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10CFR26 Comments Subparts B, D, E, F, G, H

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§26.23 Performance objectives.

B

There is nothing in this section that says something to the effect of 'provides reasonable assurance that the program will maintain a level of integrity to ensure the privacy of individuals subject to testing, and that the individuals subject to testing will not be unjustly or inaccurately portrayed as having violated this part.' It should say it.

§26.27 Written policy and procedures.

If screening for drugs in addition to those listed in the part, those drugs must be made known. No drug should be screened for if it hasn't been identified up front. If prevention is truly the goal, the best way to prevent is to forewarn. If all we want to do is catch people, then keep things a secret. (the same comment applies to 26.29 Training)

§26.31 Drug and alcohol testing.

(5) Medical conditions.

(ii) Should say.... treatment must not be delayed to conduct drug and alcohol testing.

§26.37 Protection of Information.

In (d), the donor or designated representative should be allowed access to the donors FFD records at any time with permission of the donor. Not just in the case of a positive, but to ensure that no records exist that should not be there. For example records of tests that tested non-negative initially but were subsequently declared negative by the MRO.

§26.75 Sanctions.

D

There is no mention of how past violations will count toward the new system of sanctions. [redacted] a new slate is the fairest way, especially since the harder stance on alcohol.

§26.89 Preparing to collect specimens for testing.

E

(a) Since tardiness in reporting for the test can result in loss of clearance, and further since management can arbitrarily determine if the tardiness was a subversion of testing, there should be language requiring positive contact with the individual being called for a test, i.e. through the individuals FFD supervisor. You must provide positive ID when you go to be tested, the same requirement should apply when you are called, since phone ID is impossible, face to face communication from the FFD supervisor should hold true. Additionally, since FFD testing is so

important, the supervisor should be subject to the same subversion of testing guidelines and held accountable to ensure the person selected appears when scheduled.

§26.89 Preparing to collect specimens for testing.

(b)(1), The potential, to have a claim that not having a photo ID could be construed as an attempt to subvert testing, can be avoided. Direct identification by the individuals FFD supervisor should be an acceptable form of identification for testing that is not pre-access testing. If the FFD supervisor can be trusted observe the individual then he or she should certainly be trusted to verify the identity of the individual.

(c) Since leaving the collection site before all the collection procedures are completed or refusing to cooperate in the specimen collection process are considered refusal to test, a verbal notice by the collection site person is not enough, especially if the collection site person were to forget to relate that information and the donor were to leave. This notice should be included in a conspicuous place on the consent-to-testing form that the donor is required to sign. This will eliminate any possible chance for confusion, and sanctions.

§26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use.

In (e) Quality assurance and quality control of EBTs, paragraph (3) says if the EBT fails an external calibration check, positives since the last successful external calibration check must be thrown out. The regulation is leaving the time intervals for the external calibration checks to be according to the manufacturer's instructions. What if that is a weekly or yet monthly requirement from the manufacturer. This means that an individual tested with a faulty EBT could face inaccurate sanctions for up to 30 days until it becomes apparent there is a problem with the unit. The requirement for external calibration checks should be done at the start and end of the testing day, only on days when tests are being done. No sanctions can be taken for a positive test until the EBT has been verified as having passed its external calibration check pre and post testing. Copies of the external calibration checks should be provided to the donor and representative upon request.

§26.99 Determining the need for a confirmatory test for alcohol.

Must be strongly worded to ensure that for tests below 0.02 percent BAC no further actions or sanctions against the donor may be taken. Currently [redacted] practice is to counsel, discuss with the supervisor and check the work for those who fall above 0.01 and below 0.04 percent BAC

§26.101 Conducting a confirmatory test for alcohol.

See comments in 26.91 above.

§26.103 Determining a confirmed positive test result for alcohol.

How can time periods be used to determine pass/fail on samples collected during the work period that are less than 0.04 percent BAC? Due to the differences in metabolism how can a straight line cutoff be established? If they insist on something like this, why not do several tests to calculate the decay ratio for the individual being tested, then use that to calculate if the cutoff was violated. I don't like this either, but I think it's fairer than one calculation fits all.

Also, in 26.27 Written policy and procedure, it says the policy must "State that no sanctions may be imposed on an individual who is called in to perform an unscheduled working tour and has consumed alcohol within the pre-duty abstinence period stated in the policy." But in this section is says that a confirmed positive test must be declared when the result of the confirmatory test is 0.04 percent BAC or higher. If a worker is called out and informs the caller that he has consumed alcohol, he will be tested when he arrives. This needs to indicate that positives for call-outs must be handled and declared differently.

§26.105 Preparing for urine collection.

In (b), there is an ambiguous statement regarding making the determination "if the item appears to have been inadvertently brought to the collection site".

Will there be a sign posted at the access to the collection site stating that items, that may appear to be harmless (such as Visine) can be considered as an attempt to subvert the testing process, and that those items should be left outside. If not, will a welder with dry scratchy eyes be subjected to observed testing at the whim of the collector? It seems to me the solution to this would be to post a sign and provide a locker, outside the collection area and require those being tested to place all items on their person into the locker. Then only be permitted to enter the collection area with the key to that locker and their ID.

Also, not showing the pockets to the collector is another refusal to test. Again this should not be left to just a verbal from the collector, it should be in writing on the consent-to-testing form that the donor is required to sign.

§26.107 Collecting a urine specimen.

In (a) (3), it says "The collector may set a reasonable time limit for voiding. " Let's select a reasonable time now, not give the collector another item to be subjective about.

§26.111 Checking the validity of the urine specimen.

In (b) there should be a form required for samples that fall out of the temp range, for either the actual temperature of the donor signed as observed by the donor, or for the donor to sign that he/she refused to have temperature taken and what the implications of the temperature disparity could be.

§26.115 Collecting a urine specimen under direct observation.

In (a) (1), it lists an "invalid" sample provided at a previous collection as a reason to do an "observed collection". An "invalid" sample differs from dilute, adulterated or substituted in that it contains something that can't be identified. What are the criteria used? Why can't it be identified? The flaw in the ID might be in the testing. And if so, why would the donor be subjected to "observed collections" forever? Perhaps just for the one used to replace the invalid sample would be more reasonable. If the follow up is clean, then that is the end of it. If the follow up is not clean then future observed collections would be justified.

And yet again, we have another reason for "refusal to test". If the donor refuses to do an observed, there should be a form he is required to sign stating that.

§26.117 Preparing urine specimens for storage and shipping.

Discusses chain of custody, but does not say what a break in the chain means. Does it invalidate the sample? Then what happens?

Also, there should be a record of how the sample is stored (i.e. maintained cooled) while awaiting shipment to the HHS lab.

§26.119 Determining "shy" bladder.

In (a), 5 business days is not sufficient time to get an appointment with a doctor, especially since one would assume it would be with a specialist. And why would and MRO not find another doctor acceptable? If this MRO requirement stands, then 5 days is definitely inadequate.

The issue of the MRO finding the doctor acceptable, or as in (g) concurring with the doctor, concerns me. [redacted] individual [redacted] who was accused of substituting because his creatinine was so low. [redacted] had polio and was tested for 24 hour creatinine output, it tested out below the lowest level cutoff. 2 doctors wrote the MRO and he chose to ignore them both. What good is any of this if a common practitioner can chose to ignore specialists?

If a medical condition exists, and is substantiated by a doctor then alternate testing is allowed and can be arranged. Why does the MRO need to agree with someone more specialized than he is? Since proof of a medical condition will trigger alternative testing, then why not have the MRO invoke it when the "shy bladder" appears? If the donor is feigning "shy bladder" to avoid testing, this will prevent it. Then the time to get the medical certification is not so critical. If the "shy bladder" donor refuses to cooperate with a medically acceptable alternate test then sanctions could be taken.

F

§26.125 Licensee testing facility personnel.

There is no requirement to ensure that testing personnel are not color blind. Since colorimetric testing strips are used, one would expect the tester would be able to distinguish the colors.

§26.127 Procedures.

In (b), the written chain-of-custody procedures should included guidance on what happens if the chain-of-custody is broken.

§26.129 Assuring specimen security, chain of custody, and preservation.

In (a), who ensures that the testing facility is secure? What happens if the security of the facility is compromised?

In (b) it says "If there is reason to believe that the integrity or identity of the specimens is in question, the specimens may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical." There should be no question in this.....if the chain-of-custody is suspect, the sample MUST be voided and a new test ordered. In any criminal case, evidence that has suspected c-o-c, it is not allowed to be used. This must be the case here as well. If it inconveniences the licensee, so be it. The donor has no say in who collects, transports, or tests the sample he/she provides, that is all in the licensees hands. If an error is made, it was by entities picked by the licensee, who can be replaced at the licensee's discretion if their errors cause hardship for the licensee.

§26.131 Cutoff levels for validity screening and initial validity tests.

Initial validity testing should be performed as soon as the sample is provided, and before the donor is allowed to leave the testing facility. This action serves to protect the donor against unfairly being accused of attempting to subvert the testing process, especially in the case where it might be caused by a medical condition. If a sample does not pass the

initial validity testing in (b), then it should be the trigger to do an observed test as in 26.111(d). And both samples can then be sent on to the HHS lab. If sample #2 tests clean, and it was collected under direct observation it is "pure", therefore there is no reason to test sample #1. If sample #2 is "hot" then sample #1 should be tested, and if it shows presence of adulterants identified or not then there is positive proof of the attempt to subvert the testing process as well as the motive. If sample #2 shows any adulterants, identified or otherwise, Then sample #1 must be tested as well. If both samples agree, and again since sample #2 was collected under direct observation it is "pure", a medical explanation for this occurrence, or alternate testing must be actively pursued.

§26.135 Split specimens.

In (b), the MRO should provide the donor with a form, with instructions on who to send it to, that can be used to request that the second testing process occur. The 3 business day requirement may present a hardship for shift workers. For example, a worker on a 12 hour shift is told of the positive test results on Tuesday afternoon. The next 3 MRO business days are ST days for him because he's on the week that starts nightshift on the weekend. Naturally, since the clearance would be suspended at this time, most people would act quickly [redacted] 10 days more reasonable. And the requirement should say postmarked or hand delivered to [someone] in 10 business days.

§26.137 Quality assurance and quality control.

In (e) (2) It needs to be specified here that donor information must be disassociated from samples that are "pooled" to be used in the internal QC program. This should not be a problem since they have already been certified "by an HHS-certified laboratory that the specimens are negative and valid."

§26.153 Using certified laboratories for testing urine specimens.

In (d), in situations where "licensees and other entities who choose to follow practices outside the HHS Guidelines" then NRC (not the licensee) "shall ensure that the HHS-certified laboratory takes measures that are consistent with this part to assure that the reported test results are valid and defensible."

In (f) (2), the requirement that "The laboratory shall make available qualified personnel to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory". Must have stringent provisions to force the laboratory to comply. [redacted] nobody from the lab showed up. The law says you have the right to face your accuser, and in this case it's the lab. This should be handled in the same fashion that court proceedings are, no accuser-you win.

In (f) (4) it should say "employee or authorized representative"

§26.159 Assuring specimen security, chain of custody, and preservation.

In (j), It needs to be specified here that donor information must be disassociated from samples that are "pooled" to be used in the internal QC program. This should not be a problem since they have already been certified "that the specimens are negative and valid."

§26.161 Cutoff levels for validity testing.

In (c) (8), Where "any other adulterant" is reported, what quality controls exist? How do we know what it is and if the testing unit properly identifies and/or quantifies it? Simply declaring that something is there seems weak. The substance should be identified on a machine calibrated (and QC tested) to detect it.

In (g), the requirement should be to send "the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance." The lab should not have to contact the MRO, it should be automatic. No one should suffer or be accused as "attempting to subvert" for an unidentified substance.

§26.165 Testing split specimens and retesting single specimens.

Again (a) (4) references 3 business days

In (f) (1) should not allow for loss of pay while clearance is administratively withdrawn awaiting the test of sample B.

§26.167 Quality assurance and quality control.

These QC tests should be done at the start of the testing period. If any samples show positive for any of the tests performed, then a test (especially one to prove there are no false positives occurring) confirming the machine is still valid for that test must occur. A copy of the results of the pre and post QC testing, as well a copy of the negative test results for the sample immediately preceding, must be included with the results when positive tests are reported to the MRO. If two back to back samples in the same batch run test positive for the same item, the second of the 2 samples should be tested again to ensure that carryover did not occur. This could be done by separate testing or by including the sample in another batch, provided the sample tested directly does not test for the same item. Regardless of how it is done, reports to the MRO should show the machine passed it's initial and post test QC checks for whatever is being declared positive, and that either the sample immediately preceding the sample tested negative, or it was tested alone.

§26.185 Determining a fitness-for-duty policy violation.

(d) (1) through (3) need redone for various reasons. A shift worker on nights may not have an answering machine, or it may be on the fritz. This could make notification impossible, unless contact is made at work. If the MRO were to contact work and the individual was out in the plant, what happens if the message to call gets lost? What happens if the worker is on vacation, in the hospital, or on a long set of weekday ST days, like 12 hour workers get, and the MRO can't make contact?

The best way to solve this would be to have the person that is the licensee's designee to call workers for FFD testing responsible for contacting the individual's supervisor and make arrangements for the worker to in turn contact the designee, who would then schedule a time for the MRO review. This would ensure confidentiality in the event the MRO declares the test to be negative, as the supervisor would assume the call was for an FFD test. Since the supervisor is aware of the employee's schedule and health status, this would avoid the donor being declared as having had violated the FFD program simply because he was unavailable due to perfectly innocent reasons.

In (f) (2), (f) (3) (g) (1) and (h) (1), what constitutes as "valid medical reason"? It should be specified that if the individual presents testimony or certification from a medical doctor (especially a specialist), the MRO MUST accept it as a valid reason if it explains the difference. [redacted]

In (h) (1) and (i) (1) what does "referral" physician mean? Does that mean the donor must be referred to him by the MRO, and if so why can't the donor pick his own specialist? Especially if he already has the proof from the specialist in his possession. Also 5 days is not enough time to get an appointment to get in to see a specialist if needed. Perhaps it would be better, within 5 days, to show proof of appointment with a specialist and have the clearance placed on administrative hold, pending the results from the doctor. Perhaps even allow the MRO to contact the specialist and attempt to "fast track" the appointment.

In the event the specialist exonerates the individual, the licensee should be liable for the costs of testing. If the specialist cannot confirm a medical explanation exists, the burdens of the costs are the responsibility of the individual.

In (j) (6) if a doctor prescribes medication legally as treatment for a medical condition, it should not be the responsibility of the employee to determine if it is on the list in Schedule I (or be held responsible to see if his medication has been added to it since it was prescribed). Nor should anyone be put in the position to choose between the best course of treatment prescribed by a physician and their job.

Although in 26.21 (b) (6) reference is made to "use of prescription and over-the-counter medications that could cause impairment", no mention is made requiring you to report the use of prescription and OTC medications to your supervisor. There is also no requirement

to list prescription and OTC medications when taking an FFD test, only when called in for the MRO interview after a positive test occurs. [redacted] is probably due to HIPPA, [redacted] needs to be rethought (using 26.189) for several reasons:

1. Anyone taking prescription and OTC medications may be doing it legally, but still can still be impaired. There should be a point of contact in the licensees testing program, available at all times that coincide with shift workers starting hours, who can ensure that the medication being taken does not jeopardize the safety of the individual, coworkers or the plant. This would also help with 26.185 (j) (6). If the OTC or legally prescribed medication affects the fitness of the individual, they could be designated "Not fit for duty due to accepted medical reasons" and placed into a position in which their fitness is not an issue, until the medication is no longer being taken and the MRO releases the worker. And suffer no sanctions.

2. If the workers FFD file contained prescription and OTC medication information, it would eliminate the need for the worker to endure the stress of the MRO review if the medication were the cause of the non-negative test.

3. In case where the employee were to forget, and an FFD test were to flag them due to an OTC or legally prescribed medication that affects the fitness of the individual, they could be designated "Not fit for duty due to accepted medical reasons" after the MRO reviews the test results, and be designated "Not fit for duty due to accepted medical reasons" and placed into a position in which their fitness is not an issue, until the medication is no longer being taken and the MRO releases the worker. And suffer no sanctions.

§26.187 Substance abuse expert.

In (f) that SAE documentation should be provided to the individual or designated representative upon request.

In (g) (2) (i) In order to BEST prevent a conflict of interest, once the SAE has made the recommendation for the best treatment of the individual, it should be up to the individual to select the entity that will provide the treatment, given the entity meets the credential requirements for the course of treatment provided. Since personality conflicts may interfere with treatments, the individual should be allowed to change treatment providers (with SAE concurrence) during the course of treatment, if incompatibility issues should arise.

§26.197 General provisions.

In (b) (1 When an employee "who is subject to this part makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue, and, subsequent to the declaration, the licensee