HHS-certified laboratories by registered or certified mail and from the licensee's testing facility not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

- (A) Number of specimens received;
 - (B) Number of specimens reported out;
- and
- (C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines
Benzodiazepine metabolites
Barbiturates
Alcohol

(ii) Confirmatory Testing: (A) or
Number of specimens received for
confirmation:

- (B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine
Benzodiazepine metabolites
Barbiturates
Alcohol

(7) The statistics shall be presented for both the cutoff levels in these guidelines and any more stringent cutoff levels which licensees may specify. The HHS-certified laboratory and the licensee's testing facility shall make available analytical results for licensee drug testing programs when requested by the NRC or the licensee for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the licensee in writing, all records pertaining to a given urine or blood specimen shall be retained by the HHS-certified drug testing laboratory and the licensee's testing facility for a minimum of 2 years.

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(h) *Long-Term Storage.* Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an agency may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting Specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(h) *Long-term storage.* Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an employer (or other person designated in a DOT agency regulation) may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(h) "Long-Term Storage." Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the licensee, HHS-certified laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period a licensee or the NRC may request the laboratory to retain the specimen for an additional period of time, but if no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period. Any split samples retained by the licensee shall be transferred into long-term storage upon determination by the Medical Review Officer that the specimen has a confirmed positive test.

(i) "Retesting Specimens." Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cut-off requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) "Split Samples." Urine specimens may be split, at the licensee's discretion, into two parts at the collection site. One half of such samples (hereafter called the aliquot) shall be analyzed by the licensee's testing facility or the HHS-certified laboratory for the licensee's purposes as described in this appendix. The other half of the sample (hereafter called the split sample) may be withheld from transfer to the laboratory, sealed, and stored in a secure manner by the licensee until the aliquot has been determined to be negative or until the positive result of a screening test has been confirmed. As soon as the aliquot has tested negative, the split sample in storage may be destroyed. If the aliquot tests positive by confirmatory testing, then, at the tested individual's request, the split sample may be forwarded on that day to another HHS-certified laboratory that did not test the aliquot. The chain-of-custody and testing procedures to which the split sample is subject, including cut-off levels, shall be the same as those used to test the initial aliquot. The results of any second testing process shall be made available to the Medical Review Officer and to the individual tested.

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(j) Subcontracting. Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the agency. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in these Guidelines.

(j) Subcontracting. Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part procedures. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor, and other relevant provisions of this part are observed.

(k) "Subcontracting." HHS-certified laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the licensee. The laboratory must be capable of performing testing of the seven classes of drugs (marijuana, cocaine, opiates, phencyclidine, amphetamines, benzodiazepines, and barbiturates) and of whole breath, and confirmatory GC/MS methods specified in these guidelines.

(k) Laboratory Facilities. (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(k) Laboratory facilities. (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

Inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agency) to conduct unannounced inspections.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(2) Laboratories certified in accordance with DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs must have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(1) "Laboratory Facilities."
(1) HHS-certified laboratories shall comply with applicable provisions of any State licensure requirements.
(2) HHS-certified laboratories shall have the capability, at the same laboratory premises, of performing initial tests for each drug and drug metabolite for which service is offered, and for performing confirmatory tests for alcohol and for each drug and drug metabolite for which service is offered. Any licensee testing facilities shall have the capability, at the same premises, of performing initial screening tests for each drug and drug metabolite for which testing is conducted. Initial breath tests for alcohol may be performed at the collection site.

(l) Inspections. The Secretary, any Federal agency utilizing the laboratory,

or any organization performing laboratory certification on behalf of the Secretary shall reserve the right to inspect the laboratory at any time. Agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the award of a contract the agency shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(l) Inspections. The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserve the right to

(m) "Inspections." The NRC and any licensee utilizing an HHS-certified laboratory shall reserve the right to inspect the laboratory at any time. Licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, shall permit the NRC and the licensee to conduct unannounced inspections. In addition, prior to the award of a contract, the licensee shall carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation. The NRC shall reserve the right to inspect a licensee's testing facility at any time.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by DHHS or by any Federal agency for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional Requirements for Certified Laboratories.*—(1) *Procedure Manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and Controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and Equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(n) "Documentation." HHS-certified laboratories and the licensee's testing facility shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by the NRC or by any licensee for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain-of-custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The HHS-certified laboratory and the licensee's testing facility shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(o) "Additional Requirements for HHS-certified Laboratories and Licensee's Testing Facilities."

(1) "Procedure manual." Each laboratory and licensee's testing facility shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) "Standards and controls." HHS-certified laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) "Instruments and equipment." (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) Alcohol breath analysis equipment shall be an evidential-grade breath alcohol analysis device of a brand and model that conforms to National Highway Traffic Safety Administration (NHTSA) standards (49 FR 48855) and to any applicable State statutes.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial Actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel Available To Testify at Proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on positive urinalysis results reported by the laboratory.

2.5 Quality Assurance and Quality Control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory Quality Control Requirements for Initial Tests.* Each analytical run of specimens to be screened shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

§ 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory quality control requirements for initial tests.* Each analytical run of specimens to be screened shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory

(iii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) "Remedial actions." There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) "Personnel available to testify at proceedings." The licensee's testing facility and HHS-certified laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive breath analysis or urinalysis results reported by the licensee's testing facility or the HHS-certified laboratory.

2.6 Quality Assurance and Quality Control.

(a) "General." HHS-certified laboratories and the licensee's testing facility shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) "Licensee's Testing Facility Quality Control Requirements for Initial Tests." Because all positive preliminary tests for drugs are forwarded to an HHS-certified laboratory for a screening and confirmatory testing when appropriate, the NRC does not require licensees to assess their testing facility's false positive rates for drugs. To ensure that the rate of false negative tests is kept to the minimum that the immunoassay technology supports, licensees shall process blind performance test specimens and submit a sampling of specimens screened as negative from every test run to the HHS-certified laboratory. In addition, the manufacturer-required performance tests of the breath analysis equipment used by the licensee shall be conducted as set forth in the manufacturer's specifications.

(c) "Laboratory Quality Control Requirements for Initial Tests at HHS-Certified Laboratories." Each analytical run of specimens to be screened shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cut-off).

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testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory Quality Control Requirements for Confirmation Tests. Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Agency Blind Performance Test Procedures. (1) Agencies shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-Recognized certification program in accordance with these Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

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quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory quality control requirements for confirmation tests. Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Employer blind performance test procedures. (1) Employers shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) (i) During the initial 90-day period of any new drug testing program, each employer shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(ii) These blind performance testing requirements shall not apply to an employer that submits fewer than 1,000 employee specimens per year for analysis under one or more DOT agency regulations requiring compliance with this part, if such employer utilizes a laboratory that is currently subject to blind performance testing under this part or the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs by a Federal agency or by another transportation employer required by this section to perform such blind performance testing for the substances for which the specimen is to be tested.

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In addition, with each batch of samples, a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cut-off. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration, shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(d) "Laboratory Quality Control Requirements for Confirmation Tests." Each analytical run of specimens to be confirmed shall include:

- (1) Urine specimens certified to contain no drug;
- (2) Urine specimens fortified with known standards; and
- (3) Positive controls with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(e) "Licensee Blind Performance Test Procedures."

(1) Licensees shall purchase chemical testing services only from laboratories certified by DHHS or a DHHS-recognized certification program in accordance with the HHS Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each licensee shall submit blind performance test specimens to each HHS-certified laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

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(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the agency is testing.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibited spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the licensee is testing.

(4) The Secretary shall investigate any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory

performance test result. A record shall be made of the Secretary's investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the Secretary shall send the document to the agency contracting officer as a report of the unsatisfactory performance testing incident. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(4) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the DOT agency may also require review and reanalysis of previously run specimens.

(4) The licensee shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result, and based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be responsible for the day-to-day management and operation of the HHS-certified laboratory. Then the licensee shall send the document to the NRC as a report of the unsatisfactory performance testing incident within 30 days. The NRC shall ensure notification of the finding to DHHS.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the licensee shall promptly notify the NRC. The licensee shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the licensee may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the laboratory shall submit all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operations of the laboratory. The Secretary has the option of revoking (3.13) or suspending (3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

(8) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the licensee shall instruct the laboratory to submit to them all quality control data from the batch of specimens which included the false positive specimen. In addition, the licensee shall require the laboratory to retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's substance testing program. The licensee and the NRC may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the NRC, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

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2.7 Reporting and Review of Results.

(a) *Medical Review Officer Shall Review Results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to agency administrative officials.

(b) *Medical Review Officer—Qualifications and Responsibilities.* The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an agency or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the agency's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with these Guidelines.

(c) *Positive Test Result.* Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall refer the case to the agency Employee Assistance Program and to the management official empowered to recommend or take administrative action.

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§ 40.33 Reporting and review of results.

(a) *Medical Review Officer shall review results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to employer administrative officials.

(b) *Medical Review Officer—qualifications and responsibilities.* The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of the transportation employer or a private physician retained for this purpose. The role of the Medical Review Officer is to review and interpret positive test results obtained through the employer's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the employer's policy, refer the case to the employer employee assistance or rehabilitation program, if applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

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2.9 Reporting and Review of Results.

(a) "Medical Review Officer shall review results." An essential part of the licensee's testing programs is the final review of results. A positive test result does not automatically identify a nuclear power plant worker as having used substances in violation of the NRC's regulations or the licensee's company policies. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to licensee management officials.

(b) "Medical Review Officer -- qualifications and responsibilities." The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be a licensee or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the licensee's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not consider the results of tests that are not obtained or processed in accordance with these Guidelines, although he or she may consider the results of tests on split samples in making his or her determination, as long as those split samples have been stored and tested in accordance with the procedures described in these Guidelines.

(c) "Positive Test Results." Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result with him or her. Following verification of a positive test result, the Medical Review Officer shall, as provided in the licensee's policy, notify the applicable Employee Assistance program and the licensee's management official empowered to recommend or take administrative action (or the official's designated agent).

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(d) *Verification for opiates: review for prescription medication.* Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. (This requirement does not apply if the agency's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) *Reanalysis Authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified under these Guidelines.

(f) *Result Consistent with Legal Drug Use.* If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, he or she shall determine that the result is consistent with legal drug use and take no further action.

(d) *Verification for opiates: review for prescription medication.* Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) *Reanalysis authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original sample on timely request of the employee, as provided in applicable DOT agency regulations.

(f) *Result consistent with legal drug use.* If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, the Medical Review Officer shall report the test result to the employer as negative.

(d) "Verification for opiates; review for prescription medication." Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the licensee's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.) For other drugs that are commonly prescribed or commonly included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and that are listed in the licensee's panel of substances to be tested, the Medical Review Officer shall also determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any of these substances or their derivatives.

(e) "Reanalysis authorized." Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original aliquot on timely request of the individual tested, and shall also authorize an analysis of any sample stored by the licensee.

(f) "Results consistent with responsible substance use." If the Medical Review Officer determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment, the Medical Review Officer shall report the test result to the licensee as negative.

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(g) *Result Scientifically Insufficient.* Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in 2.7(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with these Guidelines.) The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the agency. The Medical Review Officer shall report to the Secretary all negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(g) *Result scientifically insufficient.* Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in § 40.33(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the DHHS Guidelines.) The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the employer. The employer shall include in its annual report to the DOT agency a summary of any negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(g) "Result scientifically insufficient." Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation, the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the HHS Guidelines.) The licensee's testing facility and the HHS-certified laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual(s) responsible for day-to-day management of the licensee's test facility, of the HHS-certified laboratory or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the licensee. The licensee shall maintain records that summarize any negative findings based on scientific insufficiency and shall make them available to the NRC on request, but shall not include any personal identifying information in such reports.

Subpart C - Employee Protection

2.8 Protection of Employee Records.

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101-24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 552a. In addition, laboratory contracts shall require compliance with the patient access and confidentiality provisions of section 503 of Pub. L. 100-71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover both the agency's and the laboratory's records of employee urinalysis results. The contract and the Privacy Act System shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

§ 40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations.

3.1 Protection of Employee Records

Licensee contracts with HHS certified laboratories and procedures for the licensee's testing facility shall require that test records be maintained in confidence, as provided in 10 CFR 26.29. Records shall be maintained and used with the highest regard for individual privacy.

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2.9 Individual Access to Test and Laboratory Certification Results.

In accordance with section 503 of Pub. L. 100-71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

§ 40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

3.2 Individual Access to Test and Laboratory Certification Results.

Any individual who is the subject of a drug or alcohol test under this part shall, upon written request, have access to any records relating to his or her tests and any records relating to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing

§ 40.41 Use of DHHS-certified laboratories.

Employers subject to this part shall use only laboratories certified under the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 FR 11970, April 11, 1988, and subsequent amendments thereto. DHHS certification standards are set forth in Appendix A to this part for information and reference. Information concerning the current certification status of laboratories is available from: the Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

Appendix A to Part 40—DHHS Laboratory Certification Standards

Note: Reproduced below is subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs issued by DHHS. Cross-references are to sections of those DHHS Guidelines. Equivalent provisions in this part may be determined by reference to the following table:

Part 40	
DHHS Guidelines:	
Section 1.1	§ 40.1
Section 1.2	§ 40.2
Section 2.1	§ 40.21
Section 2.2	§ 40.23
Section 2.3	§ 40.27
Section 2.4	§ 40.29
Section 2.5	§ 40.31
Section 2.6	
Section 2.7	§ 40.33
Section 2.8	§ 40.35
Section 2.9	§ 40.37

Subpart D - Certification of Laboratories Engaged in Chemical Testing

4.1 Use of DHHS-certified laboratories.

(a) Licensees subject to this part and their contractors shall use only laboratories certified under the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Subpart C - "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," (53 FR 11970, 11986-11989) dated April 11, 1988, and subsequent amendments thereto for screening and confirmatory testing except for initial screening tests at a licensee's testing facility conducted in accordance with 10 CFR 26.24(d). Information concerning the current certification status of laboratories is available from: The Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857.

(b) Licensees or their contractors may use only HHS-certified laboratories that agree to follow the same rigorous chemical testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels as may be specified by licensees for the five classes of drugs identified in the HHS Guidelines or when testing for benzodiazepines, barbiturates, and for any other substances included in licensees' drug panels, and for conducting alcohol confirmatory tests as are followed when testing for the five classes of drugs identified in the HHS Guidelines.

Enclosure 6
Backfit Analysis

BACKFIT ANALYSIS
FITNESS FOR DUTY

Item 1: Statement of the specific objective that the proposed backfit is designed to achieve;

Response: The objective of the fitness-for-duty rule is to significantly increase the assurance of public health and safety by removing personnel who are judged to be unfit for duty from unescorted access to protected areas at nuclear power plants and prohibiting assignment of duties within the scope of the rule. Personnel who would be considered unfit for duty would be those who use illegal drugs, improperly use alcohol, prescription drugs or over-the-counter drugs, or have physical or mental stress or impairments that could lead to an unsafe situation. Licensees of nuclear power plants will be required to develop programs to address all of these fitness aspects. However, specific implementing provisions are stipulated only in the areas of use of alcohol and illegal drugs.

Item 2: General description of the activity that would be required of the licensee or applicant in order to complete the backfit;

Response: The proposed rule would require licensees authorized to operate a nuclear power reactor under 10 CFR 50.22, or to actively construct a nuclear power reactor, under 50.23, to implement and maintain a fitness-for-duty program. This proposed rule also requires that contractor and vendor personnel be covered by a fitness-for-duty program.

The proposed rule specifies that industry implement the following requirements:

(a) Development of written policy and procedures, including management actions in response to drug abuse

Each licensee is required to draft policies and procedures for implementing and maintaining a fitness-for-duty program. These documents shall denote all standards of conduct, physical state and mental state expected of employees and contractors, and all requirements for management action.

Since all affected licensees currently have fitness-for-duty policies and procedures in place, the staff finds that only minor revision of these documents will be required to conform to the requirements of the new rule and, since the current policies and procedures would need periodic review and revision irrespective of the NRC rule, there are no incremental costs.

(b) Awareness training program...transfer of policy and procedures to all employees

All licensee personnel and contractors (workers and supervisors) involved in the nuclear portion of the utility's business must participate in an awareness training program that explains the new policies and procedures underlying the fitness-for-duty program. Although awareness training is already an integral part of fitness-for-duty programs, the staff assumes that the

formulation of new policies and procedures will require all current employees to attend an additional orientation program because of changes made to the program. New hires would also participate in awareness training, but this would merely substitute for the training they would have had under existing licensee fitness-for-duty programs.

(c) Refresher training for all employees at least once a (year)

All licensee personnel and contractors (workers and supervisors) subject to the provisions of the fitness-for-duty program will be required to complete refresher training at least once every year. This training essentially covers all aspects of the program and includes discussions on the health and safety hazards associated with the abuse of drugs.

(d) Development of written agreements between licensees and their contractors and vendors

All contractor/vendor personnel having unescorted access within protected areas at nuclear power plants would either be subject to the licensee's fitness-for-duty program or would be subject to a program maintained by the contractor which meets the provisions of this rule. Written agreements between licensees and contractors/vendors will be required to ensure one of the two options is implemented.

(e) Chemical testing for drugs, including random testing and blind performance testing

The fitness-for-duty rule includes the following types of chemical testing: pre-badging, unannounced random, for-cause, and follow-up. Nearly all utilities are already using pre-employment and for-cause tests.

The final rule requires licensees to perform random unannounced tests throughout the year. Several options for testing rates and schemes are provided for Commission selection.

The staff is aware that about two-thirds of the plants do not presently practice random testing. The remaining one-third of the plants practice random testing, but at less than the specified level. From available data, it appears that the current rates are in the 5-percent to 25-percent range.

The rule will require licensees to use blind performance test specimens to ensure the accuracy and validity of the testing process, i.e., onsite preliminary tests and testing by an HHS-certified laboratory. The rule will require licensees to submit these test specimens to the contract laboratory at an initial rate of 50-percent for the first 90 days, and 10-percent thereafter, not to exceed 500 and 250 samples, respectively.

The rule will necessitate additional personnel for program administration, recordkeeping, and specimen collection. It would require protected storage for records and specimens.

(f) Employee assistance program (EAP)

Licensees are required to provide employee assistance programs (EAPs) as part of their fitness-for-duty activities. The EAPs offer short-term counseling, assessments, and referral services, and monitor treatment for licensee employees. All licensees currently have such EAPs in place. Generally, these EAPs are not extended to include contractor employees. Cost estimates for such EAPs assume that contractor employees will be included.

(g) Appeal procedures

Each licensee is required to establish an appeal process so its employees and contractor/vendor employees can appeal determinations

that employees are not fit for duty. The rule also would require licensees to employ a Medical Review Officer.

(h) Reporting requirements

Among a number of administrative requirements associated with the implementation and operation of fitness-for-duty programs, is a system of files and procedures for protecting personal information, as well as for recordkeeping and reporting requirements.

Item 3: Potential change in the risk to the public from the accidental offsite release of radioactive material;

Response: Banning the presence or use of illicit substances at nuclear power plants and controlling how workers at nuclear power plants use legal drugs significantly increase the assurance that employees with unescorted access to the protected areas of nuclear power plants will be fit for duty. Although the Commission concludes that it cannot quantify the reduction in risk that will occur when fitness-for-duty programs exist at all plants, the potential for significant increases in risk, as a result of increased rates of human error, has been clearly demonstrated.¹ As discussed at length in the supplementary information published with the proposed rule and in NUREG/CR 5227, "Fitness-for-Duty in the Nuclear Power Industry: A Review of Technical Issues," substance use can impair a worker's motor skills and judgment to the point that accidents attributable to neglect or error are significantly more probable.

The general upward trend in drug use in the United States is well known and the nuclear industry has not been exempt from this phenomenon. The Commission concludes that firm action is essential at this time to ensure that nuclear power plant workers remain fit for duty. The Commission concludes, for the purposes of this backfit analysis, that the proposed improvements in fitness-for-duty programs provide a substantial increase in the assurance of public health and safety and that the direct and indirect costs of implementing such improvements are justified in view of the increased protection such improvements will afford.

¹ See NUREG/CR-1879, "Sensitivity of Risk Parameters to Human Errors in Reactor Safety Studies for a PWR," Brookhaven National Laboratory, January 1981 and NUREG 1050, "Probabilistic Risk Reference Document," September 1984.

Item 4: Potential impact on radiological exposure of facility employees;

Response: As stated in item 3 above, limiting the presence or use of illicit substances and abuse of legal drugs by workers at nuclear power plants will provide significant additional assurance that workers are fit for duty and that the rate of human error will not increase to the level that an unacceptable level of risk would result. An increased level of human error in the workplace could also result in additional radiological exposure to the individual and to fellow workers. In addition, partial offset of costs may accrue to licensees from the potential reduction in absenteeism, lost worker productivity, medical and insurance costs, and plant downtime. Finally, the licensee's employees will benefit from the improved general safety of the workplace, and through their utilization of the education and support programs available to deal with drug and alcohol problems.

Item 5: Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

Response: If all of these backfit requirements were new to industry, the cost implications of such a program would be more significant.² In reality however, the NRC and industry have been actively involved in fitness-for-duty programs for a number of years. In mid-1982, the Commission published a proposed rule that would have required licensees to develop and implement written procedures concerning fitness for duty, and in 1986 the Commission issued a policy statement on this subject. Since 1982, industry involvement on the part of the Nuclear Utility Management and Resources Council (NUMARC), the Institute of Nuclear Power Operations (INPO), the Edison Electric Institute (EEI) and individual utilities has resulted in each of the nuclear power plant licensees having a fitness-for-duty program in place. In many respects these programs compare very closely to the requirements stated in the proposed rule. As a result, the incremental burden to industry as a result of this action is significantly reduced.

The staff estimates that the incremental cost to industry of adhering to the proposed rule is on the order of \$326.8 million to \$494.5 million. Assuming a reactor population of 124, the per-reactor cost for an average remaining life expectancy of 25 years ranges from about \$2.6 million to \$4.0 million. About 65-percent of industry's total estimated incremental cost will come from chemical testing.

The cost estimates include both incremental implementation and operating costs. The incremental operating costs capture cost impacts over the remaining life of the reactor population.

² For example, in 1979 the TVA estimated that the annual cost of just an alcohol abuse program was approximately \$18.5 million.

Individual costs resulting from the necessary backfit activities discussed in item 2 above are estimated as follows:

(a) Written policy and procedures

The incremental cost for backfitting written policy and procedures on fitness-for-duty programs is viewed as a one-time implementation cost. Effort may also be needed on forms and records development. The NRC staff assumes that each licensee will expend an additional 16 person week technical staff and management effort for these revisions. Utility technical staff will cost \$50 per hour in 1987 dollars. This reflects a 1984 base wage rate adjusted by a factor of 1.8 for fringe benefits and plant management, escalated to 1987 dollars based on the GNP implicit price deflator.³

Cost per licensee (640 hr x \$50) \$32,000

Industrywide cost (\$32,000 x 55 licensees) \$1.8 million

(b) Awareness training program

The incremental cost for backfitting awareness training programs is viewed as a one-time implementation cost. The NRC staff estimates that 1500 employees and contractor personnel at each reactor will participate in a one-hour program in a classroom setting to orient them to the changes in their fitness-for-duty program. On the basis of generic cost estimates for training given in NUREG/CR-4627, the estimated cost per student hour is \$15.00, exclusive of the student's time away from work.⁴ The \$15.00 estimate includes the instructor's time for development, preparation, delivery, evaluation and revisions to the course,

³ NRC has taken industry labor rates from NUREG/CR-4627, Generic Cost Estimates; Science & Engineering Associates, Inc., S. Cohen & Associates, Inc., and Mathtech, Inc.; Abstract 6.3, "Industry Labor Rates," June 1986.

⁴ NUREG/CR-4627, Generic Cost Estimates; Science & Engineering Associates, Inc., S. Cohen & Associates, Inc., and Mathtech, Inc.; Abstract 2.2.3, "Industry Cost for Training or Retraining Staff and Writing or Rewriting Training Manuals, June 1986.

and allowances for the costs of instructional materials and handouts. The student's time is valued at \$38.00 per hour. This is the average hourly salary paid to various utility workers adjusted for fringe benefits and plant management and escalated to 1987 dollars.⁵ Thus, the total hourly cost of training each employee is \$53.00 (i.e., \$15 + \$38).

In addition, staff estimates 300 supervisors will participate in an additional four-hour training class. This is estimated to cost \$65 (i.e., \$15 + \$50) per hour of training.

The staff recognizes that newly hired workers must also take the orientation program. Since new workers would have taken a fitness-for-duty orientation under the existing licensee programs, the NRC staff views this cost as non-incremental.

Cost per nuclear reactor (1500 employees x \$53)	\$79,500
(300 supervisors x \$65 x 4)	<u>\$78,000</u>
	\$157,500
Industrywide cost (\$157,500 x 124 reactors)	\$19,530,000

(c) Refresher training

Licensees currently offer annual refresher training as part of their existing fitness-for-duty programs, usually as part of their General Employee Training (GET) programs. Although some licensees may need to provide more of such training, the proposed backfit requirement will impose little burden on industry.

Industrywide cost = \$0

⁵ Ibid.

(d) Written agreements with contractors/vendors

Nearly all licensees and their contractors/vendors have entered into written agreements concerning fitness-for-duty programs. Although some of these agreements may need minor revisions as a result of changes to the licensee's policies and procedures, the effect here is expected to be restricted to those few instances in which formal agreements with contractors in this regard do not exist. The licensee's effort, expended in modifying its own policies and procedures, should provide a quick and easy basis for any needed changes to these agreements.

Industrywide cost = \$0

(e) Chemical testing for drugs, including random testing and blind performance testing

1 Pre-employment and for-cause testing

The major costs incurred under this portion of the rule relate to the random testing and, to a lesser degree, to quality control measures such as blind performance testing. Because nearly all utilities already test their employees (i) before hiring them and (ii) for-cause, staff concluded that there are no incremental costs for these types of test.

2 Random testing

Although the Commission has not determined the required sampling strategies and testing rates, a number of samples each year equal to 100-percent of the tested population is assumed for the purpose of this analysis. For this analysis, the staff assumed that the rate for those plants already conducting random tests (about one-third) is 15-percent per year. The Commission's final decision, could result in differences in cost than estimated herein.

Other assumptions important to this analysis include the following:

- 1500 employees and contractors are to be tested randomly at each plant;
- existing plants have an average remaining life expectancy of 25 years;
- initial screening of each random test costs \$20.00;
- each confirmatory test costs \$75.00;
- 5-percent of those sampled randomly require confirmatory testing for whatever reason;
- 75-percent of the nuclear power reactor units (93) conduct onsite preliminary screening tests, thereby requiring an additional screening test at the HHS-certified laboratory;
- collection of a sample for any test will take an average of 60 minutes of an employee's productive time; and
- on the basis of data relating to industry labor rates and time-related cost adjustments contained in NUREG/CR-4627, Generic Cost Estimates, the average nuclear utility employee's hourly salary and benefits were \$38 in 1987.

a The estimated annual cost per employee is first based on the sum of: the cost of the random test; plus the cost of the confirmatory test, when necessary; plus the cost of the employee's time away from his/her normal duties.

Substituting the assumed values in the equation gives:

$$\begin{aligned} & \$20/\text{initial screening test} + .05 (\text{confirmatory}/ \\ & \text{random test}) \times \$75/\text{confirmatory test} + 1.0 \text{ hour} \\ & \times \$38/\text{hour} = \$61.75/\text{random test for licensees not} \\ & \text{conducting onsite preliminary screening tests.} \end{aligned}$$

\$20/preliminary screening test + .05 (confirmatory/onsite test) x (\$20/initial screen + \$75/confirmatory test) + 1.0 hour x \$38/hr = \$62.75/random test for licensees conducting onsite screening tests.

The average sum of \$62.25/random test is then multiplied by the factors that represent the industry experience in testing rates: 67-percent of the plants will need a 100-percent annual testing rate and 33-percent of the plants will need a 85-percent (100-percent - 15-percent = 85-percent) annual testing rate.

Substituting the assumed values gives:

$(1.00 \times .67 + .85 \times .33) \times \$62.25/\text{random test} =$
\$59.17 per employee per year

b This figure is multiplied by the estimated 1500 employees and contractor personnel per plant and by 124 plants to obtain an estimated industry cost of \$11.0 million per year. Assuming an average plant life expectancy of 25 years and a 10-percent discount rate, the industry's lifetime cost becomes \$100 million. If a 5-percent discount rate is assumed, the lifetime cost is about \$155 million.

Industrywide cost = \$100 million to \$155 million

3 Blind performance testing

The costs presented here include the cost of purchasing specimens and having blind performance tests conducted on them by the contract laboratory. It is assumed that:

- 75-percent of the nuclear power reactor units (93) conduct onsite screening tests.

- 5-percent of the specimens tested on site would require further testing at the contract laboratory.
- A blind performance test specimen costs \$50.
- A "weighted" annual testing rate of 95-percent will be used for all units rather than the 100-percent and 85-percent rates used in the above calculations.
- Other assumptions used for random testing apply.

a The estimated cost per unit for the initial 90-days for 75-percent of the units doing preliminary screening tests onsite is:

1500 employees x .95 testing rate x 1/4 year
(90 days) x .05 (rate of positives) x .5 (rate
of test specimens) = 8.91 specimens

The specimens cost \$50 each X 8.91 specimens =
\$445.31

80-percent of the specimens would only receive
initial screening tests and 20 percent would
need confirmatory tests:

8.91 specimens x .8 x \$20 (cost of initial
screen) = \$142.50

8.91 specimens x .2 x [\$20 + \$75 (cost of
confirmation)] = \$169.22

Cost for 75-percent of units for first 90 days
(\$445.31 + \$142.50 + \$169.22) = \$757.03/unit x 93
units = \$70,400

b The estimated cost per unit for the initial 90
days for the remaining 25-percent of the units is:

1500 employees x .95 testing rate x 1/4 year (90 days) x .5 (rate of test specimens) = 178 specimens

The specimens cost \$50.00 each x 178 = \$8,900

80-percent of the specimens would only receive initial screening tests and 20 percent would need confirmatory tests:

178 specimens x .8 x \$20 (cost of initial screen) = \$2850

178 specimens x .2 x [\$20 + \$75 (cost of confirmation)] = \$3380

Cost for 25-percent of units for first 90 days equals - (\$8,900 + \$2,850 + \$3,380) + \$15,130/unit x 31 units = \$469,000

c The estimated annual cost per unit for 75-percent of the units doing preliminary screening tests on site after the initial 90 days is:

1500 employees x .95 testing rate x .05 (rate of positives) x .1 (rate of test specimens) = 7.12 specimens

7.12 specimens/year x \$50/specimen = \$356/year

80-percent of the specimens would only receive initial screening tests and 20 percent would need confirmatory tests:

7.12 specimens x .8 x \$20 (cost of initial screen) = \$114/year

$$7.12 \text{ specimens} \times .2 \times [\$20 + \$75 \text{ (cost of confirmation)}] = \$135/\text{year}$$

The estimated annual cost for 75 percent of the units equals:

$$(\$356/\text{year} + \$114/\text{year} + \$135/\text{year}) = \\ \$605/\text{unit} \times 93 \text{ units} = \$56,000/\text{year}$$

- d The estimated annual cost per unit for 25 percent of the units after the initial 90 days is:

$$1500 \text{ employees} \times .95 \text{ testing rate} \times .1 \\ \text{(rate of specimens)} = 142 \text{ specimens}$$

$$142 \text{ specimens} \times \$50/\text{specimen} = \$7100/\text{year}$$

80-percent of the specimens would only receive initial screening tests and 20-percent would need confirmatory tests:

$$142 \text{ specimens} \times .8 \times \$20 \text{ (cost of initial screen)} = \$2280/\text{year}$$

$$142 \text{ specimens} \times .2 \times [\$20 + \$75 \text{ (cost of confirmation)}] = \$2710/\text{year}$$

The estimated annual cost for 25 percent of the units equals:

$$(\$7100/\text{year} + \$2280/\text{year} + \$2710/\text{year}) = \$12,090/ \\ \text{unit} \times 31 \text{ units} = \$374,800/\text{year}$$

- e In summary, costs for the initial 90-day period total \$539,400 (i.e., \$70,400 + \$469,000), and recurring annual costs total \$430,800 (i.e., \$56,000 + \$374,800). Assuming an average plant life expectancy

of 25 years, the industry's lifetime cost at a 10-percent discount rate becomes \$4.4 million and at a 5-percent discount rate the lifetime cost is about \$6.6 million.

Industrywide cost = \$4.4 million to \$6.6 million

4 Collection Site

Although urine specimens can be collected in facilities not dedicated solely to that purpose, it is estimated that 75-percent of the licensees will construct an on-site collection facility, or will need to modify an existing facility to meet collection site standards. An average of \$25,000 is estimated for construction of a dedicated facility for collecting urine, and sufficient space and equipment to administer the collection process and provide temporary storage pending shipment of specimens for testing. Incremental maintenance costs are estimated at \$1000.00 per year for those plants that do not presently have an on-site collection facility.

a Industrywide installation costs are estimated as
 $.75 \times 124 \text{ plants} \times \$25,000 = \$2.3 \text{ million}$

b Industrywide incremental recurring costs are $.75 \times 124 \text{ plants} \times \$1000.00 = \$93,000$ per year.

Assuming an average plant life expectancy of 25 years and a 10-percent discount rate, the industry's lifetime cost becomes \$0.8 million. If a 5-percent discount rate is assumed, this becomes \$1.3 million.

c Adding the initial installation and recurring costs given as industrywide cost = \$3.1 million to \$3.6 million.

5 Protected Storage

The cost of long term protected freezer storage at an HHS-certified testing laboratory is included in the cost of the testing. Should a licensee desire longer than the standard one year retention period (only required by the rule) the cost would be \$10/specimen per year. The staff concludes that there would be no incremental costs for protected storage.

6 Additional Personnel

In addition to the current staff for administering fitness-for-duty programs, it is estimated that three additional clerical personnel would be required for program administration, recordkeeping, and collection and processing of specimens. At an average annual salary of \$20,000 and a burden factor of 1.8, this comes to a recurring cost of $3 \times (\$36,000) = \$108,000$ per licensee. Also, a physician would be required as a Medical Review Officer. At a salary of \$70,000 per year plus 35-percent benefits package, this would come to an additional \$94,500 per year per licensee. The annual industry cost for these additional personnel would be $55 \times (\$108,000 + \$94,500) = \$11.1$ million per year. For an average plant life of 25 years and a 10-percent discount rate, the industry's life-time cost becomes \$101 million and if a 5-percent discount rate is used it is \$157 million.

Industrywide cost = \$101 million to \$157 million.

(f) Employee assistance programs

The introduction of random testing will increase the utilization rate of the licensee's employee assistance program and would result in an increase of the licensee's current EAP staff. It is estimated that one additional professional staff person per power reactor would be hired at \$50,000 per year and one additional clerk at \$36,000 per year. This will cost the industry

\$10.7 million annually. On the basis of a 10-percent and 5-percent discount rate, the lifetime cost to the industry on a present worth basis is estimated to range from \$97 million to \$151 million, respectively, in 1987 dollars.

Industrywide cost = \$97 million to \$151 million.

(g) Appeal procedures

Procedures of this nature are either already a part of the utilities' personnel practices, or will be under the industry standard for access authorization programs. Therefore, this requirement will impose no additional burden on industry.

Industrywide cost = \$0

(h) Reporting requirements

The staff's assessment of the utilities' fitness-for-duty programs suggests that approximately 50-percent of the existing programs fully meet these requirements, and that for the remaining 50-percent, only some modest increase could be required. Recognizing that these latter utilities already have on their staffs personnel to manage and administer these programs, and that these requirements constitute only a small increment to their current level of effort, the staff concludes that these requirements could be accommodated with no or minimal added cost.

Industrywide cost = \$0

Item 6. The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

Response: The backfit does not alter the plant or operational complexity. It does not involve a reduction in a margin of safety since neither plant design nor operating procedures are changed. In addition, it does not alter any safety-related design basis of the facility.

Therefore, the backfit neither creates the possibility of a new or different kind of accident nor does it involve an increase in the probability or consequence of an accident previously evaluated.

Item 7: The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

Response: In addition to overseeing the licensees' fitness-for-duty programs, NRC staff will need to address the matter of periodic inspections, prepare event reports, initiate reactive inspection programs, and review reports and other written submittals. To a limited degree, these activities are currently being conducted with present staff.

The staff estimates that one full-time position at headquarters plus two to five staff positions in the regional offices will be required for program management, inspections, and general oversight of the utilities' fitness-for-duty programs. An estimated range is provided because of the uncertainties of the extent of the reactive inspection effort. For example, one region expended more than one FTE in FY87 investigating fitness-for-duty allegations.

Estimates of NRC labor rates (NUREG/CR-4627) suggest using a value of \$72,000 per NRC professional staff-year. This would cover salary and fringe benefits for a mid-level position as well as secretarial and management support to that individual. The annual NRC cost for this action at the upper bounds is, therefore, 6 staff x \$72,000/staff-year = \$432,000/year.

The 1987 present worth value of the estimated annual cost over a 25-year period is about \$3.9 million using a 10-percent discount rate. A 5-percent discount rate gives a lifetime cost of approximately \$6.1 million. The staff finds that the estimated resource burden on the NRC associated with the proposed backfit is \$3.9 million to \$6.1 million.

These resources will be obtained from currently budgeted NRC safeguards resources, thereby leaving NRC safeguards programs with unbudgeted requirements of that amount.

Item 8: The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit;

Response: The backfit is of an administrative nature and independent of the facility's type, design, or age. Therefore, there should be no differences in potential impact between the various facilities on a per year basis. The total cost to any facility will be proportional to the number of remaining years that the facility is operated.

- Item 9: Whether the proposed backfit is interim or final and, if interim, the
- justification for imposing the proposed backfit on an interim basis.

Response: The backfit action is anticipated to be the staff's final position regarding fitness for duty.

Conclusion: The NRC finds that the rule is not needed to provide adequate protection of public health and safety under Section 182 of the Atomic Energy Act because there is a sufficient margin of safety inherent in the design of nuclear power reactors through provision of redundant safety systems and automatic shut down features. Adequate protection is further provided by the defense in depth of multiple containment barriers and adherence to the technical specifications and operating conditions in licenses. The rule would provide additional assurance that nuclear workers adhere to the technical specifications and operating conditions in licenses.

Because this rulemaking adds a new rule to an earlier Commission position, a backfit analysis has been prepared pursuant to 10 CFR 50.109(a)(3). The NRC finds that the new rule will significantly increase the overall protection of public health and safety and that the direct and indirect costs of implementing the new rule are justified in view of the increased protection.

Enclosure 7
Draft Congressional Letters

DRAFT CONGRESSIONAL LETTER

Dear Mr. Chairman:

The Nuclear Regulatory Commission is amending its regulations to require licensees authorized to operate nuclear power reactors to implement a fitness-for-duty program whose general objective is to "provide reasonable assurance that nuclear power plant personnel are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to perform their duties safely and competently.

Enclosed for your information is a copy of the rule as finally approved by the Commission for publication in the Federal Register.

Sincerely,

XXX

ADDRESSEES:

Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate, DC 20510

Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives 20515

Chairman
Subcommittee on General Oversight and Investigations
Committee on Interior and Insular Affairs
United States House of Representatives 20515

Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives 20515

Chairman
Committee on Governmental Affairs
United States Senate 20510

Chairman
Subcommittee on Environment, Energy
and Natural Resources
Committee on Government Operations
United States House of Representatives 20510

Chairman
Select Committee on Narcotics Abuse and Control
United States House of Representatives 20515

[OCA to notify by letter Rep. Edward Markey, Senator John Warner, Sen.
Barbara Mikulski and any other correspondents on FFD rule]

Enclosure 8
Draft Press Release

NRC ISSUES RULE SETTING FITNESS-FOR-DUTY REQUIREMENTS AT
CIVILIAN NUCLEAR PLANTS

The Nuclear Regulatory Commission is issuing a new part to its regulations that requires utilities licensed to operate nuclear power reactors to implement fitness-for-duty programs.

Currently, the Commission has the authority to order remedial action where a plant's safety is potentially affected because a person is unfit for duty.

The specific program elements and procedures in Part 26 apply to illegal drugs and abuse of alcohol. Each licensee also must develop measures for addressing legal drugs (prescription and over-the-counter) and other health problems, such as mental stress and fatigue.

The rule requires utility fitness-for-duty programs to include the prohibition against consumption of alcohol prior to and during work and must address situations where a person has been called in to perform unscheduled work.

The general objective of the rule is to assure:

- 1) nuclear power plant personnel are not under the influence of any substance, legal or illegal, which in any way adversely affects their ability to safely and competently perform their duties;

DRAFT

2) early detection of persons who are not fit to perform their duties;

3) an alcohol-free and drug-free workplace.

A proposed rule that would have required licensees to develop and implement fitness-for-duty programs was published by the Commission for public comment in 1982, but rulemaking was deferred to allow utilities to develop and implement their own programs.

The Commission's evaluation of industry experience indicates that although voluntary guidelines were developed and programs put into place, it is appropriate to establish uniform standards and to achieve further improvements.

Provisions of the rule, with limited exceptions, apply to all persons granted unescorted access to protected areas, and to licensee or contractor personnel required to respond to a licensee's Technical Support Center or Emergency Operations Facility in the event of a radiological emergency at a nuclear power plant.

Under the rule, drug and alcohol testing will be conducted before granting unescorted access to protected areas. Also, testing of licensee and contractor personnel will be conducted randomly, for cause, and as a follow-up to verify continued abstention. Tests for alcohol, to be administered by a breath measurement instrument, are to be performed in conjunction with other substance tests.

Licensee or contractor personnel tested positive will be denied access to protected areas and removed from their work activities. These persons can later return to work under certain conditions after determining that they are fit to do so. A second confirmed positive test will result in removal for a minimum of three years. Involvement in the sale, use or possession of drugs by any person within a protected area will result in removal for a minimum of five years. Reassignment of individuals that were removed for three or five years to activities covered by the rule will be permitted only after certain conditions are met. Any subsequent use will result in permanent removal.

Before initially granting unescorted access, licensees will be required to conduct a suitable inquiry to determine if a person had been removed from work activities or denied unescorted access at other nuclear power plants because of any involvement in drug use or abuse of alcohol.

The rule also provides for other basic fitness-for-duty program elements, such as the development of written policies and procedures, provisions for training of supervisors and employees, standards for drug and alcohol testing, and requirements for employee assistance programs and appeal procedures.

The new Part 26 to the Commission's regulations, published in the Federal Register on _____, will become effective on _____.