

ORIGINAL

**UNITED STATES OF AMERICA**  
**NUCLEAR REGULATORY COMMISSION**

**Title: BRIEFING ON STATUS OF 10 CFR 50.59 ISSUES**

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2 NUCLEAR REGULATORY COMMISSION

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4 BRIEFING ON STATUS OF 10 CFR 50.59 ISSUES

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7 Room 1F-16  
8 Nuclear Regulatory Commission  
9 White Flint Building 1  
10 11555 Rockville Pike  
11 Rockville, Maryland  
12

13 Tuesday, March 2, 1999  
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15  
16 The Commission met in open session, pursuant to  
17 notice, at 2:07 p.m., the Honorable SHIRLEY A. JACKSON,  
18 Chairman of the Commission, presiding.

19 MEMBERS PRESENT:

20 SHIRLEY A. JACKSON, Chairman  
21 EDWARD McGAFFIGAN, JR., Commissioner  
22 NILS J. DIAZ, Commissioner  
23 GRETA J. DICUS, Commissioner  
24 JEFFREY S. MERRIFIELD, Commissioner  
25

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1 STAFF PRESENT:

2 ANNETTE L. VIETTI-COOK, Secretary

3 KAREN D. CYR, General Counsel

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## P R O C E E D I N G S

[2:07 p.m.]

CHAIRMAN JACKSON: Good afternoon.

I'm pleased to welcome members of the NRC staff and representatives of the Nuclear Energy Institute to today's meeting.

The subject of the meeting is a draft revision to the NRC regulations for changes, tests, and experiments. The draft revision is described in SECY 99-054. This paper was submitted to the Commission last week and promptly was made available to the public.

I note that the staff intends to discuss the background for this rule-making effort, as well as providing a quick synopsis of the contents of 99-054.

The regulations for change, tests, and experiments such as 10 CFR 50.59 and 72.48 are a vital aspect of our regulatory structure, because they're intended to allow licensees a reasonable measure of flexibility in making changes to their facilities.

Of course, any changes made under this blanket must clearly be consistent with the continued assurance of protection of public health and safety.

The controlling regulations also be inspectable and enforceable. This allows the NRC to deal with isolated performance problems directly without creating unnecessary



1 burden for good performers.

2 The Commission has directed the staff to work with  
3 the nuclear industry in creating revised rule language  
4 that's both appropriate and reasonable.

5 At this point, the vision provided by the  
6 Commission needs to be translated into regulatory language  
7 that assures predictable and appropriate real world results.

8 Therefore, I request that today's presenters  
9 address the practical effects of the proposed rule-making  
10 language.

11 Effects should be discussed in terms both of  
12 minimizing unnecessary burdens on licensees and on assuring  
13 adequate protection of public health and safety, but since  
14 we're a regulatory agency, I'll repeat the sentence this  
15 way.

16 Effects should be discussed both in terms of  
17 assuring adequate protection of public health and safety and  
18 of minimizing unnecessary burdens on licensees.

19 Effects also should be discussed in terms of how  
20 inspection and enforcement efforts would be impacted by the  
21 rule language.

22 Specific real world examples to illustrate these  
23 effects would be useful to the Commission, and the  
24 Commission looks forward to the presentation by the staff  
25 and the Nuclear Energy Institute.

1 I understand that copies of the presentation are  
2 available at the entrances to the meeting.

3 So, unless my colleagues have any opening  
4 comments, Dr. Travers, would you begin?

5 DR. TRAVERS: Thank you, Chairman, and good  
6 afternoon.

7 The staff has, as you've indicated, been  
8 continuing to work with our stakeholders and has made, we  
9 believe, considerable progress in developing mutually  
10 agreeable resolutions for many of the issues associated with  
11 evaluating changes, tests, and experiments at facilities.

12 However, there are areas where differences remain,  
13 and I'm sure you're going to get the benefit of some of the  
14 discussion on those issues today.

15 The paper, as you have indicated, recently  
16 forwarded to the Commission contains a draft final rule  
17 which includes the staff's recommended approach for  
18 resolving a number of difficult policy issues.

19 We are seeking Commission guidance on these  
20 recommendations before we prepare and submit to the  
21 Commission a final rule-making package for 50.59.

22 With me at the table today are Sam Collins,  
23 Director of the Office of Nuclear Reactor Regulation; Dave  
24 Matthews, Director of the Division of Regulatory Improvement  
25 Programs, NRR; Eileen McKenna from the Office of Nuclear

1 Reactor Regulation; and Marty Virgilio, who is the Deputy  
2 Director of the Office of Nuclear Material Safety and  
3 Safeguards.

4 With that, we'd like to begin the presentation,  
5 and Dave Matthews is going to start us off.

6 MR. MATTHEWS: Thank you, Bill.

7 The staff had indicated on slide one that they  
8 would go over background associated with this rule-making,  
9 but in reviewing prior opportunities to discuss this rule  
10 with all of you, I realized that there probably is not a lot  
11 of benefit in going into any detailed background.

12 On January 13, 1999, the staff briefed the  
13 Commission on reactor licensing initiatives, but a big  
14 portion of that briefing was dedicated to where we were in  
15 the process of reviewing comments on the proposed 50.59 that  
16 had been issued in October.

17 That comment period closed on December 21st, so we  
18 weren't able to give you a complete recitation of the  
19 comments and our reaction to them, but I believe at that  
20 time we indicated that we were well along and I gave a  
21 snapshot of where we saw the comments coming out and where  
22 the staff was reacting, at least from an initial standpoint.

23 As was promised in our December 21st memo to the  
24 Commission, in mid-February we provided SECY 99-054, and as  
25 opposed to a final rule-making, it was a -- the result of



1 the staff review of comments.

2 We indicated we would provide you recommendations  
3 for consideration before we moved to, as I used the word,  
4 galvanize a final rule for your consideration.

5 We think SECY 99-054 met those commitments. We  
6 even did attach proposed rule language so you could see the  
7 effect of our reaction to public comments on our proposals.

8 Eileen McKenna is going to lead the briefing  
9 today, and it is going to move very quickly into the  
10 substantive issues that remain on the table as far as the  
11 staff is concerned.

12 I'd like to make an assessment that I think  
13 convergence is at hand. I will not claim that it is there.  
14 The paper was released shortly after you received it.

15 We have had some preliminary discussion with NEI,  
16 and I think there still is a separation of views in some  
17 areas, but as the chairman and I discussed the last time we  
18 were before you, the time is upon us, I think, to make some  
19 decisions to move forward and bring this to closure, and I  
20 think my basis for saying that is that it's my view that  
21 this rule, as the chairman mentioned in her opening remarks,  
22 is a very pervasive rule, and that's my word.

23 Its practical impacts is that it spreads  
24 throughout the licensee organization, from engineering  
25 through operations, through maintenance. We see that

1 procedure that is usually developed reflected at just about  
2 every desk at a site.

3 So, I think it's pervasive. As such, I think it  
4 does impose some limits and restrictions on licensee  
5 activities, and I think clarity in this regard is needed, as  
6 proven by some of the disputes and debates we've had over  
7 issues over the last two or three years.

8 So, I say that by way of supporting a view that I  
9 think, to the extent we have not converged completely, I  
10 think the Commission has the opportunity to drive us to that  
11 convergence, and I think there's benefit in doing that.

12 CHAIRMAN JACKSON: Let me make sure I understand  
13 what you're saying. You're saying that you think it's now  
14 time for the Commission to settle the deltas as opposed to  
15 saying staff go back one more time?

16 MR. MATTHEWS: That's exactly what I'm saying.

17 CHAIRMAN JACKSON: I see.

18 MR. MATTHEWS: Not that we wouldn't be willing to  
19 continue to work, if you thought there was benefit of us  
20 doing that, to bringing some of these disparate issues  
21 closer together, but we've been at that for some time now,  
22 and I think there is a point of diminishing returns.

23 COMMISSIONER DIAZ: Would you define the  
24 convergence for me? Is it convergence with the original,  
25 you know, SRM of the -- the Commission put out or

1 convergence between who and what and how? What do you mean  
2 by convergence?

3 MR. MATTHEWS: I would put it as basically three  
4 -- the converging of three points, which is difficult to  
5 achieve sometimes --

6 COMMISSIONER DIAZ: I understand. I just want to  
7 make sure.

8 MR. MATTHEWS: -- with the Commission policy in  
9 terms of the direction that they would like the regulation  
10 and thereby the industry and the staff to go along with the  
11 views of the staff as to how that ought to be implemented  
12 and its workability and the views of the industry on its  
13 practicality.

14 So, I think those are the three elements that need  
15 to be brought together, and I would view it as attempting to  
16 achieve mutual agreement, that there is a workable solution  
17 and that there's benefit to moving forward with that  
18 workable solution, without maybe either or any of those  
19 parties having achieved the maximum benefit they'd hoped out  
20 of the process. I think there's benefit in getting  
21 agreement among them.

22 CHAIRMAN JACKSON: Okay.

23 MS. McKENNA: Okay. Thank you.

24 Could I have slide three, please?

25 On this slide, we listed the major contents of the



1 paper that we sent you -- that is, the policy issues -- and  
2 the terminology I used is kind of what we used in the  
3 proposed rule.

4 In some cases, the language may shift a little  
5 bit, but we listed here minimal increase in probability,  
6 margin of safety implications, because you know, we may not  
7 choose to continue to use that language in the future, part  
8 71 and part 72 issues that are related to 50.59 issues, some  
9 discussion of implementation schedules and enforcement  
10 strategy, and we also had the commitment to respond with a  
11 recommendation on the scope of 50.59 which we did include in  
12 the paper.

13 As Mr. Matthews mentioned, the paper also had  
14 draft rule language that reflects these recommendations that  
15 we've made and I think a fairly detailed discussion of the  
16 comments that we've received so you could see what the views  
17 of those outside the NRC were, and we listed in a further  
18 attachment some additional issues that we thought were of  
19 interest but didn't rise to the level, we thought, of being  
20 in the main paper.

21 Could I have the next slide, please?

22 The proposed rule offered a standard of no more  
23 than a minimal increase in probability of accidents  
24 previously evaluated or malfunctions of equipment previously  
25 evaluated, and the commenters were reacting to some of the

1 discussion we had in the Federal Register notice of how that  
2 would be implemented and suggested that, in that area of  
3 probability, that they would believe that qualitative  
4 assessments should be -- continue to be allowed and, in  
5 fact, that would be the way that people would approach these  
6 issues, and therefore, the guidance that we were able to  
7 develop was really more consistent with what we might  
8 characterize as a negligible standard, that you know, it's  
9 -- not really sure whether or not there's a change or not,  
10 as opposed to minimal, which has been suggested as being  
11 somewhat larger than negligible.

12 If we were to try to push to a minimal increase in  
13 probability standard, we felt that would require  
14 significantly more effort to develop to span the full range  
15 of kinds of accidents, the kinds of facilities, the kinds of  
16 equipment that are involved, because we do have operating  
17 reactors, reactors decommissioning, non-power reactors, and  
18 part 72 facilities, and therefore, trying to develop  
19 guidance on what minimal would be in all these contexts  
20 would be difficult.

21 CHAIRMAN JACKSON: As I understand, Eileen, in the  
22 SECY paper, that you would intend to treat minimal increases  
23 in probability significantly differently than you would  
24 treat minimal increases in consequence.

25 MS. McKENNA: That's correct. I think we felt

1 that, in the area of consequences, there is a better basis  
2 for quantitative assessment of those, because you do have  
3 calculations that are done, whereas in the area of what's  
4 been called probability, the information in the FSAR now is  
5 generally qualitative, and to try to judge whether there was  
6 change in the probability resulting from the particular  
7 facility change, you know, could be very difficult to try to  
8 determine.

9 CHAIRMAN JACKSON: If you're going to use one word  
10 but treat it very differently vis a vis "probability" vice  
11 "consequences," is that consistent with the principle of  
12 good regulation, of clarity, and if you really mean  
13 negligible in one case and minimal in another, why wouldn't  
14 you just say so?

15 MS. McKENNA: We considered, certainly, the use of  
16 the word "negligible." I think they're both somewhat  
17 subjective terms.

18 Certainly, we understand it was kind of a --  
19 somewhat of a dilemma of saying that you use the same words,  
20 have different meanings or use different words and whether  
21 that's more confusing.

22 I don't think we have a strong view that "minimal"  
23 is a better word than "negligible."

24 MR. MATTHEWS: I should add that "negligible" was  
25 the staff's -- excuse me. I'll just add that "negligible"



1 was the staff's original proposed language because of some  
2 of those problems. So, to some extent, we've gone full  
3 circle in our thinking in that regard.

4 COMMISSIONER MERRIFIELD: It seems to me the  
5 salient point, though, is hasn't NEI basically said that,  
6 irrespective of whether we use "minimal," that they don't  
7 intend to change their guidance as it relates to  
8 "negligible"?

9 MS. McKENNA: Yes, I think that's true. There was  
10 some suggestion that, in the longer term, there might be,  
11 you know, willingness to work to develop something that  
12 might move us more towards "minimal."

13 I think the question maybe is whether that's where  
14 we want to spend the effort or whether -- you know, to look  
15 at other kinds of changes to the rule in the longer term  
16 rather than trying to bridge the gap between negligible and  
17 minimal increases in probability.

18 COMMISSIONER MERRIFIELD: The issue, then, is --  
19 we could go through the exercise of trying to establish what  
20 minimal is, but NEI has indicated no intention to adopt that  
21 since they want to stay with negligible.

22 So, it almost seems as if -- wouldn't we be going  
23 through an exercise that ultimately wouldn't prove fruitful  
24 for the industry?

25 MR. MATTHEWS: Under the current regulatory

1 framework, I think I would draw that conclusion, that there  
2 isn't a lot of fruit to be borne by this effort at this  
3 point in time, and it's probably ripe to be revisited at  
4 such time as we come up with a 50.59 to conform to more  
5 risk-informed regulatory framework under the options that  
6 are under consideration for that purpose.

7 CHAIRMAN JACKSON: Karen, were you going to make a  
8 comment?

9 MS. CYR: Well, I was just going to say -- I mean  
10 I have -- again, we're not to the final phase of this at  
11 all, but I have an underlying concern here that I would --  
12 that we would propose to include, first of all, a term  
13 within the same regulation in which we propose to have sort  
14 of drastically different meanings for them and also that we  
15 would propose to include a term "minimal" which we don't  
16 begin to be able to describe in even a qualitative sense  
17 what that means. I think there's some potential legal  
18 drawbacks from putting out a term out there that we do not  
19 --

20 MR. MATTHEWS: We agree.

21 MS. CYR: -- purport to try to define. I mean  
22 that's not to say we can't, but I mean I think we either  
23 have to decide --

24 MR. MATTHEWS: I think in the context of  
25 probability, we can define negligible, and NEI has --

1 COMMISSIONER McGAFFIGAN: Tell me how you do that.

2 COMMISSIONER DIAZ: May I interrupt? Because I  
3 was going to remain quiet, but I can't. It's easy to work  
4 with negligible, because negligible could be so close to  
5 zero that you can say zero.

6 MR. MATTHEWS: Or is indeterminate.

7 COMMISSIONER DIAZ: Right. I mean zero is 10 to  
8 the minus infinity; negligible could be 10 to the minus  
9 infinity plus 1 or 10 to the minus infinity plus 2 or plus  
10 three. It doesn't matter. It's just there.

11 So, the net effect is essentially de facto zero,  
12 because it's so close that you cannot determine whether it's  
13 zero or not, and I believe that what the Commission intended  
14 was to get off from that level, that we wanted something  
15 that was within the margin of error of calculations, within  
16 what is the margin of error of measurements, something that  
17 is not zero, okay, because negligible is so close to zero as  
18 you want to make it, and so, if you can define negligible, I  
19 don't see how you cannot define minimal. I'm really lost.

20 MR. MATTHEWS: I think the issue is one, since  
21 we're focusing the discussion here, with regard to  
22 probabilities, okay, that the limitation is there given the  
23 fact that the qualitative description of accident likelihood  
24 that is contained in many of the FSARs doesn't lend itself  
25 to quantification.



1           We have not gone through the process, for example,  
2 of articulating a probability or a likelihood associated  
3 with design basis events, but yet, those are many of the  
4 events that are being affected by the changes that might be  
5 proposed.

6           So, the application, while in theory you could  
7 apply the word "minimal" to a quantification of likelihood,  
8 that quantification doesn't exist in the FSAR.

9           COMMISSIONER DIAZ: So, in essence, you say, well,  
10 it has to be close to zero.

11          MR. MATTHEWS: If they can only deal with it  
12 qualitatively, I think, in essence, we're saying it has to  
13 be close to zero.

14          COMMISSIONER DIAZ: And I'm saying that, in real  
15 engineering life, if you cannot put a value on the  
16 probabilities on the original product, how can you put a  
17 value on the change, and so, you know, I mean you're dealing  
18 with semantics in here, and we're not dealing with  
19 semantics, we're dealing with real changes, okay, that  
20 actually should be allowed, because they are within the  
21 margin of error of any model, of any calculational  
22 technique, of any kind of measurement that you can perform,  
23 and those errors can be quantified, quote, "qualitatively  
24 quantified" as minimal, being in the range of the margin of  
25 error that exists in the original proposal of the design

1 basis, in the original accident scenario, in whatever you  
2 do.

3 I mean who says that the error is zero, and who  
4 can say that, if we just improve the computer and go to  
5 double precision, we get a different result? It's a  
6 negligible result. It's a negligible change. But it's all  
7 within the margin of error.

8 And what I thought we were trying to do is get off  
9 from that area, which is so close to zero that anybody can  
10 say the -- you know, the change is zero. So, I really fail  
11 to see what is the difficulty in defining minimum versus  
12 negligible.

13 You can define negligible. Minimal is three  
14 orders of magnitude, four orders of magnitude larger than  
15 negligible. It's that simple. Five orders of magnitude.  
16 You know, it's two order -- something.

17 CHAIRMAN JACKSON: Five orders of magnitude on 10  
18 to the minus infinity.

19 COMMISSIONER DIAZ: That's right. I'm sorry.

20 COMMISSIONER McGAFFIGAN: I'm not sure there was a  
21 question there, and there probably won't be a question in  
22 this either, but --

23 CHAIRMAN JACKSON: We'll go down the line with  
24 testimony.

25 COMMISSIONER McGAFFIGAN: You know, Commissioner

1 Merrifield asked the question, it's the logical question  
2 that comes out of the way this paper is presented, you know,  
3 why did we make any effort to try to get to minimal, and so,  
4 just for the record, we thought that the negligible standard  
5 which NEI implements in 96-07, I think, is so small -- they  
6 don't use the word "negligible," they use the word "so  
7 small" and then they describe so small that, you know --  
8 that there had to be something more to that, and this was in  
9 the context of the risk-informed reg guides that we were  
10 looking at at the same time, and we had Gary Holahan and  
11 company saying, to get down to 10 to the minus 7 delta core  
12 damage frequency, you can't even find it, you know, and  
13 there even was, in one of the early view-graphs in Reg.  
14 Guide 1.174 and 1.177, that whole series, there was -- I  
15 think there was a negligible category --

16 COMMISSIONER DIAZ: Yes.

17 COMMISSIONER McGAFFIGAN: -- which is below 10 to  
18 the minus 7 core damage frequency and there was the "so  
19 small" category -- or "very small."

20 COMMISSIONER DIAZ: Very small.

21 COMMISSIONER McGAFFIGAN: We all decided very  
22 small is above minimal. Minimal was less than small,  
23 certainly less than significant, greater than negligible,  
24 and Gary Holahan -- and we just --

25 CHAIRMAN JACKSON: Except that the real issue, it

1 strikes me, has to do with less that -- and not that I'm,  
2 you know, trying to disagree, but rather, as the analyses  
3 are done relative to design basis accidents, can you do  
4 those kinds of calculations, which is different than what is  
5 essentially severe accident modeling when you talk about the  
6 use of reg guides --

7 COMMISSIONER McGAFFIGAN: And I understand that.

8 MR. MATTHEWS: For which we do have, you know,  
9 many plants have an understanding.

10 COMMISSIONER McGAFFIGAN: I'm not sure what risk  
11 we run -- and you have proposed "minimal," to keep the word  
12 "minimal."

13 I mean reg guides are reg guides. You know, we  
14 endorse a reg guide, you know, that NEI has that uses the  
15 words "so small" and they don't choose to change it, and we  
16 say that's certainly less than minimal and, indeed, probably  
17 negligible, but you can still, as a matter of rule, make  
18 changes that you believe result in minimal changes and  
19 likelihood if that, indeed, is something you feel you can  
20 justify, and we can't enforce against you if you make a  
21 minimal change.

22 You know, I'm probably showing my bias, but I'll  
23 probably stick with minimal even though you guys haven't  
24 been able to define the difference between negligible and  
25 minimal. Maybe practice will define the difference between

1 negligible and minimal.

2 MS. McKENNA: I think where the real test comes  
3 goes back to the Chairman's comment about the practical  
4 effects, is that where you run into these questions of  
5 minimal, as you say, and a particular licensee says I've  
6 made this change and I consider that to be minimal, it's how  
7 is the inspector going to look at that and are they going to  
8 have the same view of the matter, and I think that's where  
9 some of the difficulty arises, is we are trying to have a  
10 rule and have to revise existing guidance for inspectors, as  
11 well, to kind of steer them as to when they should look at  
12 something and say, well, this looks like it's gone too far,  
13 it's more -- really has fallen beyond that minimal, and it's  
14 drawing what that line is that I think is giving us the  
15 problem.

16 COMMISSIONER McGAFFIGAN: Well, I think we'll know  
17 it when we see it, to be honest with you.

18 CHAIRMAN JACKSON: That's the whole point, though,  
19 is the issue is how do you ensure some consistency vis a vis  
20 inspection and, you know, enforceability, not in the  
21 negative sense of the word but something that provides some  
22 clarity with respect to what you enforce against.

23 I mean I'm probably the neutral party here, but I  
24 honestly believe you have to understand that you have  
25 something that the staff can actually use.

1           COMMISSIONER McGAFFIGAN: My problem with it is,  
2 as I understand it, this is not an area that's highly  
3 fruitful from an enforcement perspective, and if we do spend  
4 our time arguing with licensees as to whether a change which  
5 they dutifully report through the FSAR update process was  
6 more than minimal or met a minimal test, that may not be the  
7 highest and best use of our resource. If we argue about  
8 them whether it's more than negligible, it may be not the  
9 highest and most fruitful area for enforcement. So, I don't  
10 know.

11           CHAIRMAN JACKSON: Commissioner?

12           COMMISSIONER MERRIFIELD: Well, this discussion  
13 reminds me of a couple of examples. One of them was when I  
14 was working on Capitol Hill as a new young staffer -- and  
15 Commissioner McGaffigan may appreciate this.

16           I had a discussion with the Senate leg counsel,  
17 and the Senate leg counsel said, you know, the thing you  
18 need to remember about legislation is you can define the --  
19 Congress can define the moon as being made of green cheese,  
20 but that doesn't mean it's so, and from a practical  
21 perspective, I understand the comments made by Commissioner  
22 Diaz and Commissioner McGaffigan about trying to have a  
23 difference between negligible and minimal, and I applaud it,  
24 and I agree perhaps that's the direction we should think  
25 about going in the future, but from a practical consequence,

1 if we have -- if we're making an effort to change something  
2 which is not going to be -- which the industry isn't going  
3 to take advantage of, it does raise a question in my mind  
4 about pursuing that.

5 Secondly, unlike Commissioner McGaffigan, perhaps  
6 the attorney in me, I'm very uncomfortable about having  
7 non-defined terms. I don't think we should just, you know,  
8 lay out minimal there without having an ability of our  
9 inspectors to understand what the difference between that  
10 and negligible is.

11 I mean, you know, it's easy for us to say, well,  
12 it's sort of like pornography, you know it when you see it,  
13 but you know, our court system, with that particular  
14 example, has lots of court cases about what --

15 CHAIRMAN JACKSON: It wouldn't be a difference  
16 between minimal and negligible. It would be a difference  
17 between minimal and zero, because zero is the current  
18 standard, and the standard you'd be moving to would be  
19 minimal.

20 COMMISSIONER McGAFFIGAN: But the standard --  
21 we're not defining negligible except we're letting NEI  
22 define it by saying it's so small and then whatever words  
23 that follow, and then we're saying -- if we put negligible  
24 back in, we're going to say, yep, NEI defined it well enough  
25 and if a licensee follows that, they'll be safe.



1           We're not defining the term "negligible" if we  
2       substitute negligible for minimal. We're letting NEI define  
3       it and saying that's good enough and we're getting a treaty.

4           If we put "minimal," NEI apparently isn't going to  
5       take the advantage of that and they're going to stick with  
6       their current guidance and most people will probably stay  
7       with that, but somebody might be brave enough someday to say  
8       no, there's more to it than this and here is an opportunity.

9           COMMISSIONER DIAZ: The fact is, if I might pounce  
10      on that, this is a very diverse industry, and you know, even  
11      if NEI adopts a position, that doesn't mean the utility is  
12      going to abide by the "negligible" term.

13          So, you know, playing devil's advocate, it could  
14      very well be that they decide that I'm going to risk it, I'm  
15      going to go into the minimal if we -- if the Commission  
16      allows that range.

17          COMMISSIONER McGAFFIGAN: I think negligible is  
18      something more than "so small." I mean NEI has said it's so  
19      small. Negligible, according to Gary Holahan, was 10 the  
20      minus 7 core damage frequency.

21          CHAIRMAN JACKSON: But you keep talking about  
22      that. The core damage frequency, 10 to the minus 7, that is  
23      a different --

24          COMMISSIONER McGAFFIGAN: That's a significant --

25          CHAIRMAN JACKSON: The point is we should have

1 risk-informed 50.59 to start with. Then we would be using  
2 Reg. Guide 1.174.

3 But we decided we couldn't do that, we're going to  
4 stay in design basis space, and then you're going to sit and  
5 try to graft something onto a design basis rule that was  
6 developed in a completely different context, and it can  
7 sound nice, sitting here on a table in Washington, but when  
8 it really comes down to people who have to be out in the  
9 field, who in the end are the ones that carry out the  
10 regulatory program, you haven't gained anything, and that's  
11 not to say whether "minimal" should be the word or  
12 "negligible" should be the word.

13 The issue is whatever the word is has to be well  
14 enough defined that it can be consistently implemented in  
15 the field, and Reg. Guide 1.174 for the existing 50.59 is  
16 not going to save us, and so, that's my basic point. You  
17 may not like it, but it's a fact.

18 MS. McKENNA: Second bullet, while our own -- kept  
19 the word "minimal" in there, we did suggest a few other  
20 changes to the rule language, and I've listed them here.

21 I think partly as a result of our discussions with  
22 ACRS and others who were asking, you know, probability, you  
23 know, what does that really mean in this context, we've  
24 decided that frequency of occurrence rather than probability  
25 of occurrence was really a more representative term of how

1 initiating events such as accidents in the FSAR are really  
2 considered and evaluated, and so, we thought that was a  
3 better word than "probability" in that instance.

4 For malfunction of equipment, we really felt that  
5 likelihood of occurrence rather frequency was a better  
6 choice because you have different equipment that functions  
7 in different ways, some is on demand, some has an operating  
8 type of thing, and that frequency wasn't really the metric,  
9 if you will, of interest but more what's the chance of not  
10 performing the way you expect it to?

11 The last change that we suggested was to move from  
12 the language of equipment important to safety to the  
13 language of systems, structures, and components important to  
14 safety.

15 This really arose out of our review of the Part 72  
16 issues, where that is the terminology that is used, and in  
17 the interest of trying to make things as consistent as we  
18 could, that question arose as to whether Part 72 should say  
19 equipment or 50 should say systems, structures, and  
20 components.

21 Looking more broadly through both Part 50 and Part  
22 72, we really see that equipment is kind of the unusual  
23 occurrence of language, that SSC is much more common, and we  
24 felt that it would be appropriate to make it conform.

25 We didn't see that this would cause any difficulty

1 in implementation, because really, that's, you know --  
2 equipment and SSC really are fairly similar in their scope  
3 of what's included, and we just felt it would help us with  
4 the consistency of language but not cause us any other  
5 problems for implementation.

6 The next slide, please.

7 The title of this is "Margin of Safety." In other  
8 contexts, we've sometimes started referring to it as  
9 criteria seven, which in the -- breaking out the existing  
10 criteria into their individual statements puts this  
11 particular criteria s the seventh one in the list.

12 As you recall, in the notice, we solicited comment  
13 on a wide range of options from the option that the staff  
14 had initially offered in SECY 98-171, the option of deletion  
15 of margin as a separate criteria, and a whole set of options  
16 dealing with various results of analyses, whether they  
17 focused on a particular fission product, barrier responses,  
18 or particular system functions, we tried to give enough  
19 variability so that people could provide their views as to  
20 what was important and how it ought to be addressed.

21 We also spoke to different approaches about how  
22 much change should be allowed, whether there should be  
23 essentially a zero change or approach to limits in some --  
24 whether negligible or directly to the limit approach.

25 We also offered in the proposed rule -- we brought

1 up the issue of controlled methods, as to whether there  
2 should be language in the role that specifically spoke to  
3 how you would control evaluation methods, whether you had  
4 language that said methods needed to be approved in some  
5 manner or you left that to other processes to control that,  
6 and in the comments, as you presumably saw, we got quite a  
7 range of views, and I've listed here in the slide the --  
8 noted the NEI proposal, since it did have support of a large  
9 percentage of the industry, as well, we wanted to give it  
10 full consideration, and so, we did look at this very  
11 carefully, we sent it out to our other offices and regions  
12 to get feedback on whether they thought this criteria would  
13 be suitable for the purpose in 50.59, and got a number of  
14 comments, and I think the primary comment we had was that  
15 people thought that, by the language here, the design basis  
16 limits, directly related to -- and I've summarized it here  
17 on the slide as fission product barrier integrity.

18 In their proposed language, they actually itemized  
19 fuel clad, system pressure boundary, and containment  
20 boundary as the proposed criteria, but many of our staff  
21 were concerned that the directly related to the barrier  
22 integrity, that that narrowed the set of information that  
23 would be controlled by this criteria too much and that  
24 certain things would fall through the cracks, if you will.

25 CHAIRMAN JACKSON: Let me ask you this. Are there

1 examples of changes that would be allowed under the NEI  
2 guidance that wouldn't be allowed under your proposal?

3 MS. McKENNA: Part of it is a function of how you  
4 look at the whole set of the criteria and how this  
5 particular one would be implemented.

6 Depending on how they're implemented, it's  
7 possible that there would be no change, that our criteria  
8 and their criteria might get you to the same place, but it  
9 may not.

10 It kind of depends if you look at the directly  
11 related to a fission product barrier and say, well, the  
12 change I'm making is in this system over here, which doesn't  
13 relate to that, and you kind of leave the process before you  
14 get to the question that we've proposed be offered, which is  
15 the system functional capability.

16 I think it's been mentioned that other criteria  
17 might also be -- trip particular changes. Say it was a  
18 change to -- we've talked about things like battery systems  
19 or -- the way this is worded would not really arise if  
20 they're not directly related to the barrier integrity.

21 What else would capture it? Perhaps tech specs.  
22 Perhaps other criteria.

23 CHAIRMAN JACKSON: Well, I guess that was going to  
24 be my next question. Is your proposal consistent with the  
25 rest of our body of regulations -- for example, the general

1 design criteria of Appendix A and tech specs, and is NEI's  
2 proposal consistent?

3 MS. McKENNA: I think they are both consistent.  
4 It's kind of a question of degree.

5 In order to reach to the barrier integrity, you  
6 have to go through, if you will a consideration of are your  
7 systems performing in the way you expect them, but it's that  
8 level of detail or rigor, perhaps, of the analysis that is  
9 really what's at issue.

10 I think the body of the regulations do focus on  
11 fission product barriers, they do focus on design basis,  
12 they focus on the systems that provide these functions.

13 So, I think, in that sense, both approaches are  
14 consistent with the regulations. It's really how far down  
15 you want to go.

16 COMMISSIONER DIAZ: If I may, I'm going to use  
17 something the Chairman said regarding the importance of  
18 definition, and you look at this modification by the staff,  
19 you know, and you look at -- as well as support functions,  
20 and I found that very undefined.

21 I mean if you come and tell me these are, you  
22 know, safety significant support functions or these are  
23 risk-significant support functions or you will bound support  
24 functions, okay -- because you know, support function could  
25 go all the way to supporting bodily functions, and we're not



1 into that business, and so, you know, again, is, you know,  
2 the issue of definition, okay, so that we can actually put  
3 them in terms that people can work with them, and support  
4 functions is undefined.

5 I mean, you know, support functions of protecting  
6 the barriers?

7 So, again, you know, I find a little bit of a lack  
8 of contact in here, and first, we want to define something,  
9 and then we are defining -- and then we add something that  
10 broadens the scope enormously, and I cannot understand why.

11 MS. McKENNA: Okay. I think the intention with  
12 the support functions, if I could speak to that point, was  
13 it's those functions -- when you're talking about the  
14 systems that directly protect the barriers, and those would  
15 be your mitigation systems and protection systems, that kind  
16 of thing, and that in order for those systems to perform,  
17 they may need cooling water, they may need electrical power,  
18 they may need air, these kinds of things, and that those are  
19 the support functions that are necessary for those systems  
20 that perform that.

21 COMMISSIONER DIAZ: But it doesn't say so, and  
22 that's precisely what the point is. It doesn't say so. It  
23 needs to be narrowed down.

24 MS. McKENNA: We mentioned we were kind of working  
25 up to the wire to try to get agreement within the staff on

1 an approach and were perhaps not able to fully amplify how  
2 --

3 COMMISSIONER DIAZ: But that's your intent.

4 MS. McKENNA: Yes.

5 MR. MATTHEWS: That's our intent, and we are  
6 working within the ambit of the FSAR and the design basis.  
7 So, it isn't an unlimited list.

8 COMMISSIONER McGAFFIGAN: Madam Chairman, this  
9 bears on a question you asked, but I think we need something  
10 more from the staff on this issue than broad sentences such  
11 as the staff was concerned with the language --

12 CHAIRMAN JACKSON: What page are you working off  
13 of?

14 COMMISSIONER McGAFFIGAN: I'm on page 5. The  
15 staff was concerned that language, quote, "directly related  
16 to fission product barrier integrity" might be too narrow.  
17 I mean I think you're going to have to define how your  
18 broadening helps us and what it gets for us and why that's  
19 important to us.

20 I have the same concern as Commissioner Diaz about  
21 this phrase that shows up in the rule or any system  
22 necessary to support the functions of these SSC, because I  
23 mean you may -- you know, it's a very broad phrase, unless  
24 you have some agreement as to what it means.

25 I also don't totally understand the margin of

1 safety, fission barrier criteria now when it talks about the  
2 result in the design basis capability being exceeded or  
3 altered.

4 If it moves in the right direction, I mean if they  
5 make a change and it's going to make a fission product  
6 barrier better, why do they have to come in and ask for our  
7 permission to do that?

8 If it's clearly -- we're not talking negligible,  
9 we're not even talking positive in bad space. We're talking  
10 negative in bad space. It's good. Why do they have to come  
11 in and get a change?

12 MR. MATTHEWS: If it's a design basis capability,  
13 it has some importance in our regulatory structure with  
14 regard to the review that was afforded it at the time that  
15 we initially licensed the plant.

16 So, if it's truly a design basis capability, then  
17 it's an important parameter.

18 So, the alteration of that parameter and the  
19 methods for calculating the direction that it moved in are  
20 important, and I think, if it's truly a design basis  
21 capability or limit, the staff wants to be involved in that  
22 reconsideration of moving it.

23 MR. MATTHEWS: Even if it's wildly positive, and  
24 they're going to report it in their FSAR update pursuant to  
25 10 CFR whatever.

1 We rarely see wildly positive changes being  
2 desired in design.

3 COMMISSIONER McGAFFIGAN: I understand the being  
4 exceeded. It's being altered that's giving me --

5 MR. MATTHEWS: And I think the altered is --

6 COMMISSIONER McGAFFIGAN: You might as well say  
7 being exceeded or changes in any way. I mean it really is  
8 being altered, because you don't need both.

9 MR. MATTHEWS: Well, it depends -- if you're  
10 really at a design basis limit that has importance with  
11 regard to safety, how you choose to decide that it can be  
12 altered is a critical part of the decision of the  
13 acceptability of which way it moved.

14 I'll give you an example.

15 In NEI, in their proposal, just looking at fission  
16 product barrier performance, they were the ones who even  
17 came up with the term "or altered" by virtue of the fact  
18 that, when they look at something like fuel cladding and  
19 certain performance parameters there, there isn't any  
20 margin. It's very close to the limit.

21 COMMISSIONER MERRIFIELD: I think what  
22 Commissioner McGaffigan is alluding to, though, is "or  
23 altered" subsumes "exceeded." We can cross out "exceeded  
24 or" and it's the same result.

25 MR. MATTHEWS: You could do that, I think.

1 COMMISSIONER McGAFFIGAN: In terms of English, if  
2 you and NEI agree --

3 MR. MATTHEWS: I was reacting more to thinking you  
4 were concerned that we were being too restricted by saying  
5 --

6 COMMISSIONER McGAFFIGAN: Well, I was.

7 MR. MATTHEWS: -- altered.

8 COMMISSIONER McGAFFIGAN: I was trying to follow  
9 the logic of the English. I mean if you and NEI enter an  
10 agreement that any change in this area is so fundamental  
11 that it has to be reviewed -- I see Tony shaking his head --  
12 then --

13 MR. MATTHEWS: Then altered would be sufficient  
14 terminology as opposed to exceed.

15 COMMISSIONER McGAFFIGAN: -- altered is  
16 sufficient, because exceeded is subsumed, as Commissioner  
17 Merrifield said, as a matter of English, as a matter of  
18 physics.

19 CHAIRMAN JACKSON: Right. But presumably, these  
20 are the kinds of things that can be -- I mean I hope we're  
21 not going to sit here and --

22 COMMISSIONER McGAFFIGAN: No, but it's important  
23 to understand them.

24 CHAIRMAN JACKSON: Mr. Matthews, would you like to  
25 -- I mean Ms. McKenna.

1 MS. McKENNA: Yes. Okay. Let me pick back up.

2 We've been talking about the NEI proposal and why  
3 the staff chose to take a somewhat different approach to  
4 this. I think I mentioned the concern on the "directly  
5 related" may not include certain information that may not  
6 protect the integrity of the design.

7 So, staff tried to take the -- some of the essence  
8 of the NEI approach.

9 I think the idea of focusing on the design basis,  
10 looking at protection of the barriers as very solid concepts  
11 that are consistent with our regulatory process, and try to  
12 address where we thought there might possibly be some gaps,  
13 and that was by taking it to the system functional level  
14 rather than at the barrier response level itself, and then  
15 part of that was, I think, was a recognition that we see in  
16 tech spec space, is that, you know, to say a system that  
17 provides -- that has a function to protect a barrier will  
18 not function unless those other systems that are necessary  
19 for it are also functioning.

20 So, that was the reason for including the language  
21 about support functions, is really -- I would agree that we  
22 may able to tighten that in -- to be clear that it is -- and  
23 I think we tried to do it by saying those that support the  
24 --

25 CHAIRMAN JACKSON: If it's a safety-related piece

1 of equipment, then you need that system to operate, but --

2 DR. TRAVERS: And we have a lot of experience in  
3 that in the context of tech specs and the supporting  
4 functions that cascade from the principle system at issue.

5 MS. McKENNA: Yes, that's correct.

6 COMMISSIONER DIAZ: And of course, when you did  
7 this, you considered the fact that the majority of  
8 commenters did favor deletion of the margin of safety  
9 criteria in favor of just having it subsumed by the tech  
10 specs, which is the basis for where all of these margins of  
11 safety are, but your paper doesn't discuss that.

12 It includes it in the end, but you did not  
13 consider that as an option.

14 MS. McKENNA: We did not consider it as an option,  
15 because we were not convinced that the other criteria and  
16 the tech specs were sufficiently comprehensive for all of  
17 the facilities that we could delete it.

18 There is a range, obviously, of what's in tech  
19 specs from plant to plant, and certainly, if you look at the  
20 statement here about the design basis capabilities, system  
21 functional requirements, some of that information,  
22 presumably for the more important systems, is going to be in  
23 the tech specs, but it may not be complete.

24 So, we were looking to make sure, through this  
25 criteria, we would capture anything that was not complete in

1 the tech specs.

2 The tech specs are already, obviously, a criteria  
3 that would immediately require the review, and if that was  
4 the case, then you would never -- a licensee would never  
5 have to look at these questions.

6 The first test they usually have is is it a tech  
7 spec change, and if the answer is yes, you kind of go  
8 immediately --

9 COMMISSIONER DIAZ: It's demanding more of the  
10 good because of the bad?

11 MS. McKENNA: I don't know as it requires more.  
12 As I said, I think in practice, people look at the tech spec  
13 question first. It's kind of straightforward, probably, to  
14 tackle, and if it's in the tech specs, you know, there you  
15 are. You don't have to go try to answer this question.

16 So, it would only be those plants that it was not  
17 in the tech specs that you might get here to try to answer  
18 is there --

19 COMMISSIONER DIAZ: Another interesting point --  
20 will that be clear if it's in the tech spec space, you don't  
21 need to argue the margin of safety?

22 MS. McKENNA: I think that's pretty clear.

23 CHAIRMAN JACKSON: But there's variability, is  
24 what you're saying, with respect to how comprehensive the  
25 tech specs are?



1 MS. McKENNA: It was variability as to whether a  
2 particular change at a licensee would affect a tech spec or  
3 not, because they don't all have the same tech specs.

4 COMMISSIONER DIAZ: That was not clear to me, but  
5 if it's clear, then obviously it's good.

6 MS. McKENNA: Yes. I think the paper presented  
7 the language that we had offered as the criteria seven.

8 I think we've kind of talked about most aspects of  
9 it, and I won't dwell on that unless there are additional  
10 comments that -- I think we've gotten some sense from the  
11 Commission of where some of the questions are on this  
12 particular item.

13 MR. MATTHEWS: I might just stop you for a moment  
14 --

15 MS. McKENNA: Sure.

16 MR. MATTHEWS: -- and go to the actual proposed  
17 wording of the rule.

18 MS. McKENNA: It's also in the paper, on page 5.

19 MR. MATTHEWS: Yes, it's on page 5.

20 The first test is whether -- in terms of whether a  
21 change test or experiment is allowed as to whether or not,  
22 to make that change, you would have to make a change to the  
23 tech specs, in which case if you needed to change the tech  
24 specs, you couldn't make it under 50.59.

25 But I mean that's clearly stated there as the

1 first stop.

2 COMMISSIONER DIAZ: It is an additional  
3 requirement rather than a release from requirement.

4 MR. MATTHEWS: It's an additional limitation.

5 COMMISSIONER DIAZ: That's right.

6 MS. McKENNA: Okay.

7 I think we're onto the next slide now.

8 I alluded to this, although we may not have stated  
9 it quite this way, but criteria for review under this  
10 statement is whether the design basis capability has been  
11 exceeded, and we would expect that, while we refer to the  
12 systems, structures, and components, we believe that, in  
13 general, it would be system functional level that would be  
14 what you would look at, rather than component, because you  
15 don't usually have particular functions that are unique to  
16 components, they usually are a matter of how the system  
17 functions.

18 The next bullet is what we've included in here as  
19 criteria eight as a question of control of evaluation  
20 methods, and this really arose from our approaches on  
21 providing the definitions of what's changed at the facility  
22 are as described, is saying that that includes the  
23 information in the FSAR that gives the analysis, that  
24 demonstrates how the requirements are met, and when you  
25 start looking at changes to the methods and analyses

1 themselves rather than changes to the facility, the criteria  
2 that are there don't always help you decide when, you know,  
3 you're making a change that really might require review.

4 For example, if you're looking at a method that  
5 perhaps has removed conservatism or included some additional  
6 assumptions, if you say, well, how did that change my  
7 consequences or how did that affect the system capabilities,  
8 your analysis may predict you have better performance, and  
9 therefore, the criteria we have don't really help answer  
10 changes to methods themselves, and that was part of the  
11 rationale for saying we really need a different standard to  
12 deal with changes to evaluation methods.

13 We had considered in the proposed rule saying  
14 basically that all methods had to be reviewed and approved.

15 In this paper, we included a concept of minimal to  
16 try to deal with changes that -- you know, there may be a  
17 change as a result of going from rev three to rev four of  
18 some model, things of that nature, that if you just said,  
19 well, you know, if they were previously reviewed and  
20 approved, can't change them at all, we were looking to  
21 provide some degree of latitude on changes to methods but  
22 didn't want to just say make any changes you want, because  
23 we do feel that how you demonstrate that you satisfy the  
24 criteria is important.

25 CHAIRMAN JACKSON: How do I inspect or enforce not

1 more than a minimal change in method?

2 MS. McKENNA: This is an area where -- I think  
3 probably the next bullet -- is we do feel we will need to  
4 give some guidance on that.

5 I think we were looking in terms of the degree of  
6 change in the result when you look at kind of the old method  
7 or the new method and look at your results, how much have  
8 they changed.

9 COMMISSIONER DIAZ: But going back to Commissioner  
10 McGaffigan's question, if you're using an improved method  
11 that give you a much higher, you know, level of confidence,  
12 even if the result is -- you know, might be more than  
13 minimal, better, is that not acceptable?

14 MS. McKENNA: I guess it goes back to the question  
15 of what you're doing -- the purpose of that analysis, and  
16 this gets into the issues of -- you know, that usually  
17 analysis changes are not done just for the purpose of doing  
18 a more refined analysis, there usually are other changes or  
19 issues that are prompting the change in methods, and I think  
20 the concern we've had is the use of changes and methods to  
21 perhaps mask the effects of other changes, that if you look  
22 at -- you know, if you make a change to method and make a  
23 change to your plant, you say, well, my answer -- you know,  
24 there's no change in my result, therefore everything's fine,  
25 but there was a change that was made that perhaps had some

1 effective interest.

2 COMMISSIONER DIAZ: I think that's wonderful, but  
3 on the same token, in the same rule, you have to be able to  
4 allow for the positive change.

5 MS. McKENNA: Yes.

6 COMMISSIONER DIAZ: For the new method, for the  
7 new model, for the new, you know, calculation scheme that  
8 comes along, and you don't want to punish people because  
9 they now have a better method and they want to use it.

10 So, you know, there is that variability --

11 MS. McKENNA: Yes.

12 COMMISSIONER DIAZ: -- and that's where the word  
13 "minimal" comes in.

14 MS. McKENNA: Uh-huh.

15 COMMISSIONER DIAZ: Okay. Thank you.

16 COMMISSIONER McGAFFIGAN: Are all the terms in  
17 this new criterion well-defined?

18 I mean I went back and looked back at your rule,  
19 and I know some of these terms, if you're only going to  
20 define them in the reg guide, that may prove to be  
21 problematic, because I'm not sure you and the industry have  
22 total agreement, not just on the word "minimal," but you  
23 know, you may -- method of analysis may be subject to  
24 interpretation, design basis values.

25 You guys are having a long discussion as to what

1 design basis is.

2 So, there may be other problems in this criterion  
3 that are going to take some time. I'll be interested in  
4 NEI's comments later.

5 CHAIRMAN JACKSON: Maybe I should move that we  
6 just table doing the 50.59 rule-making. Want to vote on  
7 that now?

8 COMMISSIONER McGAFFIGAN: Table doing it? Just  
9 quit?

10 CHAIRMAN JACKSON: Yes, just quit.

11 COMMISSIONER McGAFFIGAN: Do we endorse NEI 96-07  
12 as part of it?

13 CHAIRMAN JACKSON: Just quit. It will iterate  
14 forever. No takers. Okay. Well, then remember what Mr.  
15 Matthews told us at the beginning.

16 MR. COLLINS: I think, just as a general comment,  
17 I think we can make this so hard that you can't get to the  
18 point where we all realize that the agency and the industry  
19 needs to provide for maintaining safety, reducing  
20 unnecessary burden. It's a matter of degree, and it's a  
21 matter of how much detail do we need at this particular  
22 point in time.

23 MS. CYR: But at the same time, you have to have  
24 the sufficient information in the regulation that you have,  
25 in fact, given adequate notice to the parties about what it

1 is that you as a regulator are propounding as a rule. I  
2 mean I think there has to be enough definition.

3 COMMISSIONER McGAFFIGAN: Was this criterion, this  
4 new criterion, which I guess you say is a subpart of the old  
5 margin of safety criterion, noticed that we might have a  
6 criterion on methods in our final rule?

7 MS. McKENNA: Yes, we did. In the proposed rule,  
8 in the section on margin, we broke it into kind of three  
9 pieces.

10 The first part had to do with kind of what  
11 parameters or information would be included in it. The  
12 second was how much it might change, and the third was  
13 whether there would be language on evaluation methods.

14 MR. COLLINS: Chairman, on your previous point, I  
15 think I'm a little risk going down this road, but there is  
16 -- looking at the opportunity to, as you mentioned,  
17 risk-inform part 50, which opens up other doors, depending  
18 on the Commission's direction to the staff under that  
19 particular paper, there is a previous precedent that the  
20 industry has provided, which is the NSAC-125 document, which  
21 does get you a certain latitude, if you will, that the staff  
22 previously has not adopted.

23 There is a position that has some history to it  
24 there if, in fact, the Commission were to decide that the  
25 real opportunities for 50.59 were in the risk-informing or

1 risk-basing part 50 or portions of part 50 in the future,  
2 and that's a different track than we have taken before, but  
3 it is one that I think we have to pass through given how the  
4 processes are currently lining up.

5 MS. McKENNA: Perhaps we can move on to the next  
6 slide and talk about a little different aspect of this  
7 paper.

8 As the Commission knows, in the proposed rule, we  
9 also put out a number of proposed changes on part 72, and in  
10 particular, section 72.48, which is the counterpart to 50.59  
11 in part 72 for fuel storage facilities.

12 Those changes also included changes with respect  
13 to FSAR updating for these facilities and to extend the  
14 authority from the licensees to certificate-holders under  
15 part 72.

16 In the comment period, we did get a number of  
17 comments with respect to the changes we had offered in part  
18 72, and number of them suggested that there be closer  
19 connection between the language of 72 and in part 50 even  
20 beyond what we had offered, and in fact, many of the  
21 comments went to the parts of the rule that were already  
22 there that we weren't proposing to revise but that were kind  
23 of within those same general sections of the rule, and a  
24 couple of them, in particular, that I've listed here, where  
25 we had comments, in 72.48, there are, in addition to the



1 same seven, if you will, 50.59 criteria, there are two  
2 additional criteria, one being significant occupational  
3 exposure and the other being significant environmental  
4 impact, and commenters on part 72 said that they really felt  
5 that, in some ways, this was disproportionate, that having  
6 those criteria for part 72, where they don't exist in part  
7 50, you know, didn't really reflect the relative  
8 significance of the kinds of facilities and that, at least  
9 in the case of the certificate holders, it would not be  
10 possible to judge the environmental impact, because they  
11 were -- they don't have that kind of document to judge it  
12 against.

13 Staff is supportive of the commenters' desires to  
14 make some adjustments in the language, and you'll see that  
15 in the proposed language that was offered to you.

16 The other issue had to do with some of the  
17 specifics about the FSAR updating, for example, there's a  
18 12-month period for submitting the updates, whereas in  
19 50.71(e), it can be up to 24 months, and again, it was a  
20 question of whether there was a need to have the different  
21 frequency, and I think the staff view at this point is that  
22 it's not necessary to have 12 months for one and 24 for the  
23 other, so we're proposing to go to 24 for all of them.

24 CHAIRMAN JACKSON: How will we monitor licensees'  
25 part 72 performance?

1 MS. McKENNA: I might ask Marty to address that.

2 MR. VIRGILIO: Chairman, we have an inspection  
3 procedure, we have implemented that procedure, and we intend  
4 to continue to do that in the future.

5 With these changes, if approved by the Commission,  
6 we would have to modify the procedure. We would need also  
7 to modify the guidance that would also supplement the  
8 implementation of this new method, but we've got an existing  
9 72.48.

10 We've recognized fewer changes. If you were to  
11 compare it to a reactor, there are just a handful of changes  
12 at the facilities, mostly during the design and start-up  
13 phase.

14 So, we've got experience in implementing the rule  
15 and inspecting against the implementation.

16 CHAIRMAN JACKSON: Okay.

17 COMMISSIONER McGAFFIGAN: Are you going to address  
18 part 71?

19 MS. McKENNA: Yes, that's the next slide, if there  
20 are no more further questions on part 72.

21 Some of the other comments received had to do with  
22 part 71 -- that is, transportation requirements, and these  
23 arose primarily for those casks that serve both a storage  
24 and a transportation purpose, and the comment was really,  
25 well, you're going to allow us to do it under part 72, but

1 if there is a transportation function, you know, we don't  
2 have that flexibility under part 71.

3 Again, the staff, I think, agrees that it would be  
4 appropriate to look at this area further, and I think the  
5 preliminary suggestion is that we would like to add language  
6 to address spent fuel transportation packages for domestic  
7 use.

8 The thinking was, to go more broadly in part 71,  
9 timing and our knowledge base may not be there to cover all  
10 the kinds of packages that might be covered by part 71,  
11 limiting it to domestic shipment, because of the IAEA  
12 standards and whether we -- which don't have this kind of  
13 provision within them.

14 So, the recommendation is to go with the proposed  
15 rule to make these kind of changes in part 71.

16 COMMISSIONER MCGAFFIGAN: Could I ask -- when we  
17 started this whole process, the notion was we were going to  
18 look at all these change mechanisms, I thought, outside of  
19 high-level waste, which is being treated in part 63. Why  
20 wasn't this part 71 thing rounded up as part of our proposed  
21 rule-making this time?

22 MS. MCKENNA: I think part of it was the IAEA  
23 consistency that was being looked at, and then I think we  
24 really came to recognize the dual use, but perhaps we felt  
25 that we needed to be a little more flexible.

1 I don't know if you have anything else, Marty.

2 MR. VIRGILIO: Commissioner McGaffigan, we were  
3 also looking at the fuel facilities, part 70.72. We just  
4 put something out on the web yesterday soliciting additional  
5 comments, and what we've put out is an option that -- a  
6 proposed option that looks a little bit more like what we  
7 have here on 50.59 and an alternate version that's, I think,  
8 adjusted to recognize that we don't have FSARs, but we're  
9 using ISAs, slightly different.

10 The other area where we have a change mechanism is  
11 for the GDPs.

12 It's 76.68, and we chose not to approach that at  
13 this time because of the significant upgrading of the FSAR  
14 that's ongoing in process and also the conformance plans  
15 that these facilities are working to meet the agreements  
16 that we struck with them as part of the process of  
17 certifying those facilities.

18 So, we have looked broadly, and we've made some  
19 decisions about what we would and would not get into at this  
20 time.

21 MS. McKENNA: If there are no further questions on  
22 part 71, I'll move on to the next slide.

23 We were looking at the question of implementation,  
24 and we're recognizing that there is some existing guidance.  
25 In 96-07, we have some existing inspection guidance that

1 whatever kind of rule results would likely require some  
2 changes to those documents.

3 I also noted that, in the area of Part 72, there  
4 really is no specific guidance other than the inspection  
5 guidance that Marty referred to, and we felt it might be  
6 useful to try to see if we could develop such a thing, and  
7 we would hope, perhaps, that we could work with NEI on  
8 seeing whether you could modify, perhaps, 96-07 to speak to  
9 part 72 facilities or whether you would want some separate  
10 type of guidance.

11 You know, as I think Mr. Matthews mentioned, the  
12 question of the pervasiveness of the use of the rule, that  
13 it's not only within the licensees, it's also within the  
14 staff, all of our inspection staff, a number of our project  
15 staff, technical staff, all encounter 50.59 in their course  
16 of business, and there is going to be a training and  
17 implementation period for the staff, as well.

18 So, these kind of considerations lead to the  
19 recommendation that we had in the paper that would really be  
20 for an 18-month time period as to when a licensee must have  
21 made its changes to the rule.

22 We also recognize that there are -- because many  
23 of the changes that were being offered do provide more  
24 flexibility, that some licensees might wish to take  
25 advantage of that flexibility earlier.

1           So, we didn't want to prevent that from happening  
2 but also wanted to allow sufficient time so people could  
3 have the guidance in place, have all the people trained that  
4 needed to be trained, revise procedures as necessary.

5           So, that's why we proposed the 18-month period for  
6 it to become effective but would include within the rule the  
7 provision that, if a licensee chose to do it sooner, they  
8 could do so.

9           We had the part about notifying us. Basically,  
10 we'd need to know under what set of rules that licensee is  
11 and how we should then look at their operation, either under  
12 the old rule or under the new rule, and so, that was the  
13 rationale for that proposal.

14           COMMISSIONER MCGAFFIGAN: If NEI hasn't completed  
15 96-07, rev whatever, and we haven't put out guidance, how do  
16 they get to the new rule?

17           When we had the discussion last summer, I remember  
18 Tony Pietrangelo and Harold Ray and company -- we were  
19 reaching the tree on consequences, minimal increase in  
20 consequences, which is different from 96-07 at the moment,  
21 but I think we're now all converged there, and that's good,  
22 but if they -- is that in the can?

23           I guess I'll ask NEI at the next panel, but they  
24 know how to change that part of 96-07 on consequences very  
25 quickly and get it out there?

1 MS. McKENNA: I think certain parts -- and that's  
2 probably one -- I think that the answer is yes. The  
3 question of whatever criteria seven looks like -- that may  
4 or may not be a longer period for development of guidance,  
5 and it was hard to judge exactly how long the guidance would  
6 take versus -- you know, development of the guidance, staff  
7 endorsement of the guidance, and then implementation of the  
8 guidance.

9 So, we tried to allow for what we thought would be  
10 a sufficient period of time but also said have the provision  
11 that, if things happen more quickly or the extent of the  
12 changes are less than was necessary, it could be sooner.

13 COMMISSIONER McGAFFIGAN: The FSAR update  
14 guidance, which has been straightforward for a good six or  
15 eight months now, is grinding through a process, and I  
16 think, in this case, NEI doesn't mind, but it's grinding  
17 through a process that's taking about 15 months from the  
18 date that the treaty sort of got settled until it gets  
19 endorsed, and so, 18 months may be -- I just -- I wish we  
20 could have done it faster, I guess, is what I'm saying, but  
21 I think this provision to allow earlier -- the rule taking  
22 effect earlier -- rule taking effect earlier, if the  
23 guidance is going to require a lot of work, effectively, you  
24 know, may turn out to be a two-week window or two-month  
25 window, but it's certainly not very long, given past

1 history.

2 MS. McKENNA: The last slide that we had was on  
3 enforcement.

4 This has always been an issue, I think, of  
5 concern, and in the period where we may be changing from one  
6 set of rules to another set of rules, we felt we needed to  
7 discuss this issue in a little bit of detail so the  
8 Commission could understand how we were proposing to look at  
9 issues that would arise in enforcement space, whether they  
10 be as a result of an examination of an evaluation that was  
11 done some time ago or an evaluation that's done during the  
12 period of -- from when the rule is finalized to when it  
13 becomes implemented, and we do recommend continuing the use  
14 of discretion with respect to issues of low significance,  
15 and we did try to give some specific items about how we  
16 would do that in the paper -- for example, that if it's  
17 looking at something that would be viewed as a violation  
18 under the existing rule but would not be a violation under  
19 -- had it been done when the new rule was effective, that we  
20 would not issue -- take an enforcement action for that  
21 particular action, and I think another one we mentioned here  
22 was -- it is kind of in the existing policy of -- call it  
23 the good faith misunderstanding, if we felt that a licensee  
24 was really attempting to implement the rule and, because of  
25 some confusion on terms or clarity in the guidance or



1 whatever, that if there was not some other reason that, you  
2 know, because of the significance of the issue, then again  
3 we might refrain from issuing -- taking an enforcement  
4 action.

5 CHAIRMAN JACKSON: How long would that go on?

6 MS. McKENNA: I think we were thinking that those  
7 would be through the 18-month period and perhaps a little  
8 beyond that, just until we're, I think, satisfied that  
9 things are clear and straight.

10 CHAIRMAN JACKSON: So, not for 20 years.

11 MS. McKENNA: Not for 20 years, no. It's a  
12 transition approach.

13 I think what we said in the paper was that, after  
14 that, you know, after we felt the rule was in place and  
15 people should understand it, that -- revert back to it, if  
16 they don't seek an amendment when it's necessary, that that  
17 would be a level three.

18 CHAIRMAN JACKSON: You'd need to have clarity  
19 about how long you would do that.

20 COMMISSIONER DICUS: Madam Chairman?

21 CHAIRMAN JACKSON: Yes, please.

22 COMMISSIONER DICUS: I have a question about the  
23 recommendation.

24 Specifically, early on in the 18-month period,  
25 before the rule goes into effect -- I'm assuming we are

1 going forward with the rule.

2 CHAIRMAN JACKSON: Hope springs eternal.

3 COMMISSIONER DICUS: The staff won't be trained on  
4 this. How does that impact your recommendation on  
5 enforcement?

6 MS. McKENNA: I think one of the things we  
7 indicated in there, we would continue to have the  
8 enforcement panel in place to try to deal with those  
9 questions that arise of wherever the confusion is, whether  
10 it's on our staff's part or with the licensee's part, that  
11 -- and one of the reasons, also, for using discretion is to  
12 recognize that, you know, people aren't going to be looking  
13 at these things in all the same way while we're in this  
14 transition.

15 It's been kind of -- that's been kind of the  
16 situation for the last few years, I think, to a certain  
17 degree, that there are questions sometimes of a particular  
18 inspector looking at a change and looking at the rule and  
19 really trying to see, well, what is the answer here?

20 I mean there's a spectrum. There's cases where  
21 everybody agrees it was clearly one side or the other.  
22 There's always a space in the middle where different  
23 people's view as to whether -- was that, you know, a  
24 malfunction of equipment that was created or what really  
25 happened as a result of the change, and I'm not sure we can

1 totally resolve that.

2 We tried to deal with it through some of these  
3 other provisions.

4 CHAIRMAN JACKSON: Okay.

5 MR. COLLINS: Commissioner Dicus, I think there is  
6 -- if I understood your question correctly, we learned a bit  
7 from the maintenance rule application and that there's  
8 really two types of confirmatory reviews that need to be  
9 done.

10 One is the process itself, which, when we  
11 implemented the maintenance rule, was more of a programmatic  
12 review, if you will, deterministic type of review, than an  
13 application type of review.

14 With that background and with the benefit of the  
15 maintenance rule, I think we'll have to work with the  
16 industry and amongst the staff to determine how to do those  
17 two separate reviews and with what touch and what frequency.

18 Clearly, there's process implications of this, not  
19 for ourselves but for licensees, as far as implementation,  
20 and then there is the individual application. Each of those  
21 will have to be defined.

22 We were taken to task as an agency initially  
23 because we took enforcement based on the process reviews. I  
24 think we would want to go back and revisit that to determine  
25 whether that's the right approach and ensure that we have

1 consistency with process application, process  
2 implementation, before we look at the application.

3 CHAIRMAN JACKSON: Anything else?

4 MS. McKENNA: There's one other topic I was just  
5 going to mention, going back to the slide we had on policy  
6 issues, which was the question of recommendation on scope.  
7 We didn't actually provide a slide on this, but I did want  
8 to mention it, because it is an issue that had been raised  
9 by the Commission and was addressed in the paper.

10 We indicate in the paper what we had tried to do  
11 with respect to the definitions of change in facility as  
12 described in the FSAR, which in a way is a question of  
13 dealing with what are those changes that have to be looked  
14 at with respect to the evaluation criteria. So, it's a way  
15 of getting at this issue.

16 Beyond that kind of definition, the staff did not  
17 really see a particular benefit or need to try to make a  
18 change to the scope of 50.59 at this time.

19 I think we recognize there are other initiatives  
20 going on in the risk-informed arena that are addressing  
21 scope and that, obviously, as part of that process, the  
22 question of what's the right scope for 50.59 would need to  
23 be looked at, but we didn't really see that it was something  
24 to pursue as a separate initiative.

25 CHAIRMAN JACKSON: Anything else?

1 DR. TRAVERS: That concludes our presentation.

2 CHAIRMAN JACKSON: Thank you very much.

3 We'll have Mr. Beedle and Mr. Pietrangelo from NEI  
4 come forward.

5 CHAIRMAN JACKSON: Good afternoon.

6 MR. BEEDLE: Madam Chairman --

7 CHAIRMAN JACKSON: Welcome back.

8 MR. BEEDLE: -- good afternoon. Appreciate the  
9 opportunity to discuss 50.59. I would probably -- I would  
10 like to agree with Mr. Matthews that we are on a convergence  
11 course but sometimes I get the distinct impression we are  
12 approaching this thing asymptotically.

13 CHAIRMAN JACKSON: Well, you know, it could be a  
14 Bessel function.

15 MR. BEEDLE: Could be. Could be.

16 CHAIRMAN JACKSON: Do you know what a Bessel  
17 function is?

18 MR. BEEDLE: Oh, yes, yes.

19 We probably don't disagree perhaps as much as it  
20 would appear in some of these comments with where the Staff  
21 is going. I do feel that we do need definition of some of  
22 these terms, in terms of margin and so forth and negligible.  
23 I don't think we are all that far apart. We think that by  
24 sticking to negligible we kind of stayed below the boundary  
25 that the Staff has set and so we are comfortable with that,

1 although I recognize the difficulty that presents from  
2 perhaps a legal point of view in trying to deal with some of  
3 the margin issues.

4 But what I told Tony, that he is going to provide  
5 absolute clarity to this issue of minimal and negligible, so  
6 that is his challenge, to try to make sure that we  
7 understand what that is all about before we leave today, but  
8 we do appreciate the opportunity and I will turn it over to  
9 Tony to discuss some of these issues.

10 MR. PIETRANGELO: Well, why don't we just jump  
11 right into the lion's mouth on minimal versus negligible,  
12 and I think Commissioner McGaffigan basically explained our  
13 position on this --

14 COMMISSIONER MCGAFFIGAN: That there was a  
15 mistake.

16 [Laughter.]

17 MR. PIETRANGELO: At the current time there is no  
18 intent on our part to change the existing guidance in 96-07  
19 on negligible. We think there's some comfort gained in  
20 that, that the industry knows negligible meets minimal based  
21 on the Commission's SRM from last year on this. Just  
22 because it says negligible in the industry guidance does not  
23 preclude someone from trying to go further than that. At  
24 this point in time we have not taken the effort to try to  
25 define minimal any further in a qualitative way, plus we

1 wanted to leave the door open for potential quantitative  
2 approaches to defining minimal in the future or probability  
3 when the rule becomes more risk-informed.

4 But in the meantime if someone wants to take a cut  
5 at a qualitative attempt to go beyond negligible and still  
6 be less than minimal, there is no reason why our guidance  
7 would preclude them from doing that, and maybe through some  
8 people taking a stand at that we could incorporate that back  
9 in our guidance.

10 I don't know how much of a problem it presents not  
11 having it defined in the rule but just because it is not  
12 defined doesn't mean it is inconsistent with the  
13 consequences of minimal either -- necessarily mean it is  
14 inconsistent, so again we are going to leave it as is for  
15 now, but it does not preclude one of our members from trying  
16 to take it a little bit further either qualitatively or  
17 quantitatively and they will have to make their case and  
18 make it stand up with the Staff when they make a change.

19 CHAIRMAN JACKSON: But how would you propose that  
20 licensee engineers or NRC inspectors or enforcement  
21 specialists or others determine whether a change that is  
22 greater than negligible satisfies the minimal standard?

23 MR. PIETRANGELO: Well, I think even some of the  
24 things Commissioner Diaz mentioned is a way to do it. I  
25 mean I could brainstorm other ways to do it but again we

1 have not had a great deal of problem in the implementation  
2 of this regulation over the years with negligible standards,  
3 so I suspect most people will stay to that for the time  
4 being, and maybe when we have a little bit more time and  
5 when the rule becomes more risk-informed we can devote some  
6 more resources in taking a cut at that, but we would  
7 encourage you to keep the rule language of minimal to allow  
8 that growth to occur in the future.

9 CHAIRMAN JACKSON: Right, but if you are going to  
10 risk-inform Part 50 and this is part of it, you know, the  
11 rule may look completely different --

12 MR. PIETRANGELO: It may, Chairman, but perhaps  
13 not.

14 CHAIRMAN JACKSON: -- this is artificiality having  
15 to do with the fact that you are still dealing with the  
16 design basis rule and you are trying to build flexibility  
17 into a design basis rule.

18 MR. PIETRANGELO: Right.

19 CHAIRMAN JACKSON: If you can risk-inform the  
20 rule, a lot of this stuff goes out the window.

21 MR. PIETRANGELO: Perhaps. The criteria may stay  
22 exactly the same but the scope is really what needs to  
23 become risk-informed and then I am not certain the criteria  
24 would necessarily have to change so --

25 CHAIRMAN JACKSON: But you are not certain that



1 they won't have to change it --

2 MR. PIETRANGELO: I am not certain about that  
3 either.

4 Okay. Could we go to the second slide, please.  
5 First of all, thank you very much for releasing a SECY so  
6 quickly last week. Let me take a moment to commend the job  
7 the Staff did in pulling the SECY together. On the web page  
8 I kind of browsed through the 59 comment letters that were  
9 received by the Staff and I don't know how many pages it is,  
10 but it is probably well over 300 pages of comments that the  
11 Staff had to address.

12 We were quite surprised that the SECY addresses  
13 and dispositions all the comments. In fact, we only  
14 expected to see proposed language and a rationale for it,  
15 but we did not expect to see the disposition and the  
16 comments. On first blush it looks like they were really  
17 done, dispositioned well by the Staff in the short timeframe  
18 they had from the comment deadline. That is just one heck  
19 of a job by the Staff.

20 Again, it appears to us that the comments have  
21 been adequately resolved in most of the areas. I am going  
22 to limit almost in its entirety our remarks to the margin of  
23 safety criteria and from our perspective we see that is as  
24 the last issue that needs to be addressed to meet the  
25 Commission's objective with this rulemaking. Next slide,

1 please.

2 In the short time that we had, we used the two  
3 groups we have used for the last three years in trying to  
4 look at changes to 50.59. We distributed the SECY to our  
5 50.59 task force and the regulatory process working group  
6 that Harold chairs. We had conference calls with each group  
7 yesterday to try to get feedback on the document so that we  
8 are not just shooting from the here, so we have had some  
9 discussion with the task force and the working group.

10 Nevertheless, it has not been a lot of time to  
11 digest the paper. We did not have the benefit when we had  
12 these conference calls of hearing the Staff's presentation  
13 or talking to the Staff. We did have a brief telephone  
14 conversation this morning with the Staff, so we didn't have  
15 that full understanding of where the Staff was going and why  
16 they were going that way, so some of the concerns you may  
17 see in here may be -- certainly they are preliminary but  
18 perhaps with a better understanding we would not have the  
19 concerns we have today, but I am going to go through with  
20 what we came up with with the task force and working group.

21 I think there is also going to be a need for some  
22 more dialogue but in terms of what you said to open,  
23 Chairman, it is time to fish or cut bait and I think the  
24 paper's before you and the Commission needs to decide on  
25 this issue. Next slide, please.

1           The next two slides are really the concerns  
2 expressed then. These are kind of the consensus ones that  
3 came out of the discussion with the task force and working  
4 group.

5           Let me start just conceptually, first of all, with  
6 what is margin of safety. That has been the issue. It was  
7 not defined in 1968 when the rule was promulgated. We took  
8 a cut at that. I have got a slide later on from the  
9 statements of considerations in 1968 on that.

10           What we see in the Staff's proposal, at least our  
11 preliminary concern, is that they have taken this concept  
12 and we think it does apply only to the fission integrity of  
13 the fission product barriers. That was its purpose and  
14 trying to take that margin of safety concept down to the  
15 system and the component level is misapplying the intended  
16 concept of margin of safety.

17           We talked a little bit about the scope of the  
18 evaluation being extended being tech specs. First of all,  
19 the tech specs are not consistent at all plants and the  
20 scope of the margin of safety criterion has been the basis  
21 for any tech spec so unless the Staff has a concern in terms  
22 of what people have been doing in that regard over the  
23 years, to say that the tech specs does not, has not -- that  
24 scope for this criterion has been inadequate -- I mean that  
25 is the case you would have to make to expand the scope

1 beyond what it currently is.

2 We do think, and I think this was really  
3 articulated in Commissioner Diaz's vote on the original  
4 paper, that there is a lot of redundancy with this criterion  
5 and tech specs, and that is part of why we went back to look  
6 at the statements of considerations in '68 and looked at  
7 what they said, what the criteria for the content of tech  
8 specs is to try to make some sense out of that, and  
9 expanding the margin of safety concept down to the system  
10 and component level really just turns the concept on its  
11 head, and it is even more than what people have been doing  
12 in the past so it is an expansion of the scope.

13 But again, to take margin on fission product  
14 barriers and equate it with I will call it design margin at  
15 a component level, and there's parts of the SECY, even  
16 though the Staff says in the paper that this is primarily  
17 intended to look at it at the system level, if you read  
18 further in the SECY it does go down to component level,  
19 piping, pumps, supports, et cetera, and that is a vast  
20 expansion of what we believe margin of safety was intended  
21 to do. Next slide, please.

22 CHAIRMAN JACKSON: Before you go on, let me talk  
23 to you about these bullets. Let me talk about, first of  
24 all, this idea of expanding the concept beyond the fission  
25 product barriers to the component level. I mean aren't the

1 plants -- weren't they designed, reviewed and licensed at  
2 the structure, system and component level?

3 MR. PIETRANGELO: That's a pretty broad question.

4 CHAIRMAN JACKSON: I mean that is my  
5 understanding.x

6 MR. PIETRANGELO: Well, my understanding is that  
7 when you get a licence you have to do a number of analyses  
8 and demonstrate that your plant can be placed in a safe  
9 condition --

10 CHAIRMAN JACKSON: I understand that, but I  
11 want -- I need an answer to that question. Are the plants  
12 designed, reviewed and licensed at the system, structure and  
13 component level, yes or no?

14 MR. MATTHEWS: Yes.

15 MR. BEEDLE: Yes, they are.

16 CHAIRMAN JACKSON: Okay, so I guess I am trying to  
17 get at then if that is the case, okay, why a 50.59 approval  
18 criteria at the component level is unacceptable.

19 MR. PIETRANGELO: I didn't say that. I didn't say  
20 that. I am talking specifically about the margin of safety  
21 criterion and the next slide will talk about redundancy with  
22 the other criteria in 50.59, but I think this is indicative  
23 of what happens sometimes. We know this has been the  
24 remaining issue on 50.59. There's another six criteria in  
25 the rule but we have got the blinders focused on --

1 CHAIRMAN JACKSON: Well, this is --

2 MR. PIETRANGELO: -- margin of safety criteria.

3 CHAIRMAN JACKSON: This is the particular issue  
4 that you put the blinders on based on your discussions, so I  
5 am -- you know, my eyes are going where your eyes have gone.

6 MR. PIETRANGELO: Okay.

7 CHAIRMAN JACKSON: Okay? Therefore, we are going  
8 to talk about it. Doesn't the SECY paper say that component  
9 level reviews will be limited to the fission product  
10 boundary -- the fission product barrier of the reactor  
11 coolant system boundary with other components only being  
12 evaluated at the system level?

13 MR. PIETRANGELO: It supports systems. I think  
14 the tech specs when you ask the question about are the  
15 systems and components licensed, I think primarily that is  
16 done within the technical specifications.

17 CHAIRMAN JACKSON: Let me ask you about your  
18 second bullet where you talk about the scope of the  
19 evaluation being expanded beyond tech spec system.

20 Hasn't the definition of operability, which  
21 includes required support systems, always made the scope of  
22 50.59 reviews greater than the tech specs themselves?

23 MR. PIETRANGELO: All this bullet is intended to  
24 convey is that the current language in the rule is the basis  
25 of any technical specification.

1 I am not arguing the point, Chairman.

2 COMMISSIONER DIAZ: Say that again, please.

3 MR. PIETRANGELO: The current language -- "You  
4 shall seek an amendment if there is a reduction in safety as  
5 defined in the basis for any technical specification."

6 CHAIRMAN JACKSON: And relative to the third  
7 bullet in terms of this apparent redundancy with tech spec  
8 controls, as I understand tech specs, they typically require  
9 that the structures, systems and components be capable of  
10 performing their design safety function and as I understand  
11 the proposed 50.59 language, licensees would be required to  
12 obtain NRC approval before making changes that altered  
13 design safety functions.

14 Now that sounds complementary as opposed to  
15 redundant to me.

16 MR. PIETRANGELO: I go back to the original point  
17 that these are controlled in tech specs. If you make a  
18 change to -- and it is the first part of 50.59 involves a  
19 change to the tech spec it kicks you out of 50.59 and you  
20 are seeking an amendment, so there's some redundancy. I  
21 don't think there is any question about it.

22 I don't think they are complementary at all.

23 CHAIRMAN JACKSON: Well, they are complementary in  
24 the sense that there's variability of the tech specs as you  
25 go from plant to plant.

1 MR. PIETRANGELO: That's true.

2 CHAIRMAN JACKSON: And in the sense that what the  
3 tech specs control relative to SSCs performing their design  
4 safety functions can vary.

5 MR. PIETRANGELO: But the variability has been  
6 there since day one --

7 CHAIRMAN JACKSON: That's correct and --

8 MR. PIETRANGELO: -- across the spectrum of plants  
9 because the tech specs have been there.

10 CHAIRMAN JACKSON: That is correct, but if you are  
11 talking about proposed changes that can be made without  
12 coming in for prior review --

13 MR. PIETRANGELO: Right --

14 CHAIRMAN JACKSON: -- then one wants to understand  
15 that this envelope in terms of design safety functions not  
16 being compromised is maintained.

17 MR. PIETRANGELO: Before we leave this slide,  
18 again conceptually on margin of safety -- maybe it is better  
19 to go to the next slide because I think that is the first  
20 bullet on here -- in terms of redundancy with other  
21 criteria.

22 CHAIRMAN JACKSON: Okay.

23 MR. PIETRANGELO: What was three criteria before  
24 are now a proposed seven, possibly eight.

25 We have got probability of an accident. We have



1 got probability of malfunction. We have got consequences of  
2 an accident. We have got consequences of malfunction. We  
3 have got accident of a different type and we have got  
4 malfunction of a different result.

5 Now even in discussions with the ACRS with Dr.  
6 Apostolakis, he said, well, if you have got the probability  
7 and the consequences, you put those together, that's the  
8 risk. What else is there? And our point here with  
9 redundancy with other criteria, and that is why I think the  
10 Staff's papers falls short is that they are concerned that  
11 what we proposed might be too narrow, but there is no  
12 objective evidence that it is, and we point to -- and we  
13 went through 10 examples in our 25-page basis for what we  
14 proposed in the comments on the rule, examples of stuff that  
15 was related to the barriers and not related to the barriers  
16 and how they would be addressed under the criteria we had  
17 proposed.

18 I think these are very, very broad criteria and it  
19 covers the spectrum of the performance of the equipment and  
20 a lot things you just mentioned, Chairman -- the design  
21 functions and things.

22 I see margin of safety as kind of a sanity check  
23 or backup after you get done with all this stuff. Have I  
24 done anything that affects those fission product barriers?  
25 Because I have covered them individually through these other

1 things.

2 Is there some combination of what I have done that  
3 has affected the integrity of those barriers? That is what  
4 margin of safety is about, not down to the system and  
5 component level and trying to apply this principle.

6 The next point is that you can't. There are no  
7 curves on a lot of the systems or analysis results that you  
8 can compare to a design basis limit.

9 Second point is that a lot of the component level  
10 things don't have 50.2 design basis limits. They are pretty  
11 much up at the plant and system level so I am even  
12 concerned -- I want to make sure this is not just me, this  
13 is concerns from the task force and the working group --  
14 that what the Staff has proposed can even be done, because  
15 there are no analysis curves to apply to it at the system  
16 level.

17 CHAIRMAN JACKSON: Mr. Matthews, what would you  
18 say to that?

19 MR. MATTHEWS: I think that is why we look at the  
20 multiplicity of criteria. Our hope is that the fabric of  
21 those criteria will address those instances where there  
22 might not be a design basis capability addressed, but where  
23 there is a design basis capability addressed I think it is  
24 of significance because, as we keep going back to, it was  
25 the licensing basis of the plant.

1 CHAIRMAN JACKSON: Commissioner Diaz?

2 COMMISSIONER DIAZ: You talk about hierarchy in  
3 here or rules, you know, and the Chairman referring to  
4 structures, systems and components and, you know, Appendix A  
5 and 50.34 --

6 MR. PIETRANGELO: A bunch of them.

7 COMMISSIONER DIAZ: Right, and you getting there  
8 and you start talking about integrity of fission product  
9 barriers and then of course the immediate question is how do  
10 you define integrity. Do you define it in terms of  
11 functionality or maybe a better question now -- no, it's not  
12 a question, it is a statement -- is what is the relationship  
13 between functionality as applied to fission product barriers  
14 and technical specifications. I mean isn't the technical  
15 specifications in the hierarchy, you know, kind of the  
16 second level that try to explain the functionality that will  
17 apply to determine the integrity of fission product  
18 barriers?

19 MR. PIETRANGELO: I think there is a hierarchy and  
20 I think that you are right, Commissioner, but at least in  
21 the proposed approach that we made we took parameters that  
22 would try to measure the integrity of the barriers, and they  
23 are well known -- they have been in NSAC 125 since 1989 --  
24 and try to use that set, and we didn't represent it as a  
25 complete set -- there may be other ones -- to try to gauge

1 what the integrity of the barriers are, and they are not  
2 hard to do I don't think.

3 COMMISSIONER MCGAFFIGAN: Could I ask an  
4 implementation question that will help me probably on this?

5 If we decide that we want to go back to what you  
6 proposed, and I regard it as a good faith effort to define  
7 this term, "margin of safety," that wasn't previously  
8 defined, do you -- the comments that you put together in  
9 order to make that proposal to the Staff is there the  
10 essence of any change that you would have to make to NEI  
11 96-07 and could you do it very promptly?

12 If this issue were resolved that way, could 96-07,  
13 Rev whatever, be out quickly?

14 MR. PIETRANGELO: I believe so. We have been  
15 keeping track of changes that we would make to Rev Zero.  
16 Obviously you have to wait for the final rule to be able to  
17 make conforming changes to the guidance, but actually if you  
18 just look at the margin of safety criteria, which is the  
19 area that may change the most, what was written in 1989 is  
20 pretty darn consistent with --

21 COMMISSIONER MCGAFFIGAN: Close.

22 MR. PIETRANGELO: -- with what we are saying now  
23 and in fact the example cited in that document were fission  
24 product barriers and the parameters we pulled out were  
25 pulled out of NSAC 125.

1 COMMISSIONER McGAFFIGAN: Whereas what the Staff  
2 is proposing and the broadening they are proposing there  
3 would be a long discussion if the Commission decides to do  
4 that presumably to tie down what a lot of these undefined  
5 terms mean.

6 MR. PIETRANGELO: I believe there would be,  
7 Commissioner, and I got to tell you, I mean we are making  
8 progress in other activity on design basis but today I do  
9 not have confidence that we have it nailed down at the -- I  
10 think we have the big stuff nailed down, and the reason we  
11 had confidence in the fission product barrier approach is  
12 that I can be very prescriptive in 96-07 about what the  
13 design basis limits are on the fission product barriers I  
14 think without too much discussion.

15 I am not sure I could be that confident when I  
16 start going out to the system and component level.

17 COMMISSIONER McGAFFIGAN: And the other question I  
18 had, you are the ones who came up with this exceeded or  
19 altered?

20 MR. PIETRANGELO: I am going to explain that when  
21 we get to the chart.

22 COMMISSIONER McGAFFIGAN: Okay.

23 MR. PIETRANGELO: There is a very good explanation  
24 for that.

25 We have already started in on this use of

1 undefined terms --

2 CHAIRMAN JACKSON: You know, I think we ought to  
3 set that one aside because there's inconsistency. It seems  
4 that we are willing to take undefined terms if it, you know,  
5 makes us comfortable -- and that's us too -- but we are not  
6 willing to take undefined terms if it doesn't make us  
7 comfortable, and so if the standard is undefined terms, we  
8 all better go back and get everything defined and start  
9 over, and so I just think we ought to just skip on down the  
10 line, because, you know, one man's undefined terms is  
11 another woman's defined terms.

12 MR. PIETRANGELO: Okay. Let me go to a defined  
13 term then -- definition of change. Eileen went through this  
14 in some detail.

15 The key addition to that definition of change is  
16 that we pick up changes in methodology. In the proposed  
17 rule in the statements of considerations there was also  
18 language regarding the need to use terminology that has been  
19 approved by the Staff and there is another sentence about  
20 common practice in the industry, so we think that we  
21 addressed this concern about consistency and use of  
22 terminology by incorporating changes in methodology to  
23 receive a full 50.59 evaluation, so we don't think there is  
24 a need for a separate criteria later on that has been  
25 proposed in the SECY on this point, that including it in the

1 definition of change and in the statements of consideration  
2 and the rule, and we do plan to amplify this portion of our  
3 guidance regarding methodology, and one last thing --

4 CHAIRMAN JACKSON: Let me ask you though how do  
5 licensees today control analysis methodologies that are not  
6 part of the 50.46 LOCA analysis?

7 MR. PIETRANGELO: You mean in terms of 50.59,  
8 Chairman?

9 CHAIRMAN JACKSON: Yes.

10 MR. PIETRANGELO: The guidance has been if you are  
11 going to change the method to do it both ways to see what  
12 the difference was, and then to report to the Staff what the  
13 difference has been in the two methodologies, but there was  
14 one part that Eileen got into that I wanted to clarify about  
15 potentially masking changes in methodology with an actual  
16 change to an input parameter of the plant.

17 The way the guidance is currently written, you  
18 cannot group changes unless they are interdependent. That  
19 is, if you had a change in methodology you would have to  
20 evaluate that on its own, and unless it was a bunch of  
21 changes in the methodology all at the same place you would  
22 look at that in its entirety but you wouldn't take some  
23 design change with a methodology change and do a single  
24 50.59 on them.

25 Therefore, you would be able to discern whether

1 the change in methodology had an increase that was more than  
2 minimal in consequences or had an impact on margin of  
3 safety.

4 COMMISSIONER McGAFFIGAN: Madam Chairman, on that  
5 point my recollection is the famous risk-informed Reg Guides  
6 also make a similar point, that you can't, you know, package  
7 changes, so this is not new turf for us.

8 CHAIRMAN JACKSON: Right. Right. Okay, let's go  
9 to the next slide.

10 I wanted to put this in the presentation to  
11 provide in part how we arrived at fission product barriers  
12 and we went back to the original rule and there it was, and  
13 that is truly what guided the proposal that the task force  
14 developed. Next slide, please.

15 Here is where we can explain exceeded or altered,  
16 Commissioner.

17 When we put exceeded or altered in our wording for  
18 the new Criterion 7, the exceeded applied to a change in the  
19 analysis result -- that is the curve here -- that would go  
20 above the limit. Altered means a change in the limit  
21 itself, so there are two separate things, and so it is not  
22 one is covered by the other. The exceeded has to do with  
23 the analysis result; the altered has to do with the limit  
24 itself and to clarify Dave's point on this about design  
25 basis being important things, we put the altered in on the



1 limit, not just non-conservative, because design basis  
2 limits on fission product barriers are big deals and if you  
3 are going to change that, you should come in for prior  
4 review and approval.

5 I would argue that other types of design basis  
6 limits on systems and components and things aren't that big  
7 a deal and we wouldn't use the altered language in that  
8 regard.

9 Does that clarify the --

10 COMMISSIONER MCGAFFIGAN: Okay.

11 MR. PIETRANGELO: Okay. Let me say one more thing  
12 about -- this chart as we have worn it out, this originally  
13 appeared in NSAC 125 in 1989. It was reproduced in NEI  
14 96-07 as is, so this is what the industry has been using for  
15 quite a number of years now, and again, it is still in  
16 there.

17 Talking about some of the terms that are used in  
18 here, one thing -- we tried to listen to the Staff's  
19 concerns about -- before, when the discussion was, well, is  
20 margin of safety between the top of the curve and the limit,  
21 and there was a concern about what methods you are using or  
22 have you changed an assumption in the method and such.

23 We tried to listen to that and also in some of our  
24 guidance we said we would take the acceptance limit from the  
25 safety evaluation reports that the Staff did on the FSAR.

1 There was a concern about whether the limits that were  
2 removed from SERs were legally binding on licensees. That  
3 is what led to our picking out the design basis limit for  
4 the fission product barriers. That is a value that appears  
5 in the FSAR. It is required to -- which would be legally  
6 binding -- so we thought we addressed that concern with the  
7 SER problem here.

8 Again, the things we talked about previously about  
9 methodology, including it in the definition of change,  
10 including some things in the statements of considerations  
11 and amplifying the guidance would address the Staff's  
12 concerns about how close you are getting to the limit and at  
13 least solidify the methods that were being used in this  
14 regard.

15 CHAIRMAN JACKSON: I think, Mr. Matthews, you  
16 wanted to make a comment?

17 MR. MATTHEWS: Yes. I wanted to go back to the  
18 point of the margin of safety criteria and its utility or  
19 usefulness seems to have been questioned from several fronts  
20 at times, and one of the concerns, and I think Eileen tried  
21 to make this point in response to Commissioner Diaz's  
22 question, we do have to deal with the issue of the quality  
23 and extent of analyses previously performed.

24 When you look at the six criteria preceding  
25 Criteria 7, they are always caveated by "previously

1 evaluated in the final safety analysis report" -- whether  
2 you are talking about consequences, probabilities,  
3 likelihoods, whereas when you get to the margin of safety  
4 criteria it is the design basis capability of the structure,  
5 system and component, so you can't be guaranteed by virtue  
6 of the variability in FSARs, their quality, and of course  
7 since they formed the basis or the foundation for the tech  
8 specs, the variability and completeness of the tech specs as  
9 we look over the whole range of plants drives you to a  
10 concern, I believe, that you may miss something in those  
11 first six criteria that is design basis related, therefore  
12 important in terms of the safety function -- that these  
13 calculations of previous evaluations may not have reached  
14 to, so I think there is a benefit to having a margin of  
15 safety criteria to address the possible shortcomings that  
16 might exist in the existing FSARs and the existing analyses  
17 performed that developed the basis for the tech specs.

18 COMMISSIONER DIAZ: But only if the tech specs are  
19 not good?

20 MR. MATTHEWS: Pardon?

21 COMMISSIONER DIAZ: But only if the tech specs are  
22 not complete or good? If the tech specs are complete or  
23 good you don't need to have it, right?

24 MR. MATTHEWS: The need would be less.

25 COMMISSIONER DIAZ: Negligible?

1 [Laughter.]

2 COMMISSIONER McGAFFIGAN: Minimal.

3 MR. PIETRANGELO: I think I agree with what David  
4 said but to a different degree.

5 I believe the margin of safety criterion is a  
6 backup also, but suppose you didn't have any of the rest of  
7 that stuff and all you did was the margin of safety criteria  
8 and let's say it was on our approach that is focused on  
9 fission product barriers. At least you would know those  
10 three principal barriers that protect the public health and  
11 safety are intact and you have full confidence in their  
12 integrity.

13 Despite any of the other stuff. The question is,  
14 it's really a scope question now on the criteria and what  
15 you apply it to. Do you have to go back and apply it, we  
16 think in a redundant manner, to the other systems and  
17 components, or do you do it in an integrated way as a check  
18 to make sure that barrier integrity is maintained? I think  
19 that is the question on the table.

20 MR. MATTHEWS: I will point out that there are  
21 some issues that we think that the margin of safety criteria  
22 reach to that may not be addressed in either tech specs of  
23 the other criteria. A good example is station blackout and  
24 coping time associated with station blackout. If you were  
25 to move from a six hour to a four hour coping time, you

1 would have an issue that addresses concern associated with  
2 design basis and fission product barrier integrity, but I  
3 don't know of a matrix of the other criteria that would  
4 necessarily capture that in terms of a concern.

5 So, you know, we can argue the degree to which  
6 each plant would need a margin of safety criteria to ensure  
7 continuity of the design basis, and I think, you know, one  
8 person's example versus another person's example, you know,  
9 we could go on all day doing that. But the staff, again,  
10 viewed that there was a fabric, a criteria, and then there  
11 was an additional need for one addressing maintenance of the  
12 design basis capability within certain limits.

13 COMMISSIONER DIAZ: But that is why you have the  
14 rule itself, that is why there is a hierarchy, and that is  
15 why, you know, you cannot eliminate the station blackout  
16 rule just because you have a 50.59.

17 MR. MATTHEWS: But you might change it, and its  
18 implementation on a plant-specific basis, which did allow  
19 flexibility.

20 COMMISSIONER DIAZ: Can you? Once you have it  
21 established, can you change it? You can't change your  
22 station blackout conditions.

23 MR. MATTHEWS: Well, I think you could change your  
24 commitment.

25 COMMISSIONER DIAZ: Oh, you can change the

1 commitment.

2 MR. MATTHEWS: Definitely.

3 COMMISSIONER DIAZ: Yes, you can change the  
4 commitment.

5 MR. MATTHEWS: And it could change the character  
6 of your design and the degree to which your plant is  
7 protected under certain circumstances. So, yes, I think you  
8 could change it.

9 COMMISSIONER McGAFFIGAN: But this is, earlier,  
10 when Eileen was talking, this is the first example we have.  
11 I guess I would be interested in Tony or Ralph's reaction to  
12 coping time for station blackout as the first specific  
13 example of something that will fall through the cracks if  
14 your fission product barrier criterion is the only  
15 criterion.

16 MR. PIETRANGELO: We had 10 examples in our  
17 approach on how -- on different things. I mean I would have  
18 to go through it for station blackout. But I think you  
19 still have to -- you don't use 50.59 to get out of  
20 compliance with the rule, you can't do that. You can't do  
21 that.

22 There was a coping analysis that was -- and I  
23 wasn't the station blackout person, so I have limited  
24 knowledge of this, but my understanding is that it was a  
25 coping analysis that was submitted to the staff. There is

1 probably an SER associated with it. Okay. There are  
2 probably some commitments associated with that. And whether  
3 those are programmatic or hardware changes makes a big  
4 difference, too. If they are programmatic changes, they  
5 probably get screened out of 50.59 anyway, and it would be  
6 more attuned to a commitment management type approach to  
7 answer the question.

8 Hardware changes have to do with the diesel and I  
9 think they would be directly relevant to the questions in  
10 50.59.

11 COMMISSIONER McGAFFIGAN: Could I ask Mr.  
12 Matthews, does he believe they could take out a diesel, if  
13 this isn't kept in the way you want it?

14 MR. MATTHEWS: It would surprise me that one of  
15 the other criteria wouldn't catch you first.

16 COMMISSIONER McGAFFIGAN: You just made Mr.  
17 Pietrangelo's point.

18 CHAIRMAN JACKSON: But you have to have the other  
19 -- if you didn't have the other criteria.

20 MR. MATTHEWS: Pardon.

21 COMMISSIONER McGAFFIGAN: No, no. I think you  
22 just made Mr. Pietrangelo's point, that the other criteria  
23 will keep you from doing that.

24 MR. MATTHEWS: In that instance, that is what I am  
25 agreeing with. Okay. I think the other criteria would --

1 would prohibit you from making that change without NRC  
2 involvement, okay, because of the interrelationship between  
3 that and system performance relative to probability and  
4 consequences.

5 MR. PIETRANGELO: If there are no further  
6 questions on the chart, can we move to the next slide,  
7 please?

8 The intent with this slide was to help us  
9 understand what action is required. In looking back at the  
10 history, again, that chart hadn't changed since 1989. When  
11 there was a lot of interaction back then, and I was not a  
12 part of that interaction, but there were letters exchanged  
13 and correspondence exchanged. Margin of safety wasn't an  
14 issue, and that wasn't one of the reasons that was held out  
15 as not being able to endorse NSAC-125.

16 When we redid NSAC-125, and NEI 96-07, we received  
17 a letter from the staff last January on the eve of our  
18 workshop. There were a couple of things that were laid out  
19 in that letter -- we would not be able to endorse the  
20 document in any event, and the others were you would have to  
21 have a rule change to be able to endorse what your guidance  
22 says. Margin of safety was not one of those elements, only  
23 about a year ago.

24 This real difference in interpretation came out at  
25 the June Commission briefing, and now it is on the table.



1 And that brings us to the last slide.

2 CHAIRMAN JACKSON: Before you jump to the last  
3 slide.

4 MR. PIETRANGELO: Okay.

5 CHAIRMAN JACKSON: I am not going that fast, Tony.  
6 You know, again, I mean I need to have some understanding.  
7 As I read the staff's proposed criterion for design function  
8 capability, it seems that they are codifying the intent of  
9 the existing rule as described in your own guidance  
10 document, 96-07. And if you ultimately agree that that is  
11 the case, why would you oppose the proposed rule language?

12 I mean you have a sentence, a section in 96-07  
13 that is entitled, "Defense-in-Depth Philosophy in 10 CFR  
14 50.59."

15 MR. PIETRANGELO: Right.

16 CHAIRMAN JACKSON: And it says,  
17 "Non-safety-related systems are not excluded by the scope of  
18 10 CFR 50.59."

19 MR. PIETRANGELO: No.

20 CHAIRMAN JACKSON: "For example, instrumentation  
21 and control systems are explicitly addressed by the general  
22 design criteria. Certain losses of non-safety-related  
23 systems represent critical operational occurrences  
24 identified as initiators in the SAR accident analysis.  
25 Therefore, changes to non-safety-related systems described

1 in the SAR must be considered and may be determined to  
2 involve a USQ under 10 CFR 50.50."

3 MR. PIETRANGELO: Right.

4 CHAIRMAN JACKSON: And, again, that is where I am  
5 confused.

6 MR. PIETRANGELO: Yeah, and I think that  
7 particular part of the document, Chairman, deals more with  
8 scope. We didn't want to be bound by "as described in the  
9 SAR." I think you have to look at things that aren't  
10 described in the SAR. The extent of changes across a plant  
11 can be very, very broad. We have had this discussion in the  
12 past about -- I think we sent letters to this effect, that  
13 tying the scope of 50.59 to the SAR is both too broad and  
14 too narrow at the same time.

15 CHAIRMAN JACKSON: Right. But what I am saying is  
16 we are talking design function capability, and so if you  
17 have, you know, non-safety-related systems whose  
18 functionality affects --

19 MR. PIETRANGELO: Right.

20 CHAIRMAN JACKSON: -- that of the safety-related  
21 systems, you are saying that you don't want to see anything  
22 in the rule that allows to be captured, is that what you are  
23 saying?

24 MR. PIETRANGELO: No, no. Again, I think we are  
25 confusing what the margin of safety criterion addresses in

1 the context of all the evaluation criteria. I am not saying  
2 to exclude any of that stuff. I am just specifically  
3 limiting our remarks to this margin of safety criterion and  
4 what its intent is.

5 CHAIRMAN JACKSON: Okay. Well, Mr. Matthews looks  
6 like he wants to say something again.

7 MR. MATTHEWS: In my view this issue has been  
8 sufficiently explored. I don't need to add anything.

9 CHAIRMAN JACKSON: Okay. Thanks.

10 COMMISSIONER McGAFFIGAN: Just to clarify, I will  
11 always remember the June '98 Commission meeting and you  
12 going to the podium and saying that the problem is we have  
13 different words, we have different interpretations of what  
14 margin of safety means and everybody nodding. So, to some  
15 degree, this issue was always there, it was just not -- it  
16 was not dealt with.

17 MR. PIETRANGELO: Right.

18 COMMISSIONER McGAFFIGAN: It was avoided.

19 MR. PIETRANGELO: Right.

20 COMMISSIONER McGAFFIGAN: But it was a getcha --  
21 it was a gotcha that was going to getcha at some point.

22 MR. PIETRANGELO: That's right.

23 COMMISSIONER McGAFFIGAN: So it is good that it  
24 out on the table.

25 MR. PIETRANGELO: I think it is good, and I think

1 the Commission should be commended for getting it out on the  
2 table. And we have talked -- yeah, Mr. Ray has talked about  
3 this at length, about not -- going forward in 1989 -- I mean  
4 we are as guilty as anybody for not insisting upon closure  
5 when that document was issued in 1989. We should not have  
6 allowed to get it. We developed a comfort zone, I think,  
7 with the staff on how this was implemented, because it was  
8 done so conservatively over the years, and as long as it was  
9 stable, people didn't complain about it. I think that was  
10 the reality back then. But we should and, hopefully, we  
11 will close this thing out the right way this time.

12 Can we go to the last slide, please?

13 To us, the objective has not changed since we  
14 started this activity, and that is to, if possible, simplify  
15 and clarify the rule to obtain stability. Our proposal is  
16 only way to do that. The staff's proposal may be another  
17 way to do that. I think I could probably come up with some  
18 others, maybe even based on the existing words that could do  
19 that. Okay. We are not looking for perfection here on the  
20 margin of safety criterion.

21 I think we are looking -- the objective here is  
22 stability. If we can get some efficiency and effectiveness  
23 at the same time, that's gravy. Stability is still the key  
24 issue, and we are interested in a timely resolution and our  
25 only, I guess, objection to the staff, it doesn't go beyond

1 -- I may be mischaracterizing it as does no harm here, but  
2 it could if we introduced new terms, and I think we have  
3 kind of discussed that at length, the potential that new  
4 terminology brings and implementation in the field and  
5 potential confusion could do harm to the stability  
6 objective.

7 So, finally, you know, we will do whatever is  
8 necessary. In terms of the guidance, Commissioner, I think  
9 we can turn it around very, very quickly. We have been  
10 trying to keep up with the changes, and as well as on this  
11 last margin of safety criterion, whatever comes out of that.

12 But we still strongly believe in our proposed  
13 approach and that it meets the objective the Commission laid  
14 out last year, and yet we recognize there may be other means  
15 to achieving that objective. So, with that, that's our  
16 formal remarks. Thank you.

17 CHAIRMAN JACKSON: Commissioner Dicus?

18 COMMISSIONER DICUS: I am going to go back to the  
19 word "minimal," take us back to that discussion. We worked  
20 awfully hard last year to come up with that term, frankly,  
21 and for that reason I am somewhat reluctant to abandon it.

22 MR. PIETRANGELO: Which term are you referring to,  
23 Commissioner?

24 COMMISSIONER DICUS: Minimal.

25 MR. PIETRANGELO: Minimal.

1 COMMISSIONER DICUS: But at the same time it has  
2 to be redefined. We have to be able to use it, because we  
3 have to be able to implement something, and I see the  
4 problem in implementation, which has been a problem for the  
5 agency in the past, so I think we have our work cut out for  
6 us. It is also somewhat a concern if you are going to stick  
7 with the term "negligible," and if those terms mean the same  
8 thing or different depending upon how we are able -- if we  
9 are able to come up a definition of minimal, but I think we  
10 have our work cut out for us.

11 MR. PIETRANGELO: Well, I will commit on our part  
12 to take a cut at it with our task force and working -- we  
13 have the working group in tomorrow morning, and the task  
14 force is a conference call away. It is certainly not  
15 impossible, I got some ideas just from listening to  
16 Commissioner Diaz earlier about how to define it. So it is  
17 obviously do-able.

18 Again, though, I think I explained before, we are  
19 probably going to stick with our guidance, but that doesn't  
20 meant that you can't go beyond that. Again, the reason we  
21 are sticking with the guidance as-is is for the stability  
22 question more than anything, and the confidence one has in  
23 the change and complying with the rule. But we will commit  
24 to take a stab at defining minimal for probability.

25 CHAIRMAN JACKSON: Commissioner Diaz, let me just

1 go down the line.

2 COMMISSIONER DIAZ: I guess just a simple comment.  
3 Looking at this objective, it remains to simplify and  
4 clarify rule to obtain stability, and I wonder if we really  
5 have been true to that in the last year. It seems to me  
6 like, by some reason or another, we have been adding degrees  
7 of freedom to everything that we try to do, and we had,  
8 instead of simplified a process, we made it more  
9 complicated.

10 Maybe this is the time in which to look back and  
11 say let's simplify it and try to obtain something that is  
12 workable. It doesn't have to be perfect.

13 MR. PIETRANGELO: Right.

14 COMMISSIONER DIAZ: It does not have to be  
15 perfect. Perfection -- it doesn't have to cover every  
16 angle. This is something that we have to understand, it is  
17 not possible to cover every angle whenever you do something.  
18 And whoever reaches for that is asking for complication.  
19 And because there is always another angle, we need to come  
20 to the realization that this has to be a workable rule, and  
21 it has to be simple, and it has to be implementable. Thank  
22 you.

23 CHAIRMAN JACKSON: Commission McGaffigan.

24 COMMISSIONER MCGAFFIGAN: Could I clarify, on the  
25 eighth criterion, the method of analysis, your view is that

1 that is covered by the definition of change, and you don't  
2 need an eighth criterion?

3 MR. PIETRANGELO: Well, that is one place it is  
4 covered. The second place, in the proposed rule under  
5 statement of considerations about the staff's expectations  
6 on use of methodology for these analyses. Thirdly, there's  
7 existing guidance in 96-07 that my understanding is the  
8 staff is quite comfortable with it, and we are even  
9 proposing to, now that the definition of change encompasses  
10 it, to enhance that portion of the guidance. And given all  
11 that, we wouldn't think this eighth criterion is necessary.

12 COMMISSIONER MCGAFFIGAN: The other question I  
13 asked, on the maintenance rule, what Rev. of NUMARC 90 -- is  
14 it three or four --

15 MR. PIETRANGELO: 301.

16 COMMISSIONER MCGAFFIGAN: 301. Are we on at the  
17 moment, without having changed the rule?

18 MR. PIETRANGELO: It is Rev. 2, Commissioner.

19 COMMISSIONER MCGAFFIGAN: Okay.

20 MR. PIETRANGELO: When we had the other briefing,  
21 we have had a lot of drafts of a particular section that  
22 deals with the assessment provision on that.

23 COMMISSIONER MCGAFFIGAN: So you are on Rev. 2,  
24 but you started with Rev. 0?

25 MR. PIETRANGELO: Yes.



1 COMMISSIONER McGAFFIGAN: So this is really the  
2 third. So there is some hope that if you didn't -- if we  
3 left minimal in, you would be able to, in a future revision,  
4 you say it was so small the first time --

5 MR. PIETRANGELO: Oh, absolutely.

6 COMMISSIONER McGAFFIGAN: -- that you might be  
7 able to get --

8 MR. PIETRANGELO: These are living documents.

9 COMMISSIONER McGAFFIGAN: -- something that the  
10 staff would be able to endorse. Meanwhile, most people  
11 would prudently stay probably with the so small.

12 MR. PIETRANGELO: As a matter of fact, let me just  
13 say we have set our workshop on licensing issues that  
14 include 50.59 and SAR and design basis for June 3rd and 4th  
15 in Philadelphia. One of the objectives of that workshop is  
16 to get early feedback on the implementation of NEI 98-03  
17 dealing with FSAR updates. We are going to collect the  
18 feedback we get at that workshop. We may be working on  
19 Revision 1 of that document very soon thereafter in tandem  
20 with the endorsement through the Reg. Guide.

21 So, yeah, if people find a problem with the  
22 document in the field, I think it is incumbent upon us, if  
23 it is significant, to revise the document.

24 COMMISSIONER McGAFFIGAN: Thank you.

25 MR. PIETRANGELO: The same here.

1 CHAIRMAN JACKSON: Commissioner Merrifield.

2 COMMISSIONER MERRIFIELD: Yes, I appreciate the  
3 kind offer to have your task force take a look at the  
4 definition of the word "minimal." We have been struggling  
5 with that. You know, I raise that issue only because, you  
6 know, if we are going to have that, you need to have, you  
7 know, work about defining it.

8 But I guess the other thing, if you could do this  
9 with your task force, you are going to go that direction, is  
10 also find out if people are going to use it, if there is an  
11 interest in having that change. I mean, again, I say this,  
12 you know, if it is something that people are going to use,  
13 it is worth going through the effort, but if we have a lot  
14 of effort, and in the end no one utilizes it, then it really  
15 -- you know, we have enough other things to do around here.

16 MR. PIETRANGELO: Okay.

17 CHAIRMAN JACKSON: I want to thank you for coming  
18 and kind of laying out clearly where you see the issues, as  
19 well as for the work that you have been doing with the  
20 staff. But I will tell you that, frankly, I am discouraged  
21 about the whole thing. It seems to me that, you know, we  
22 have been going around and around on it, and it is not clear  
23 to me, you know, even with the Commission, how much closure  
24 we are really going to come to. And I remain, you know,  
25 where I started, that if, you know, we didn't have the

1 wherewithal to risk-inform the rule in the first place, you  
2 know, it causes us to be stuck in certain spots.

3 But whatever I decide is not going to be something  
4 that -- I would not support something if I -- if the staff  
5 fundamentally feels it is forcing us to gut our fundamental  
6 regulatory responsibility, nor will I support something that  
7 is essentially impossible to implement. And so that is  
8 where I remain. Thank you.

9 [Whereupon, at 4:15 p.m., the briefing was  
10 concluded.]

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CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON STATUS OF 10 CFR 50.59  
ISSUES

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Tuesday, March 2, 1999

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Martha Brazil

Reporter: Mark Mahoney



# Commission Briefing on 10 CFR 50.59

Ralph Beedle  
Tony Pietrangelo  
March 2, 1999

REC'D BY SECY

29 FEB 99 7: 07



# SECY-99-054

- Excellent job by NRC staff in short time period since comment deadline
- Appears that comments have been adequately resolved in most areas
- Remaining issue of importance is margin of safety criterion



# Limited Industry Review

- SECY was distributed to NEI's 50.59 Task Force and Regulatory Process Working Group last week
- Conference calls held yesterday to discuss the document
- Today's feedback is preliminary
  - Likely need for further dialogue



# Preliminary Concerns with Proposal on MOS

- Concept expanded beyond fission product barriers to component level
- Scope of evaluation expanded beyond tech spec systems
- Apparent redundancy with tech spec controls





# Preliminary Concerns (Continued)

- Redundancy with other criteria
- Use of undefined terms
  - Design basis capability
  - Minimal change in a method of analysis  
(not addressed in proposed rule)
- How does proposal differ from original staff proposal?

# 1968 Statements of Consideration on Margin of Safety

In the revised system, emphasis is placed on two general classes of technical matters: (1) Those related to prevention of accidents, and (2) those related to the mitigation of the consequences of accidents. By systematic analysis and evaluation of a particular facility, each applicant is required to identify at the construction permit stage, *those items that are directly related to maintaining the integrity of the physical barriers designed to contain radioactivity.*

(emphasis added)

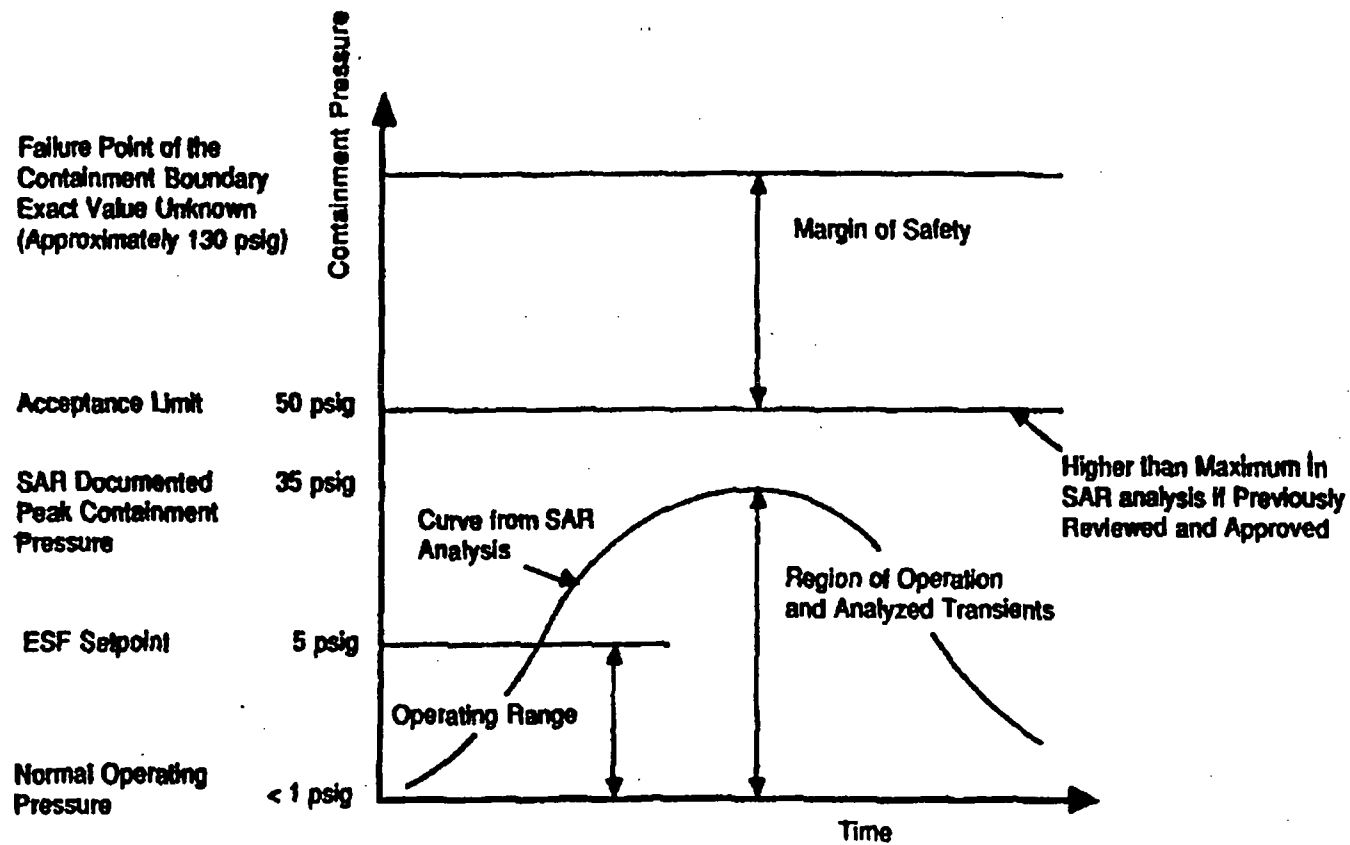


Figure 3-2. Example of Margin of Safety Using Containment Pressure Transient

# How did we get here?

- Margin of safety was not an issue on NSAC-125
- Margin of safety was not an issue last January in NRC comments on NEI 96-07
- Difference in interpretation surfaced at June 98 Commission briefing



# Outlook

- Objective remains to simplify and clarify rule to obtain stability
- Industry interested in timely resolution that at a minimum does no harm
- We will support expeditious interactions to obtain closure



**RECOMMENDATIONS FOR FINAL  
RULEMAKING FOR 10 CFR 50.59, 72.48,  
AND RELATED SECTIONS**

**March 2, 1999**

**Office of Nuclear Reactor Regulation**

**Office of Nuclear Materials Safety and Safeguards**

## **BACKGROUND**

- **March 24, 1998 SRM directs proposed rule**
- **SECY-98-171 dated July 10, 1998 forwards proposed rule for Commission approval**
- **September 25, 1998 SRM approves publication for comment with additions and changes**
- **Proposed rule published October 21, 1998**

# **CONTENTS OF SECY PAPER**

- **Policy issues**
  - **minimal increase in probability**
  - **“margin of safety”**
  - **Part 72 and related Part 71 issues**
  - **Implementation and enforcement strategy**
  - **Staff recommendation on scope**



## **MINIMAL INCREASE IN PROBABILITY**

- **Commenters support qualitative evaluations of probability; available guidance is more consistent with “negligible” increases. Larger increases would need to include quantitative criteria which would require additional development**
- **Staff recommends minor wording changes**
  - **frequency of occurrence of accidents**
  - **likelihood of occurrence of malfunction**
  - **systems, structures and components**

## **“MARGIN OF SAFETY”**

- **Commenters offered several different ideas on “margin”**
- **NEI proposal focusing on design basis limits directly related to fission product barrier integrity**
- **Staff modification of this proposal to focus on SSCs that protect the barriers (prevention and mitigation), as well as support functions**

## **“MARGIN” (CONT'D)**

- **Criteria for review is whether design basis capability is still satisfied - evaluations generally at system functional level**
- **Additional criterion for “minimal” changes to evaluation methods used to establish design basis values**
- **Guidance will need to be developed to assist in consistent implementation**

## **PART 72 ISSUES**

- **Commenters seek greater consistency between Parts 50 and 72 (for change control and SAR updating)**
  - **§ 72.48 evaluation criteria**
  - **frequency and content of update submittals**
- **Staff agrees and proposes revisions that would achieve this consistency**

## **RELATED PART 71 ISSUES**

- **Commenters seek change control process for Part 71 (transportation), particularly for dual purpose casks**
- **Staff agrees and would add new language for spent fuel transportation packages used for domestic shipments as rulemaking to change Part 71**

## **IMPLEMENTATION**

- **Existing guidance (NEI 96-07) and inspection guidance require modification; supplemental guidance for Part 72 facilities needs consideration**
- **Staff recommends implementation of rule in 18 months to allow for development and review of guidance, and for licensee implementation of revisions to their procedures and training**
- **Provisions within the rule for earlier implementation if licensee is ready, upon notification to NRC**

# **ENFORCEMENT**

- **During implementation period, staff recommends continuation of enforcement discretion for violations of low significance**
- **Paper describes specific aspects**
  - **refrain from enforcement if matter would not be a violation under the revised rule**
  - **continue practice of reduced severity levels if underlying action is acceptable**
  - **for good faith misunderstanding, use discretion in policy and refrain from enforcement action**



# **RULEMAKING ISSUE**

(Notation Vote)

February 22, 1999

SECY-99-054

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: PLANS FOR FINAL RULE - REVISIONS TO 10 CFR PARTS 50, 52,  
AND 72: REQUIREMENTS CONCERNING CHANGES, TESTS, AND  
EXPERIMENTS

PURPOSE:

This paper (1) provides an overview of the comments received on the proposed rulemaking on 10 CFR 50.59, (2) forwards the staff's proposals to resolve several issues related to implementation of § 50.59 and (3) recommends final rule language for a revision of § 50.59 and related provisions in Parts 50, 52, and 72. These changes affect the regulatory requirements controlling licensee changes, tests, and experiments for production and utilization facilities and for facilities for independent storage of spent nuclear fuel and high-level radioactive waste.

SUMMARY:

The staff is revising § 50.59 (and related sections) to clarify the criteria that determine when changes require evaluation by the licensee and when changes require NRC approval before they are implemented. A few key issues from the proposed rule and from the public comments on the proposed rule require Commission direction before the staff can finalize the rulemaking package. This paper discusses (1) the background of the proposed rulemaking, (2) the public comments on the proposed rulemaking, and (3) staff recommendations for the final rule based upon review of these comments. In addition, this paper contains staff's recommendation concerning the question of the scope of § 50.59 as requested by a Staff Requirements Memorandum (SRM) dated March 24, 1998.

CONTACT: Eileen McKenna, NRR  
415-2189



**BACKGROUND:**

Section 50.59 defines the conditions under which reactor licensees may make changes to their facilities or procedures, or to conduct tests or experiments without prior NRC approval. In general, such changes, tests, or experiments may be carried out unless they would involve a change to the technical specifications, or an unreviewed safety question (as defined in § 50.59(a)(2)). Similar language exists in § 72.48 for independent spent fuel storage installations (ISFSI) or monitored retrievable storage installations (MRS) for storage of spent nuclear fuel or high-level waste.

The Commission approved a staff recommendation to initiate rulemaking in its SRM on SECY-97-205, dated March 24, 1998. The Commission directed that the proposed rule allow "minimal" increases in probability or consequences (where minimal is greater than negligible). In this SRM, the Commission also directed staff to consider conforming changes for other parts of the regulations.

The Commission also asked staff to provide (1) a recommendation concerning the scope of 10 CFR 50.59, in February 1999; (2) a status report on the effectiveness of the short-term actions (from SECY-97-205); and (3) recommendations on whether to pursue more resource-intensive and high-impact long-term actions. The staff recommendation concerning the scope of § 50.59 is discussed in this paper below. Commission papers that provide information on the short-term actions include SECY-99-001, dated January 5, 1999 (updating guidance for final safety analysis reports (FSARs)) and SECY-98-224, dated September 28, 1998 (on commitment management). Staff is also preparing a separate memorandum that provides the current status of interactions with the Nuclear Energy Institute (NEI) concerning guidance to determine what constitutes design basis information. The staff recommendations on long-term actions to make Part 50 more risk-informed were provided in SECY-98-300, dated December 23, 1998 (which was also responsive to an April 25, 1997 SRM requesting an integrated approach to the requirements in Part 50 that includes clear, consistent definitions and risk considerations).

In SECY-98-171, dated July 10, 1998, staff forwarded a proposed rulemaking package to the Commission with a recommendation to issue the proposed rule for public comment. In this rulemaking, staff proposed a number of changes to § 50.59, including the addition of definitions and reformatting, deletion of the term "unreviewed safety question," revisions to criteria to allow changes involving minimal increases in probability or consequences or creation of malfunctions of a different type (but not with a different result from what was previously evaluated), to be made without prior NRC approval. Staff also proposed an approach for "margin of safety reduction" that would focus upon the safety analyses that established the technical specifications. In the proposed rulemaking, similar changes were proposed for those sections in Part 72 relating to change control and also to extend the change control authority to Certificate of Compliance holders (for spent fuel storage cask designs). Other conforming changes necessitated by the changes in §§ 50.59 and 72.48 were also proposed.

In its SRM of September 25, 1998, the Commission approved staff's proposal to issue a proposed rule for public comment. The Commission did not adopt staff's proposed recommendation on margin of safety and also offered other questions and issues for consideration. The Commission specified a number of topics for which public comment should be sought in the *Federal Register* (FR) notice, most particularly, for a broad range of options on

margin of safety. Further, individual Commissioner vote sheets were included in the FR notice so that interested parties would understand preliminary views of the Commission on these issues. The proposed rule was published in the *Federal Register* (63 FR 56098; October 21, 1998) for a 60-day comment period ending December 21, 1998.

The Commission's SRM of September 25, 1998, requested staff to complete the rule on an expedited schedule (by February 19, 1999). Because of the range of views on a few important issues, such as margin of safety, staff concluded that Commission direction was needed on an approach for these issues before staff finalized its rule package, as discussed in a memorandum to the Commission dated December 21, 1998.

### DISCUSSION:

Fifty-nine letters commenting on the proposed rule were received. A list of the commenters is provided in Attachment 1. Further, Attachment 1 discusses and analyzes the comments, which are organized by topics as presented in the proposed rule. A summary of the major issues and staff recommendations for resolving these issues are presented herein. Commission approval of these recommendations, or selection of an alternative approach is requested so the final rule package can be prepared. In addition, the staff notes the degree of consistency of the proposed approach with the existing industry implementation guidance, NEI 96-07.

The proposed rule reorganized the rule requirements, including separation of the evaluation criteria into seven separate statements. The following discussion refers to this numbering. Attachment 2 presents the revised rule language, which has been modified in accordance with the recommendations presented herein. Additional refinements to the rule language may arise as staff completes the comment review and concurrence process.

## **1.0 MAJOR TOPICS**

### **1.1 Probability of occurrence of an accident or malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is more than minimally increased (§§ 50.59(c)(2)(i) and (c)(2)(ii))**

The proposed rule included language that states that a license amendment was required if there was more than a minimal increase in the probability of an accident or malfunction of equipment important to safety previously evaluated in the final safety analysis report (as updated).

Several comments were offered on the guidance concerning how a minimal increase would be determined. Many commenters stated that evaluations of probability would be qualitative, and they wanted the supplementary information to indicate more explicitly that quantitative analyses are not expected. Commenters also thought that it was not clear how to determine qualitatively that there was no more than a minimal increase in probability if some discernable increase could be noted. NEI has indicated that it does not intend to modify the current guidance in NEI 96-07 that establishes a qualitative "negligible" threshold.

A few commenters wanted some quantitative guidance, particularly to allow use of probabilistic risk analyses. Some commenters suggested reliance on the process established in Regulatory

Guide (RG) 1.174 for changes involving quantitative evaluations. Staff's view is that if greater use is to be made of PRA information, more fundamental changes to the rule would be necessary to provide a coherent set of requirements and that the regulatory processes established in RG 1.174 would have to be reexamined for applicability to changes being made by a licensee without NRC review (for example, criteria for preservation of sufficient defense-in-depth might be needed). Further, applicability to facilities such as nonpower reactors, reactors undergoing decommissioning, and Part 72 facilities would also need to be considered.

While the rule language in Attachment 2 retains the term "minimal", the staff notes that in practice, distinctions between "negligible" and "minimal" cannot be achieved for qualitative evaluations. The staff attempted to provide more quantitative guidance, but was unable to develop a meaningful value that could be used generically (for all accidents and malfunctions), or a means of judging when the increase would be too large, when applied to the deterministic analyses in the FSAR. The staff presently plans to make certain clarifying changes to the guidance offered in the proposed rule supplementary information for qualitative assessments to implement the rule language of "minimal" increases in probability in a manner more akin to a "negligible" standard. Existing guidance in NEI 96-07 concerning "negligible" increases will satisfy the rule requirements. The "minimal" language would allow effects to be more than negligible and yet still satisfy the "minimal" criterion in the rule.

The staff also recommends that the term "probability" be changed to "frequency" for occurrence of accidents, and to "likelihood" for occurrence of malfunctions. The staff concludes that these terms provide a better representation of the attribute of concern, and also how the evaluation would be conducted. Also, as discussed under topic 1.3, the staff proposes to use the term "structures, systems and components" rather than "equipment."

#### Resolution:

As noted, the staff recommends minor changes to the rule language, as presented in Attachment 2.

#### **1.2 Margin of safety as defined in the basis for any technical specification is reduced (§50.59(c)(2)(vii))**

The FR notice solicited comment upon a wide range of options related to the regulatory treatment of margin. Staff included a number of possibilities and also noted that other proposals were welcomed. The range of options presented included deletion of the criterion, as well as options focusing upon specified parameters. For instance, some of the options concerned fission product barrier response with another suboption proposing inclusion of mitigation system capability. Staff considered a range of approaches from "no change" to these parameters, up to meeting specified limits, including a concept of "minimal" reductions. In addition, staff proposed an option that would control evaluation methods used to demonstrate that the selected parameters are satisfied.

Although a large number of comments were submitted, they can be grouped into a few major themes: those supporting the discussion in NEI 96-07 (acceptance limits), those supporting deletion of margin as a criterion, and those supporting a new proposal from NEI.

NEI proposed to replace the existing margin of safety criterion with one that states that a change requires approval if it would result in a design basis limit directly related to integrity of fuel cladding, the reactor coolant system pressure boundary, or the containment boundary being exceeded or altered. NEI noted that this recommendation is not based on the concept of minimal changes because the fission product barrier design parameters of interest are not suited to this approach. Conservative margins were built in when the design basis limits were established, and plants routinely operate at or near these limits, so a "minimal" change concept has little meaning. In its proposal, NEI also proposed controls on evaluation methods associated with demonstrating that the design basis limits have not been exceeded for parameters directly related to fission product barrier integrity. As discussed in their comment letter of December 21, 1998, NEI would define evaluation methods as including such elements as methods for reducing data, correlations, physical constants, and modeling techniques.

Staff examined the NEI proposal to determine whether important design parameters would be protected through application of this criterion in conjunction with the other criteria and regulations. Staff was concerned that the language of "directly related to fission product barrier integrity" might be too narrow. Staff was supportive of the concept of using the design basis as the determinant of when NRC approval was needed and for control of evaluation methods. Thus, the staff's current proposal would be a modification of that suggested by NEI that focuses upon the effectiveness of systems to protect the barriers, that is, changes would be allowed without prior NRC approval that would close the gap between current calculated values and "controlling" values, provided the barriers are not challenged. This would be demonstrated by showing that the systems are still capable of performing their design functions.

In developing its approach, the staff was seeking to allow flexibility to licensees, yet also to provide confidence that the effects of such changes remain within acceptable boundaries. The staff criteria is intended to broaden the NEI proposal to encompass overall plant performance, including fission product barrier response, mitigation system capability and those support systems that must function for these systems to perform their functions. The focus upon functions (including support systems) and lowest functional capabilities also provides consistency with the philosophy for establishing TS. For certain systems and structures, these capabilities are already included within the TS; this approach thus brings a degree of uniformity to all plants.

The staff has developed the following as recommended rule language for when prior NRC approval is required for a proposed change, test, or experiment. A change would require NRC approval if the change would:

(vii) Result in the design basis capability for any structure, system or component directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered.

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

## IMPLEMENTATION

These criteria would then be implemented through guidance that has the following provisions:

The extent of SSCs that would need to be considered under this criterion are those whose functions are to maintain integrity of the physical barriers intended to contain radioactivity (that is, for reactors, fuel clad, the RCS, the primary containment, and any others), or those used to mitigate accidents or the release of radioactivity, and those support systems that must function in order to assure the functioning of accident prevention and mitigation systems, for the range of accidents and events that the plant is required to withstand.

The design basis capability (for an SSC) is the lowest functional capability that accomplishes the required functions for all required conditions, including the range of accidents and events that the facility is required to withstand. This philosophy is consistent with the 50.2 definition of design bases, and would reflect a condition that if the design basis is not met, some other system or characteristic would be materially impacted, as for instance the fission product barriers being challenged. For purposes of this evaluation, assessment of design basis capability for components is intended to be limited to those components necessary for ensuring the capability of the reactor coolant pressure boundary and containment barriers. Thus, the components would include such items as the reactor vessel, reactor coolant pumps, reactor coolant pressure boundary piping, and containment isolation valves, which have a distinct function in preserving integrity of the barriers. Changes to other components, e.g., other system piping, pumps, supports, etc., may be evaluated in terms of their effect on system functional capability under design basis conditions.

Changes to design basis capabilities would require NRC approval. Where a design basis capability has been established in the FSAR, a change in which the design basis capability continues to be met, as demonstrated by the same analysis methodology as previously used (in the FSAR), does not require NRC approval.

For analytical methods, the staff has proposed a minimal change standard, to allow licensees to use different methods, yet prevent loss of all margin. A change in a method as a single change should be benchmarked by assuring that parameters that are acceptable in the changed method would not cause systems and structures to exceed their design basis capabilities under the method that previously had been approved by the NRC. This determination would be made by comparison to previously acceptable method(s) of evaluation. The staff intends to discuss this criterion with NEI in the near future.

In implementing these criteria for NRC review, staff notes that the licensee remains responsible for demonstrating that TS and other regulatory requirements continue to be met for this revised system capability as part of its safety assessment of the proposed change.

As noted in previous guidance, changes are to be evaluated separately. Thus, if a licensee wishes to make changes to the facility in conjunction with changes to methodology, the above standards would apply to the individual changes.

Based on the relatively high threshold which would be established under these proposed criteria, it is likely that many changes requiring a license amendment under these criteria may

also involve a significant hazards consideration. Thus, many license amendments which are necessitated by these two criteria likely will have to be noticed in the *Federal Register* and an opportunity for a hearing provided prior to issuance of the license amendment; any hearing granted on these cases must be completed prior to the issuance of the amendment.

Significant revision to NEI 96-07 is anticipated to explain in detail the criteria and how they would be implemented. The staff believes that the use of examples will help facilitate understanding of these criteria and interpretation of minimal changes with respect to methods.

#### Resolution:

The staff supports the goals of the NEI approach, but recommends a modification of the approach offered by NEI that focuses on effectiveness of structures, systems and components to protect fission product barriers, rather than just on the barrier parameters themselves. Staff believes that an approach such as that described above would provide a criterion that would control system capability such that barriers are not challenged, yet allow licensees flexibility to make changes that do not prevent the systems from performing their minimum functional requirements.

### **1.3 Part 72 Changes and related issues**

Several commenters stated that the requirements in Part 72 should be made even more consistent with those of §§ 50.59 and 50.71(e). These commenters also believe that certain of the requirements of Part 72 (i.e., release limits, § 72.48 evaluation criteria on occupational exposure and environmental impact, and update frequency and content requirements) are more stringent than the similar provisions in Part 50. These commenters further state that these requirements are not commensurate with the relative potential risks of the two types of facilities. Staff notes that many of these differences are in existing rule requirements and do not arise from the proposed rule changes. The staff has revised Part 72 in response to these comments to provide greater consistency with Part 50. A few of the recommended changes may require renoticing because they were not within the scope of the proposed rule (e.g., removal of the occupational exposure and environmental impact tests from § 72.48), and therefore, the staff proposes to prepare a supplemental proposed rulemaking for any such issues.

Although the bulk of the changes the staff has included in Attachment 2 would conform Part 72 to Part 50's language, staff would propose the reverse in one instance. Staff would propose the use of the term "structures, systems, and components (SSCs) important to safety" in both Parts rather than the term "equipment important to safety" as presently in § 50.59. Staff believes that the term "SSCs important to safety" is already common terminology and is currently reflected in Part 50's general design criteria. Also staff would not propose revising release and accident

limits in the supplemental rulemaking, because such changes would be significantly beyond the scope of the original rulemaking on "changes, tests and experiments."

Additionally, several commenters stated that the change control process allowed under Part 72 should be expanded to include transportation packages (i.e., casks) certified under 10 CFR Part 71, especially for dual-purpose casks (i.e., casks certified for both the storage and transportation of spent fuel under both Part 71 and 72). Staff notes that current International Atomic Energy Agency (IAEA) safety standards for transportation of radioactive material (i.e., ST-1) do not provide for a § 72.48 type change control process allowing for changes to the design of a transportation package without prior approval. However, staff believes that the comment to provide for a § 72.48 type change control process in Part 71 has merit — if limited to transportation packages used in the domestic shipment of spent fuel. Staff would propose to expand the scope of the suggested change to both dual-purpose casks approved under both Part 71 and 72 and to transport-only casks approved under Part 71. Consequently, this change would apply to casks used to domestically ship spent fuel, including dual purpose casks.

Staff believes that such a regulation in Part 71, while departing from IAEA standard ST-1, would be acceptable for spent fuel transportation packages used in domestic commerce only. Staff also believes that Part 72 licensees that ship spent fuel, Part 72 certificate holders, and Part 71 spent-fuel certificate holders have the necessary experience to implement these potential Part 71 regulations without adversely affecting the safe transport of spent fuel. NRC staff has discussed this concept with staff from the Research and Special Programs Administration of the U.S. Department of Transportation (DOT), and DOT staff did not object to this concept. Staff will coordinate this proposed change to Part 71 with the DOT in the supplemental rulemaking described above. Staff will address the question of allowing a § 72.48 type change control process for all other types of Part 71 transportation packages as part of a different rulemaking (NMSS-C3MP-26, "Compatibility with IAEA Transportation Standards, Part 71").

#### Resolution:

Staff recommends acceptance of the comments and proposed resolution as described above. In order to provide a final rule as soon as possible, the staff recommends that a final rule be issued for both §§ 50.59 and 72.48. Staff also recommends that simultaneous with this final rule, a supplemental notice of proposed rulemaking be issued to provide for "§ 71.48" change authority and to address any staff responses to comments which would require renoticing for public comment. Staff recommends that a supplemental final rule on the revisions to Parts 71, and any necessary Part 72 sections, follow within 18 months of issuance of the final rule for Parts 50, 52 and 72 (see Section 2.0 for a discussion of staff proposals for the implementation schedule). Guidance on the changes to Parts 71 and 72 would be developed in concert with the guidance on Part 50 and would be issued in accordance with the implementation schedule discussed below. As noted, other Part 71 changes would be handled as part of a different rulemaking.

#### **1.4 Other issues**

In the *Federal Register* notice for the proposed rule, the Commission also specifically sought comment on other topics. For instance, comment was specifically requested as to whether the scope of § 50.59 should be revised to include information other than that "as described in the

safety analysis report.” After careful consideration, staff is not proposing any change to the scope in this rulemaking. As noted, staff has provided definitions of terms such as “facility as described...”, to more clearly define those changes that require evaluation and thus allow others to be screened out without a detailed evaluation. Only a few commenters indicated interest in a redefinition of the scope, and these commenters also suggested it occur as part of a longer-term revision that might be more risk-informed with respect to evaluation criteria as well. As discussed in SECY-98-300, staff is proposing to define a risk-informed scope for use in a number of Part 50 regulations. In this effort, applicability for § 50.59 is being examined. Therefore, the staff concludes that a separate effort to revise the scope of § 50.59 itself is not warranted.

In addition to the topics discussed within this paper, there are some other topics that affect the rule language changes or are otherwise considered to be of Commission interest which are discussed in Attachment 3. These topics include definition of change, need for definition of accident, the evaluation criterion on increase in consequences, and reporting requirements. Other comments received are for the most part editorial or minor comments. Some will be resolved through clarifications of rule language or in implementation or inspection guidance; others will not be adopted. Comment resolution will continue while this paper is before the Commission for deliberation to expedite completion of the final rule package. Attachment 1 contains this information and the final resolutions of the comments will be included with the final rule package when it is submitted.

## **2.0 ENFORCEMENT AND IMPLEMENTATION STRATEGY AND SCHEDULE**

Staff is also interested in obtaining Commission direction concerning timing of implementation of §§ 50.59 and 72.48 and on enforcement strategy. As noted in the comment letter from NEI, time will also be needed to revise existing industry guidance (and NRC endorsement through a Regulatory Guide). Further, guidance for Part 72 licensees (and potentially for Part 71) will need development. Staff will work with NEI and industry to develop specific guidance for Part 72 during this period as well as on the revisions to guidance for reactor licensees. Once the guidance is complete, there will be a need for revisions to procedures, conduct of training, and other activities to facilitate implementation of the revisions to the rule.

These factors would suggest a relatively long period before the rule changes become effective. On the other hand, many reactor licensees may wish to use the enhanced flexibility provided by the revised criteria as soon as possible. Accordingly, the staff recommends that the Commission follow a strategy by which the existing §§ 50.59 and 72.48 rules would remain in effect for an 18 month period and the revised rules would be issued and made effective during this 18 month period. The revised rules, will by their terms, replace the existing rules at the end of the 18 month period. If a licensee (or certificate holder) wishes to implement the revised rule(s) sooner than the 18 month deadline, this could be done upon written notification to NRC of the effective date by which that licensee would implement the revised rule in place of the existing rule. Future development of the inspection and enforcement strategy will also be coordinated with the changes occurring to NRC oversight and assessment processes.



During the period until the revised rules are implemented, staff also recommends that it continue to exercise some enforcement discretion, using the following approach for violations of §§ 50.59 and 72.48:

- 1) The staff intends to exercise discretion to refrain from enforcement action for non-willful violations of existing §§ 50.59 or 72.48 requirements that would not be violations had the evaluations been performed using the revised rule. The staff does not plan to document such matters in inspection reports.
- 2) Failure to perform written evaluations or maintain required documentation would be considered Severity Level IV violations and generally treated as non-cited violations. The failure during the implementation period to submit an amendment as required, where the NRC finds the underlying licensee action acceptable without the need for substantial review, would also be categorized at a Severity level IV (consistent with current practice for enforcement discretion in this area).
- 3) A failure to submit an amendment as required would be considered a Severity Level III violation if either a) a substantial review is needed by the NRC before it could conclude that the licensee's actions were acceptable or b) NRC would not have found the licensee's actions acceptable.
- 4) However, if the licensee's failure to meet the new rule appeared to be in good faith based on either a misunderstanding of the new requirements as a result of lack of guidance or insufficient time to implement changes from the old rule, discretion would be exercised under section VII B.6 of the Enforcement Policy.
- 5) After the effective date for §§ 50.59 and 72.48, a failure to submit a required amendment would be considered a Severity Level III violation. If NRC would not have found the changes made by the licensee or certificate holder (without NRC approval) to be acceptable, the severity level could be increased to a Severity Level II.

The staff would maintain an enforcement panel made up of NRR (and NMSS as applicable), OE, and OGC representatives for some months after publication to maintain consistency. In addition, as part of the final rulemaking package, changes will need to be made to the Enforcement Policy.

#### CONCLUSION:

Staff is seeking Commission direction concerning the recommendations contained herein, and on the (draft) final rule language presented in Attachment 2. Upon receipt of this direction, staff will then forward a final rule package (including any supplemental proposed rule for Parts 71 and 72) consistent with this guidance as expeditiously as possible.

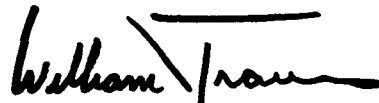
RECOMMENDATIONS:

1. That the Commission approve staff's recommendations discussed above;
2. That the Commission allow early release of this paper to facilitate industry's interaction with the staff on these proposals and to initiate preparation of guidance.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

The staff will meet with the Advisory Committee on Reactor Safeguards during its March 1999 meeting to discuss the recommendations in this paper.



William D. Travers  
Executive Director for Operations

Attachments:

1. Discussion of public comments on the proposed revision to 10 CFR Parts 50, 52 and 72 (63CFR 56098)
2. Recommended final rule language for 10 CFR 50.59 and related provisions
3. Other rule language changes and issues

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Tuesday, March 9, 1999.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT March 2, 1999, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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**ATTACHMENT 1: DISCUSSION OF PUBLIC COMMENTS ON THE  
PROPOSED REVISION TO 10 CFR PARTS 50, 52 AND 72  
(63 FR 56098)**

## DISCUSSION OF COMMENTS

This attachment provides the initial staff analysis of the comments received in response to the FR notice published on October 21, 1998 (63 FR 56098), for a proposed revision to 10 CFR 50.59, and related provisions including Part 72.

Fifty-nine responses were tabulated. As noted, one filing was a duplicate, so there are fifty-eight documents included in this analysis. A list of the submittals is included in this attachment.

For purposes of analysis, each letter was reviewed to identify comment areas and topics. For the most part, comments were specifically tied to one of the numbered subsections from the notice, so this numbering system was used in the tables that follow. Those comments that could not be directly tied to one of these sections were placed at the end. A number was assigned to each section or paragraph of each letter that was considered as being a separate comment. The tables group the comments by using a system where the first digit refers to the number assigned to the comment letter (see list), and the second set of numbers link to either the numbering system used by the commenter or these staff-assigned numbers, so that all comments could be accounted for, and also grouped with comments on the same topic.

The Nuclear Energy Institute (letter 22) submitted a set of comments that had been circulated among its members in order to provide consolidated views. This is reflected by the 35 letters from power reactor licensees that generally endorsed these comments, sometimes with modification or additional comments. Further, submittals from three law firms, on behalf of a number of licensees, were made. For these reasons, a precise accounting of the number of commenters making a particular comment, or agreeing with a comment is difficult.

COMMENT LETTERS ON 63 FR 56098

<u>Number</u>	<u>Date</u>	<u>Author name</u>	<u>Affiliation</u>
1.	11/3/98	Paul Sicard	none
2.	11/3/98	Brendan Ryan	Kansas State University
3.	11/18/98	Kurt Schaefer	A&K Nuclear Licensing
4.	12/11/98	S. Gambhir	Omaha Public Power District
5.	12/18/98	Ian Rickard	ABB-CE
6.	12/17/98	Steven Toelle	USEC
7.	12/17/98	Michael Croson	INEEL
8.	12/18/98	J.Beasley	Southern Company
9.	12/17/98	K. Singh	Holtec International
10.	12/18/98	James Mallay	Siemens Power Corporation
11.	12/21/98	Steven Franz	Morgan, Lewis and Bockius
12.	12/18/98	Richard Phares	Illinois Power
13.	12/17/98	James O'Hanlon	Virginia Power
14.	12/18/98	Sherry Bernhoft	Florida Power
15.	12/18/98	Kenneth Peveler	Alliant Utilities
16.	12/21/98	Daniel Stenger	Winston and Strawn
17.	12/17/98	Michael Kansler	Entergy
18.	12/18/98	Larry Grime	L.A.Grime And Associates
19.	12/18/98	Lester Slaback	NIST
20.	12/18/98	Donna Alexander	CP&L
21.	12/18/98	Ted Fiegenbaum	North Atlantic Energy
22.	12/21/98	Anthony Pietrangelo	NEI
23.	12/21/98	Malcolm Philips	NUGEQ
24.	12/21/98	R. Krich	ComEd
25.	12/21/98	Joseph Quirk	General Electric
26.	12/21/98	Norman Peterson	Detroit Edison
27.	12/21/98	Paul Gaukler	Shaw Pittman Potts ...
28.	12/21/98	(SAME AS 23)	
29.	12/21/98	E.D.Fuller	BNFL Fuel Solutions
30.	12/21/98	G. Zinke	Maine Yankee Atomic
31.	12/21/98	David Powell	PSE&G

32.	12/17/98	John Oddo	YAEC
33.	12/17/98	Lew Myers	First Energy
34.	12/xx/98	Bill Ellis	none
35.	12/18/98	Robert McCredy	Rochester Gas & Electric
36.	12/20/98	Lynne Goodman	none
37.	12/21/98	John Fornicola	GPU
38.	12/21/98	Charles Cruse	Baltimore Gas & Electric
39.	12/21/98	Bradford Houston	Nebraska PPD
40.	12/21/98	Al Passwater	Ameren UE
41.	12/21/98	Matthew Petitclair	none
42.	12/17/98	Rajiv Kundalkar	Florida Power and Light
43.	12/18/98	James Levine	Arizona Public Service
44.	12/18/98	Mike Tuckman	Duke Energy
45.	12/21/98	H.A. Sepp	Westinghouse Electric
46.	12/21/98	Martin Bowling	Northeast Nuclear
47.	12/21/98	James Baumstark	Consolidated Edison
48.	12/21/98	Garrett Edwards	PECO
49.	12/21/98	J. Knubel	NYPA
50.	12/21/98	Edward Scherer	Southern California Edison
51.	12/21/98	Gary Taylor	SCE&G
52.	12/21/98	Michael Wadley	Northern States Power
53.	12/21/98	Lance Terry	Texas Utilities
54.	12/21/98	M.A. McBurnett	South Texas Project
55.	12/21/98	Richard Muench	Wolf Creek
56.	12/29/98	Richard Olson	none
57.	12/21/98	Mark Burzynski	TVA
58.	12/22/98	Nathan Haskell	Consumers Power
59.	12/22/98	Carl Terry	Niagara Mohawk

**A.1 50.59(b) Applicability:** The provisions of this section apply to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been permanently modified to allow possession but not operation of the facility.

Comment	Commenter & Item Number
Consolidating the existing 10 CFR 50.59 applicability statements into one paragraph that is labeled in a new Section (b) "Applicability"	22-2, 32-2, 39-8
<u>Summary:</u> The commenters agreed with the staff's proposal.	
<u>Resolution:</u> Retain in final rule	

A.2 Form of Approval (Changes to (a) and (c); Moving Requirement to 50.90 for TS)	
Comment	Commenter & Item Number
Relocate the existing requirement in 10 CFR 50.59(a) and (c) on control of TS to 10 CFR 50.90.	13-1, 17-9, 22-4, 39-9 39-10
<u>Summary:</u> The commenters agreed with the staff's proposal.	
<u>Resolution:</u> Retain in final rule	



A.3 Deletion of USQ Term & Criteria Itemization	
Comment	Commenter & Item Number
1. USQ Term	
hhh. Support deletion of the term "USQ"	1-6, 13-1, 17-6, 20-1, 22-3, 32-3, 39-11
2. Breakout of Criteria	
a. Support listing of seven separate criteria	17-8, 22-3, 32-3
b. Offers other screening criteria, e.g. impact safety of operation, change to TS, change to facility from its description in the FSAR, etc..	3-14
3. The staff needs to address how to treat previous guidance and accepted practices that have used the term of "USQ."(e.g. GL91-18, Rev 1)	13-1, 22-5
4. Establish a simple process to change the existing TS that contain the term "USQ" or safety evaluation without licensees having to submit license amendments.	17-7, 22-6
<p><u>Summary:</u> The commenters generally agreed with the staff's proposal. However, some commenters expressed concerns that with the proposed rule language change it may inadvertently impact previous guidance and accepted practices that have used the term "USQ." It may also have impact on many licensees' TS which contain "USQ."</p>	
<p><u>Resolution:</u> Retain in final rule. Include text in supplementary information concerning existing guidance. Staff plans to issue inspection guidance following approval of final rule. With respect to TS changes, the staff is considering options - one approach may be to allow pen-and-ink changes to TS substituting the term "requires license amendment" for "unreviewed safety question". Suitable rule text may need to be added to speak to conflicting requirements, noting that the rule supersedes TS text. This approach was used for a final rule on section 50.4, see 51 FR 40303, dated November 6, 1986.</p>	

B.1 Change: Change means a modification, addition, or removal.	
Comment	Commenter & Item Number
<p>Propose alternative definition for change, <i>"Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished."</i></p> <p>Believe this change needs to be made because: it will be clear that insignificant changes are screened out of the 50.59 process, which will result in more effective resource allocation by licensees and the NRC. Specifically, evaluation against the seven criteria of the proposed Section (c)(2) should not be required for changes to design details that do not impact design functions or methods of performing or controlling design functions.</p>	<p>20.2(p1), supports focus on design function  21.2(p2)  22.9 (II.A.1, pp3-4)  24.2(p1)  27.12(p9)  35.1(p1)  38.3(II.B.3,p6)  39.1&amp;2(pA1&amp;2)  43.1(p1)  46.1(p1)  52.1&amp;3(p2)  53.1(pA1)</p>
<p>(Similar to above) Unclear what changes constitute <u>"addition."</u> Could imply that trivial additions (tags) or any new procedure. Need to limit to significant additions. Believe Commission did not intend all additions, but language not precise.</p> <p>Recommend that NRC clarify that "addition" means an addition to <i>the facility</i> that either (1) introduces a new hazard that potentially could affect a safety function described in the FSAR, (2) changes the operation or response of the facility as described in the FSAR, or (3) is otherwise inconsistent with the FSAR or outside the controlling parameters of the design basis as described in the FSAR.</p>	<p>11.7(2.3,p5)  38.3(II.B.2&amp;3,p5&amp;6), specific changes suggested.</p>
<p><u>"Additions"</u> should be treated the same as tests and experiments. That is, a 50.59 would only be required for procedures that are inconsistent with the FSAR or outside the design basis of the FSAR.</p>	<p>11.8(2.3,p5),  38.4(II.B.3,p6)</p>
<p>Equipment removed from service, or to support <u>maintenance</u>, should not be considered a <i>change</i>, and should instead be controlled by tech specs or the maintenance rule (suggested adding clarification to suppl info in final rule)</p>	<p>1.9(II.B.3,p4)  17.16(II.B.8,p4)  22.10 (II.A.2, p4),  38.7(II.B.8,p8)  52.3(p2)</p>

50.59 evaluations do not have to be performed unless the proposed change meets the definition of <i>change</i> and either the definition of <i>facility</i> or <i>procedure</i> as described in the FSAR (suggested discussion should be added to Suppl info by some commenters)	21.2(p2) 22.11(II.A.3,4,pp4) 24.2(p1) 27.12(p9) 38.3(II.B.2,p6) 39.1&2(pA1&2)
A change to an ' <u>analysis method or parameter</u> ' is only a <u>change to the facility</u> only if the method or parameter is described explicitly or implicitly in the FSAR.	1.7 (II.B.1,p3) 17.11(II.B.2) 39.2(maybe,pA2) 55.1(p1, notes that method term is too broad)
Provide specific examples for integrated (or <u>interdependent</u> ) changes. Clarify, too narrow (comment 11.11 suggested within same accident analysis)	1.8 (II.B.2, p3) 11.11(2.6,p7&8) 27.16(p10-11) adds language (see below)
<u>Interdependent</u> , adopt position: "Multiple changes to the facility or its procedures may be evaluated collectively (i.e., may be considered elements of a single change for purposes of review under section 50.59) if they are interrelated. Changes are considered interrelated if (1) they are interdependent, as in the case where a modification to a system or component necessitates additional changes to other systems and components (or procedures) in order for the modified system to perform its function or comply with its design or licensing basis; (2) they are proposed collectively to address a design or operational issue; or (3) they are otherwise planned as elements of a single project undertaken to restore, maintain or improve plant performance or safety."	27,16 (p10-11), see above as well
<u>Interdependent</u> : Proposed position on what constitutes a single change is consistent with the guidance in NEI 96-07. However, there is no need to develop a definition in the rule.	17.15(II.B.7,p4) 39.3(pA2)
Remove discussion of <u>interdependent</u> changes, encourage licensees to group changes provided that net effect reduces risk or is a minimal increase in risk.	7.5(5,p4)
<u>Nominal Values</u> , NRC should provide guidance on treatment of nominal values (when do they become a change?).	1.10(II.B.4,p4), 17.12(II.B.4,p3)
If change is made in response to issues in <u>generic communications</u> , does this constitute a 'change' or is it already previously approved by the NRC, and thus a 50.59 or amendment not required?	1.13(II.B.7,p4) 17.14(II.B.6,p4)

Replacement of components with equivalent components should only be considered a <i>change</i> if the replacement component has characteristics that are different from those described in the FSAR.	11.22(3.1,p10) 53.1(pA1)
50.49 EQ, similar to preceding, equipment replacements that are qualified per 50.49 should not be treated as changes under 50.59; e.g., do not alter underlying design bases.	23.1, 23.4 (p2,3,4)
Installation and testing of Mods prior to License Amendment should be allowed provided that the mod is not implemented (and its installation and testing would not require an amend). This is equivalent to drafting a procedure before its approved for use.	11.23(3.2, p11) 12.3(p2-3) 22,7 44.10(p4)
Agree with NEI that GL91-18 approach should remain unchanged. Therefore, to ensure that Appendix B, Criterion 16 and 50.59 do not interfere, suggest 50.59(c)(2) be modified to read, "A licensee shall obtain an amendment to the license pursuant to Section 50.90, prior to implementing a change, test, or experiment unless the activity is in accordance with Section 50, Appendix B, if it would ..."	13.2(p2)
To avoid a legal conflict (that exists today) between 50.59 and GL91-18, a clarification needs to be made such that licensees following GL91-18 will not be in violation of 50.59.	38.5(II.B.6,p8)
Consistent with Commissioner Diaz's comments, adding definitions is not necessary and only adds confusion. As industry commented on NUREG-1606, changes to the SAR, whether to procedures or the facility, require a 50.59 (unless it is an inconsequential change).	17.10(II.B.1,p3)
If the level of discussion within the <u>FSAR</u> is <u>unaffected</u> by the proposed change, and there is no change to the results of any underlying design analysis, then there is no requirement to perform a 50.59 evaluation.	17.11(II.B.3,p3), 38.3(II.B.3,p6) 39.1&2(pA1&2)
Rule should clearly indicate that "changes" include "additions". Also should be clear that changes under 50.59 (72.48) are not limited to physical changes, but include standards, procedures or calc methods (which can potentially affect the design bases)	32.4(II.B,p2)
Terms in rule need to be defined, but concerned that by making them part of the rule any subsequent interpretation would require rulemaking.	35.1(p1)

Proposed definition of change fails to recognize that there are two separate changes that need to be defined. The first is the actual change to the plant, which must be evaluated to determine if 50.59 is applicable. The second is the text or drawing change to the FSAR description of the facility, which requires a 50.59 safety evaluation. Safety evals should only be applicable to the FSAR described facility and any text-drawing changes. All other changes should screen out.	38.4(II.B.3,p8)
Definition should recognize that changes are only proposed changes. This will avoid the problem with 'de facto design changes'.	38.6(II.B.7,p8)
In §B of the FRN, use of word 'parameter' is too broad, clarify to read, "...changes to parameters that affect regulatory limits", or "effects of the parameter change."	45.1(p1)
Rule should specifically address and exclude from the 50.59 process administrative changes to organizational, reporting relationships, and job titles.	48.2(pA1)
Since the term <u>design bases</u> does not have a consensus, its use can be misleading.	55.1(p1)
The term 'removal' should be clarified to include: removal from service, physical removal, retirement in place, discontinued availability, removal from the FSAR text or tables, and removal from FSAR figures.	56.1(pA1)
If change is <u>limited</u> to those that affect content of UFSAR, then effective scope of 50.59 will be reduced, as practiced by some licensees, who interpret 50.59 to mean that a change to anything that <u>appears</u> in the UFSAR must be evaluated.	56.3(p1)
<p><u>Summary:</u></p> <p>Commenters offered several proposed clarifications and concerns about the definitions. Most were directed at allowing screening of changes that did not affect functions, or of other activities that should not require 50.59 evaluations.</p> <p>A few commenters wanted the rule language to explicitly codify the philosophy in GL 91-18 concerning the "de facto" changes and corrective action.</p>	
<p><u>Resolution:</u> The staff recommends a revision to the rule language on change that would accommodate screening. No rule changes are recommended concerning the "de facto" changes - staff believes existing guidance is adequate. Other comments can be handled through appropriate implementation guidance.</p>	

**B.2 Facility As Described:** Facility as described in the final safety analysis report (as updated) means: (i) The systems, structures, and components that are described in the final safety analysis report(as updated), (ii) The design, performance requirements and methods of operation for such systems, structures and components required to be included or described in the final safety analysis report (as updated), and (iii) The evaluations or methods of evaluation required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished.

Comment	Commenter & Item Number
Delete " <i>required to be included or</i> " from §§ii & iii. Requirements for FSAR are in §50.34(b) and 50.71(e)	10.2(p1) 11.10(2.5,p6) 22.12 (II.B.1,pp5) 27.13(p9) 39.4(pA3) 52.2(p2)
Replace " <i>required to be included or</i> " with a reference to the definition of safety-related SSCs contained in 50.2	31.1(p1)
Delete " <i>methods of operation</i> " from §§ii because the information is captured by the definition proposed for "procedures as described"	22.13 (II.B.2,pp5)
Endorse treatment of information " <u>incorporated by reference</u> " as in NEI 98-03.  Commenter 38 suggests the definition of incorporated by reference be added to the rule.	1.11(II.B.5,p4), 17.13(II.B.5,p4) 38.12(II.E.2,p11)
Limit criteria (iii) to 'plant-specific input variables and results' from the evaluations included in the FSAR.	3.6(3(a),p6&A-1)
Delete third criterion (50.59(a)(2)(iii), on evaluations and methods because its inclusion discourages licensees from adopting new (improved) methods.	7.10(10,p6)
Modify definition to include only "those aspects of systems, structures and components as are described in the final safety analysis report." As proposed by staff, any change to a SSC would require 50.59. Need to screen out some changes.	27.12(p9) 39.4(p2&3)
Discussion in NOPR is inconsistent in use of FSAR, sometimes uses SAR, where FSAR would be appropriate.	38.2(II.B.1,p5)

Support Chairmans position that definition of procedures (and by extension of facility), needs clarification. Specifically, suggest: 'Facility as described in the final safety analysis report (as updated) means (1)[sic] The FSAR description of the design, function or method of performing the function of any system, structure or component (SSC).	38.8(II.B.9,p8&9)
Limit applicability of 50.59 to design bases to FSAR-described design bases.	38.19(p11)
Clarify in the rule or NRC endorsed guidance that there is no need for 50.59 evaluations for 'second tier' programs such as procurement specs, evaluation methods and other sub-tier design info docs that are controlled by App B.	44.1(p1)
'As described in the final safety analysis report (as updated)' may narrow the scope of the regulation, in practice, because some licensees have interpreted current language to include licensing documents not specifically reference in the FSAR text.	56.2
<p><u>Summary:</u></p> <p>Commenters offered ideas on other ways to phrase the requirements, especially with respect to the language of "required to be included".</p>	
<p><u>Resolution:</u> The staff has accepted some of the comments concerning wording of the definition of facility. See also comments on "change" - other comments will be addressed in the statement of considerations for the final rule.</p>	

**B.3 FSAR (As Updated):** Final safety analysis report (as updated) means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with §50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71(e) and (f).

Comment	Commenter & Item Number
Replace " <i>as modified as a result of changes made pursuant to Section 50.59 and Section 50.90, and, as applicable, Section 50.71(e) and (f),</i> " with, " <i>as updated per the requirements of 10 CFR 50.71(e).</i> " This is consistent with NEI 98-03	18.2(p2) didn't propose wording, just simplify 22.14(II.C.1,pp5) 39.5(pA3),proposed similar language
To simplify section (c)(2), expand definition of FSAR by including the phrase in criteria (c)(2)(i)-(vi), by adding the following, " <i>For purposes of implementing this section, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last update of the final safety analysis report pursuant to Section 50.71 of this part.</i>	18.2(p2)didn't propose wording, just to simplify 22.15(II.C2-3,pp5-6)
Agree with NEI 22,15 comment, except delete phrase, " <i>evaluations pursuant to this section and</i> "	39.5(pA3&4)
Delete from §(c)(2)(i-iv), " <i>...or evaluations performed pursuant to this section and analyses performed pursuant to Section 50.90 after the last final safety analysis report was updated pursuant to Section 50.71 of this part.</i> "	39.5(pA3)
<p><u>Summary:</u></p> <p>Commenters offered rephrasing of the definition to reduce complexity in the rule text.</p>	
<p><u>Resolution:</u> The staff recommendation is to revise the final rule along the lines proposed by NEI to simplify the criteria statements by including the language about other evaluations as part of the definition of FSAR (as updated).</p>	



<p><b>C.1 Procedures:</b> Procedures as described in the final safety analysis report (as updated) means information in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times) and information describing the conduct of operations.</p>	
Comment	Commenter & Item Number
<p>Delete "<i>conduct of operations.</i>"</p> <p>Basis: while required to be in FSAR, admin procedures are under AppB (&amp;50.54), criteria in §(c)(2) don't work, changes don't meet proposed change (see comments 22.11-12) definition.</p>	<p>11.9 (2.4,p5-6), except asked for clarification 22.16(II.D,pp6-7) 27.14(p10) 52.4(pA2)</p>
<p>The proposed definition or procedures is welcome and will reduce utility burden by not requiring 50.59 reviews of support procedures.</p>	<p>1.14(II.C.1,p4)</p>
<p>Add criteria of, "The analytical methods of the evaluations required to be included in the FSAR (as updated) for such SSC and which demonstrate that their intended function(s) will be accomplished".</p>	<p>3.6(3(b),p6&amp;A-2)</p>
<p>Proposed new definition of 'procedures as described' is more definitive than the current rule and appropriately emphasizes operator actions and response times, which can affect critical factors in the safety analysis.</p>	<p>32.5(II.C,p3)</p>
<p>Share Chairman's concern that definition of procedures is flawed (p56115). Suggest following definition: "Procedures as described in the final safety analysis report (as updated) means the FSAR description of the operation and control (including assumed operator actions and response times), of any system, structure, or component (SSC) and information on conduct of operations.</p>	<p>38.9(II.C.1,p9)</p>
<p>Discuss and clarify that 'information on conduct of operations' excludes procedures of an administrative nature.</p>	<p>48.3(pA1)</p>
<p>Terminology of "assumed operator actions" is too vague, should only include explicitly described (in the FSAR) operator actions as changes under 50.59</p>	<p>55.1(p1)</p>
<p><b>Summary:</b> Several commenters offered clarifications of the definitions. The major objection was to the phrase "conduct of operations", which many thought was too broad and would encompass administrative procedures not suitable for 50.59 review.</p>	

**Resolution:** The staff recommends clarifications to the definition, including deletion of the words "conduct of operations"

**C.2 Applicability Re. Procedures:** The provisions in this section do not apply to changes in procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

Comment	Commenter & Item Number
Support the change	17-17, 22-8, 32-5, 39-46, 57-4
Expand the scope to include modifications to the plant as well as to procedures.	22-8
Clarify how 10 CFR 50.59 applies to TRM COLR, ODCM, PTLR, FPR and Safeguards Contingency Plan	57-4 1-44
<p><u>Summary:</u> There are 5 comments commenting on this item; they all agreed with the staff's proposed change. However, some commenters suggested the staff go further: (1) to expand the scope to include modifications to the plants, not only "procedures" and (2) to clarify how 10 CFR 50.59 applies to some special documents, such as Technical Requirements Manual, Core Operating Limits Report, Offsite Dose Calculation Manual, Pressure and Temperature Limits Report, Fire Protection Report and Safeguards Contingency Plan. As noted under topic N, the change process for topical reports was also raised by commenters.</p>	
<p><u>Resolution:</u> The staff plans to accept the wording revision proposed by NEI. Other comments will be addressed in the SOC or guidance as applicable.</p>	

**D. Test and Experiments:** Tests or experiments not described in the final safety analysis report (as updated) means any condition where the reactor or any of its systems, structures or components are utilized or controlled in a manner which is either: (I) Outside the controlling parameters of the design bases as described in the final safety analysis report (as updated) or (ii) Inconsistent with the analyses in the final safety analysis report (as updated).

Comment	Commenter & Item Number
Definition acceptable	1-15,32-6
Definition should be in guidance or use NEI 96-07 definition	17-18
Recommends the use of the term "activity" rather than "condition" to be consistent with the proposed rule language and to avoid confusion with discovered "conditions" covered by GL 91-18.	22-18
50.59 should define tests and experiments and address how their control as procedures should be controlled	38-10
Term "reactor or any of its SSCs" could be misleading. May want to reference 50.2 definition of design bases	39-7

**Summary:**

Of the 58 responses received, there were 15 responses that did not address this item, 35 responses that indicated agreement with the comment from NEI and 5 independent comments. The majority of the comments supported the proposed wording with minor clarifications. The suggestion to revise the section to address procedures that control tests and experiments should not be necessary as the proposed wording appears to be well understood.

The comment from NEI had no objection to the proposed wording except to recommend the use of the term "condition" rather than "activity" in the final rule so as to avoid confusion with discovered "conditions" which are by the guidance in Generic Letter 91-18, Revision 1. Two responses agreed with the proposed wording as written. One response recommended placing the definition in the guidance or using the definition from NEI 96-07. One response felt that because "tests and experiments" are controlled by procedures, Section II.D should be revised to address how the control of these activities as procedures is controlled.

See also comments under topic P about use of the term "design basis".

**Resolution:** The staff proposes to retain the definition with some clarifications, such as referring to "activity" rather than "condition."

**E.1 Final Safety Analysis Report - Definition:** Final safety analysis report (as updated) means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as modified as a result of changes made pursuant to § 50.59 and § 50.90, and, as applicable, § 50.71(e) and (f).  
(See B.3)

Comment	Commenter & Item Number
Should be made clear that TS and their Bases are part of the FSAR. In some cases, the TS, have detail not in the FSAR, such as applicable modes, that may be relevant to 50.59.	38.11(II.E.1,p9&10)
Define the FSAR such that it recognizes it is updated so that each time FSAR is stated, it is not necessary to add the term (as updated). Adds no value.	38.12(II.E.3,p11)
Propose following definition for FSAR in 50.59: <i>"The set of licensing basis documents used to support issuance of a plant operating license. These documents include, but are not limited to, the Facility Operating License, the NRC Safety Evaluation Report, the UFSAR, Selected Licensee Commitments, the Technical Specifications, and other licensing documents."</i>	44.2(p1&2)
<u>Summary:</u> Only a few comments were received on this subitem, generally seeking clarification.	
<u>Resolution:</u> No changes to rule text planned. While staff agrees with last comment with respect to implementation, the definition is considered too broad to be included in the rule.	

**E.2 Safety Analysis Report and Pending Changes:** ...as previously evaluated in the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part.

Comment	Commenter & Item Number
A change could be made (50.59 or 50.90) that would significantly lower probability or consequences from that described in the FSAR. Normally, the FSAR would not be updated to reflect this. Literal compliance with proposed wording would make the new evaluation become the acceptance criteria for all future 50.59 evaluations. Could also require that all previous 50.59/50.90 evaluations be reviewed to ensure most conservative result is reflected in the FSAR.	1.21(II.G.2,p11) 4.1(1,p1)
It is appropriate for proposed rule to require evaluation to include changes already made for which the UFSAR update has not been submitted, to ensure the evaluation is based on most up to date information.	32.7(II.E, p3)
The phrase "and safety analyses pursuant to Secs 72.56 or 72.244" [corresponding part wording is "and safety analyses performed pursuant to Sec 50.90]" used in six of the license amendment criteria makes it appear that a licensee could prepare a license amendment pursuant to 70.56 or 72.244 [50.90] and use the associated safety analysis for subsequent changes permitted by 72.48 [50.59] before the amendment is approved.]	7.6 (would also apply to Part 50)
<u>Summary:</u> Commenters had concerns on two aspects - whether the rule would require systematic review of all evaluations since the last update, and whether the rule language suggests that licensees update the FSAR or use as the baseline for evaluation amendment requests that are still pending.	

Resolution: See also topic B.3. The staff still concludes that it is appropriate for licensees to consider changes made subsequent to the last update to ensure that evaluations reflect current configuration of the facility. The process that a licensee would follow to confirm this is not being prescribed. If the changes were such that the FSAR information (description, analysis) is still accurate, subsequent changes could be evaluated with respect to the FSAR(as updated) description - otherwise, there should be a planned FSAR update awaiting submittal that should be used as the basis for review.

With respect to the last issue, this can be addressed in guidance or the supplementary information. Staff believes that this is not generally misunderstood and notes that existing language in 50.71(e) that refers to evaluations in support of requested amendments could be similarly misinterpreted. However, staff also notes that other rule changes in 50.59, such as in (c)(1) make more explicit the need to obtain approval before implementation. Staff also plans to revise "requested" amendments to instead say "approved amendments" in 50.71(e)

**F. Probability or Consequences No More Than Minimally**

**Increased:** Result in more than a minimal increase in ... previously evaluated in either the final safety analysis report ...

Comment	Commenter & Item Number
Comments are discussed in sections G.1 and G.2	



G.1 Guidance on "More Than Minimal" - Probability	
Comment	Commenter & Item Number
<p>Unclear whether the guidance on a change in accident classification is intended as the definition of a more than minimal increase in probability of an accident or as an example of such an increase.</p> <p>NRC should provide guidance on whether a change in probability class for an event analyzed in the SAR constitutes merely an increase in probability or the change in probability class results in a new accident.</p> <p>NRC should recognize that changes within the frequency classification do not constitute an increase in probability. An increase in probability would be realized only if the event moved into a more frequent classification.</p>	22-20, 1-19, 17-19, 18-3, 38-16
Does not agree with the proposed wording concerning the concept of minimal increase. "Minimal" is itself an arbitrary expression. The NRC uses an oversimplified depiction of safety analysis in trying to define "minimal increase". However, safety limits involve many parameters.	2-2 29-3
Modify the discussion on probability of equipment malfunction in Section II.G of the NOPR to " <i>The probability of malfunction of equipment important to safety previously evaluated in the FSAR (as updated) is no more than minimally increased not increased if design requirements are met.</i> "	22-21 39-13 43-2
Agrees with the statement "the probability of malfunction... is no more than minimally increased if 'design basis' assumptions and requirements are still satisfied [i.e. ....]," but recommends deletion of the reference to "procurement requirements as a design basis assumption or equipment" because procurement requirements normally are in excess of the design bases requirements and procurement requirements do not establish the design basis; the design basis helps to determine the procurement requirements.	18-5

<p>The evaluation of a change against the probability of malfunction criterion should be performed consistently. Modify it to <i><del>"The Commission believes that the probability of malfunction is more than minimally increases if a new failure mode as likely as existing modes is introduced. The determination of whether the probability of malfunction is introduced is more than minimally increased should be made either at a the component level, or consistent with the failure modes and effects analyses in the FSAR, taking into account single failure assumptions, and the level of change being made."</del></i></p>	<p>22-21 20-3 22-22 18-4 31-3 11-5 38-17</p>
<p>The guidance in the final rule should expressly reflect Commissioner McGaffigan's comments, and expressly state that, although the current NEI guidance certainly satisfies the rule, the rule affords greater flexibility than that provided for by the current NEI guidance.</p> <p>Recommends that the NRC develop quantitative standards for "minimal increase" and define "minimal" in the context of probability.</p>	<p>27-3,27-4</p>
<p>Quantitative methods (e.g., PRA) could be used to better define when a change involves more than a "negligible" --- but less than a "minimal" --- increase in probability and thus may be implemented without obtaining a license amendment.</p> <p>NRC needs to provide additional guidance on using risk insights, if there is an increase in probability of undesired outcome.</p>	<p>22-23 32-9 1-18 38-15 27-4 39-13</p>
<p>Agrees with the proposed guidance which states that several provisions in NEI 96-07 satisfy the proposed standard on minimal. However, the NRC should clarify that NEI 96-07 does not represent the outer bounds of what is acceptable under the proposed rule because NEI 96-07 was developed to implement the current rule, which is more restrictive than the proposed rule.</p>	<p>11-4, 32-8</p>
<p>The above positions would not require the term "minimal increases in probability" to be defined. If the above approaches are not acceptable, the NRC should endorse the existing industry positions presented in NEI 96-07.</p>	<p>17-19</p>
<p>Agrees with NRC's conclusion and the proposed language that "minimal increase" should not require prior NRC approval.</p> <p>NRC should provide clarifications to the proposed rule to clarify and better define what is meant by minimal.</p>	<p>27-2 36-2</p>

In defining minimal increase in probability or consequences, the SOC should explicitly acknowledge that in the case of non-power reactors, these risks are already minimal so that the primary thrust of a 50.59 analysis in this instance is more in terms of consistency with SAR than quantitative assessment. This adds burden to both NRC and licensees.	19-2
The NRC concludes that licensee can treat changes in external hazard design requirements as potentially affecting equipment probability rather than as accident probability. - This should be reflected in guidance.	39-14
Agrees with the proposed rule change to allow a minimal increase in probability, and corresponds to NSAC-125 and NEI 96-07	1-17
<p><u>Summary:</u></p> <p>Most comments agree with NEI comments and/or NEI 96-07. Specifically, these comments address:</p> <ul style="list-style-type: none"> <li>▶ need a description/definition of “minimal increase”</li> <li>▶ evaluations of changes against the probability of malfunction criterion should be performed at a level consistent with existing analyses in the FSAR</li> <li>▶ clarify position if the resulting probability (even though increased) still satisfies the event frequency classification provided in FSAR, whether the change is considered to be more than a minimal increase</li> </ul>	
<p><u>Resolution:</u> The staff was not able to provide a definitive standard for “minimal” that is more than “negligible” as judged in a qualitative evaluation. Quantitative criteria that might use PRA would be best developed in a different context, such as RG 1.174, rather than for the existing criteria of changes in probability of FSAR accidents and malfunctions. The proposed guidance offered in the FR notice will be modified to respond to the comments, and will either be part of a RG or included in industry guidance.</p>	

G.2 Guidance on "More Than Minimal" - Consequences	
Comment	Commenter & Item Number
Clearly state that the term "consequences" refers to radiological dose.	22-24,20-4, 38-14, 39-15, 43-3, 44-4, 59-2
<p>Prefers the third option in NOPR because it is easier to implement and it is self limiting. With following comments:</p> <p>Acceptance guidelines - NOPR approach is too restrictive, illogical, and lacks regulatory standing. Recommends changes allowed by the lesser of the following:</p> <ul style="list-style-type: none"> <li>• 10% of the margin to 10 CFR limits, or</li> <li>• the applicable acceptance guidelines (if any).</li> </ul>	22-24, 20-5, 33-1, 11-6, 13-3, 38-21, 43-3, 51-1, 52-6, 38-22, 1-22, 59-3, 39-17, 39-18
<p>NRC should endorse the existing guidance of NEI 96-07 which sets the limit as the value accepted by the NRC in the SER, which are generally tied to the acceptance limits in the NRC SRP.</p> <ul style="list-style-type: none"> <li>• provide examples on why it is more preferable to determine increases in consequences based upon the SRP and/or SER acceptance limits instead of the values documented in the SAR</li> <li>• Tying "increase in consequences" to the values reported in the SAR rather than to the acceptance limits quoted in the SER will penalize those plants which maintain a greater level of detail in the SAR.</li> </ul>	1-20
To maintain the original NRC acceptance bases, plants should be categorized as Pre-SRP and Post-SRP plants. For Post-SRP plants, the SRP acceptance dose criteria per accident type, used as the basis for their original NRC acceptance, should be used as threshold values for determining a minimal increase in consequences. For Pre-SRP plants, the graduated percentage table in FR 56105 should be acceptable as long as the limits are based on full Part 100 guideline values.	3-3
Acceptance limits should be based on SER rather than those reported in SAR..	17-20 27-7
Agrees with the second Option which addresses the concern of cumulative affect.	17-22

NRC should address the case of plants that have lowered dose due to one changes and subsequently increased dose due to a later change. The concern is that the minimal increase definition might require review for the second change while it might not had the first change not been made.	1-21, 4-1,17-23
For the example given in the second paragraph under "Consequences of an accident or malfunction" in Section II.G (a bounding analysis that is still satisfied), the example has no increase in consequences because the new analysis result remains bounded by the previous analysis result.	17-24
Supports percentage guidance of 20% versus 10% as proposed by the draft guidance.	18-6, 27-6 39-19, 44-5
Does not agree with the NRC's position on "controlling" inputs, assumptions, and methodologies associated with dose calculations, not described in the FSAR, as rigidly as those described in the FSAR. This goes beyond the scope and intent of 50.59 rule.	38-19
Commenters believe that changes to methodology related to consequence calculations that have been generically accepted by NRC (such as ICRP dose conversion factors or SRP assumptions concerning fission product scrubbing) can be used by licensees without approval.	1-36 (p.16),17-31
Consequences of "malfunctions" and consequences of "accidents" should be combined into one, (not discussed separately as existed in the proposed rule). Consequences are based on analyzed DBAs.	18-9, 38-20
The graduated approach seems to capture the spectrum of potential licensee scenarios while not impacting the basis for acceptability. This option provides the maximum flexibility by referencing to the limit.	32-9
Agrees with option 3, which allows for minimal changes up to a certain percentage of remaining margin. Guidance should expand upon the application to GDC 19 considerations, and whether it should be included in the scope.	39-16
Recommends that the new rule be applied appropriately to the radiological consequences of accident and not to the radiological consequences associated with normal operations or anticipated operational occurrences.	59-2

Summary:

Most comments agree with NEI's comments in that, a clear statement should be included that states the term "consequences" refers to radiological dose. In addition, most comments received endorses NEI's comments on Option 3 with the acceptance limits to which minimal is applied being regulatory values (Part 100, GDC 19) or not to exceed any applicable SRP guidelines. Also, comments supported proposal of 10% of the margin to Part 100 limits (with a few comments proposing 20%). Some commenters would prefer use of the limit alone, without a "minimal increase" standard.

Resolution: The staff proposal on consequences is presented in the Commission Supplementary information and guidance will address other issues raised by the comments

<b>H.1 Accident - Definition:</b> An initiating event or combination of events and/or conditions that could occur from equipment failure, human error, natural or manmade hazards which challenges the integrity of one or more fission product barriers (fuel, reactor coolant system, release of radionuclides (confinement/containment), required to be analyzed and/or accounted for by the Commission and addressed in the licensee's safety analysis report.	
Comment	Commenter & Item Number
No need to change the definition of "accident" that exists in guidance such as NEI 96-07	11-13
Accidents should be limited to the bounding "design basis accidents"	17-25
Definition of the term "accident" should be in the guidance for implementation of 50.59 and not in the final rule. The definition used by industry since 1989 is part of NSAC-125 and currently in NEI 96-07.	22-19,33-3
Commenter concurs with NEI and espouses the definition of accident used in Reg Guide 1.70.	25-1 25.4
Suggests definition of an accident to include DBAs, AOOs, and special events that are analyzed to demonstrate safety	39-21 39-22
Proposed wording vague, suggests using the definition in 50.49 and NEI 96-07	33-3
Definition of DBE reasonable, can be more specific by referring to accidents analyzed in the SAR, including AOOs and external events which result in accidents analyzed (also could treat external events as malfunctions).	1-24
Definition of accidents tied to SAR Chap. 15 events is very different from CDF used in PRA	1-25, 17-26
Delete "required to be analyzed or accounted for by the Commission" from the definition	44-8
Definition of event should be "a combination of postulated challenges and failure events against which plants are designed to ensure adequate and safe plant response"	44-8
The proposed wording is too convoluted to be applied consistently. Propose using "new failure mode with a different result to safety items, new limiting AOO, or sequence of events resulting in a rad release above current operating limit in App-I or section 20"	3-3

Adding phrase "design basis accident" to the three criteria referring to accidents is adequate. Adding a definition unnecessary	32-10
Add "credible" to definition of accident	44-7
<p><u>Summary:</u></p> <p>Of the 58 responses received, 11 responses did not address this item, 35 responses indicated agreement with the comment from NEI, and 11 responses gave independent comments.</p> <p>The response from NEI recommended that the term "accident" should not be defined in the rule but should be in the guidance for implementation of 50.59. NEI also stated that the definition of "accident " used by industry since 1989 is part of NSAC-125 and is currently in NEI 96-07.</p> <p>Only two responses agreed with the definition as written. Almost all responses felt that the NRC definition tended to expand the scope of an "accident of a different type." Several comments recommended criteria such as, "creates the possibility of a new limiting AOO (transient), or creates a new sequence of events that can result in a radiological release (via a normal pathway) above a current operating, Section 50 App. I or Section 20 limit."</p>	
<p><u>Resolution:</u> Staff recommendation is to provide guidance, either in RG or industry guidance document on understanding of accident - no rule language changes (beyond "is created") are recommended.</p>	



**H.2 Design Basis Accident of a Different Type (in Criteria):** Create a possibility for a design basis accident of a different type than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 with respect to design basis accidents after the last final safety analysis report was updated pursuant to section 50.71 of this part.

Comment	Commenter & Item Number
For an event to be classified as a design bases "accident" it must have radiological dose consequences and require plant design change as corrective action	3-1, 3-4
Endorses proposed use of DBA in the criteria for accident of a different type	11-14
Commenters concur with NEI in general but the phrase "accident of a different type" should be defined in the rule. Commenter emphasizes that the change needs to result in a new failure mode, new release path, or has a new sequence of events that results in significant cladding failure	3-4, 25-1 25-4
Agrees with the proposed wording and emphasizes that the accidents should be "credible"	27-11
Adding phrase "design basis accident" to the criteria referring to accidents is adequate. Adding a definition unnecessary	32-10
There should be a list of types and examples of accidents of a different type	38-24
For an accident to be of a different type it must result in a new or greater fission release path than originally considered or result in a new fission product barrier failure mode. Suggest using "would this be included if the FSAR was being written today."	3-1
10. Concerned that a slightly different initiator that leads to the same DBA would be considered a new accident	36-4
Commenter believes revised language of "with a different result" should also be used here	38-25

Do not use "Design Basis Accident" as this is a severely limited definition for some older plants	39-20 39-23 44-6
<p><u>Summary:</u></p> <p>Of the 57 responses received, 12 responses did not address this item, 34 responses indicated agreement with the comment from NEI, 9 responses gave independent comments.</p> <p>Only a few responses indicated that use of the term "design basis accident" was acceptable as written. The remaining independent responses indicated that the term "design basis accident" would not be understood consistently by licensees and that the term should be defined in the guidance. Most of these comments favored making it clear that the term "accident of a different type" referred to design basis types of accidents and gave criteria to be used to define this term. As an example, GE emphasized that "an accident of a different type means an accident that results in a new fission product release path, results in a new fission product barrier failure mode, or creates a new sequence of events that results in significant fuel cladding failures."</p> <p><u>Resolution:</u> The staff recommendation is to include discussion in guidance but not to include the term "design basis" in the criterion on accident of a different type.</p>	

**I. Malfunction with a Different Result:** Create a possibility for a malfunction of equipment important to safety with a different result than any previously evaluated in either the final safety analysis report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to section 50.90 after the last final safety analysis report was updated pursuant to section 50.71 of this part.

Comment	Commenter & Item Number
Distinction between accident probability and failure rate of safety equipment is unnecessary and counterproductive	2-3
Malfunctions of equipment should be considered different if the new failure mode results in a different outcome than previously considered	3-2
NEI supports the change to "Create the possibility for"; use of the phrase "important to safety"; and change to "malfunctions with a different result."	22-46
Agrees with proposed wording	32-11,39-24
NRC definition of a malfunction is too broad, NEI-96-07 is narrower, A different malfunction exists only if result as described in FSAR is different regardless of cause e.g. air versus a motor operated valve	38-26
Adding the term "of equipment important to safety" is inappropriate & should not be pursued. Suggests "If a possibility for a malfunction of a different type with a different result, of FSAR-described equipment, than any evaluated previously in the FSAR is created."	38-27
This evaluation is part of the design change evaluation and should not be part of the evaluation for need of an amendment. If a design evaluation determines a change from FSAR is effected, <u>then</u> a 50.59 evaluation is required	38-26 38-27
Summary: Commenters generally agreed with the proposed rule change. Some had concerns about interpretations on the level (that is, subcomponent, component or system) at which malfunctions need to be considered. As noted in comments on Part 72 (topic M), some commenters seek greater commonality in terms, equipment important to safety vs. SSC important to safety.	

Resolution: The staff recommends proceeding with the language as offered in the proposed rule - other issues can be addressed in the guidance. Staff will retain SSC ITS in Part 72 as this term is defined and modify 50.59 to conform. Consideration of changes to definitions of ITS is part of SECY-98-300.

J. Margin of Safety- Several Options were offered for comment; also, the notice invited commenters to offer other proposals for NRC consideration.	
Comment	Commenter & Item Number
1. Ten commenters specifically stated that they strongly oppose option 1 (control inputs to analyses) as being too restrictive, making inputs equivalent to TS requirements. (Others would seem to agree by virtue of endorsing NEI comments). One agreed that this was best approach if NRC allowed compensating changes such that the validity of TS LCO or SL is maintained.	1-27, 11-1, 17-28,18-7, 22-17, 27-8, 36-7, 38-28, 39-27, 46-2. (3-10)
2. Fifteen commenters favor option 2 (delete margin as criterion). Basis given is that other criteria (including the TS and rules) are sufficient. A few commenters said not acceptable to delete, as this might leave gaps which might lead NRC to redefine probability or consequence criteria, or that there may be non-accident events involving malfunctions of equipment "not important to safety" not covered (e.g., generator load rejection). One thought the NEI proposal would "collapse" to deletion of margin since the TS include all the parameters covered by the NEI proposal for particular plants	1-32, 7-7,9-2, 10-1,11-2,12-1,14-1,17-29,18-7, 31-2, 32-12, 33-4, 38-29, 48-10 (3-11, 25-2) 26*
3. Option 3(A) variations (Results of analyses, specific parameters) - many commenters had issues with the options as outlined in the notice, either that the parameters selected were not appropriate, or that there would be uncertainty about which parameters involve margins. Alternative proposals were offered.	1-28, 3-12, 17-30
One commenter stated there was a need to clarify which safety analyses are covered - e.g., for ventilation or support systems performance vs. ECCS or other systems	1-31
NEI proposed to replace the margin of safety criterion with a criterion that requires NRC review for a change that would: result in a design basis limit directly related to the integrity of fuel cladding, RCS pressure boundary, or containment boundary being exceeded or altered.	22-17,27-9
Commenters noted that some fission product barriers are covered by other requirements, e.g., PCT is covered by 50.46	3-12, 22-17, 25-5

The parameters affected should only be those directly related to Fission product barriers.	1-28, 7-30, 11-2, 22-17
This criterion should only apply where there are clearly defined "design basis limits"	1-30; 3-9, 22-17
One commenter stated that changes involving mitigation systems were covered by the other evaluation criteria and thus did not need to be part of a "margin" criterion	11-1
One commenter wanted clarification in the SoC that changes to equipment qualification (including accident profiles) are not reductions in margin if 50.49 still satisfied.	23-
4. Amount of Reduction allowed without review - notice offered range of options from no net change up to not exceeding limits	
Several comments stated that reductions in margin would only occur from the design basis limits (or other terms) without restriction to minimal reduction in the difference between the calculated value and the limit, as suggested in some of the options.	1-29, 3-13, 18-7,36-2
Some commenters preferred the terminology in 96-07 of reductions being measured from "licensed acceptance limits", One commenter would clarify that these are the limits approved by NRC and would modify NEI words to read "a prescribed NRC acceptance or design code limit is exceeded or altered". (These commenters also favored increases up to these limits without a "minimal" concept).	3-13, 25-2, 44-9 (NRC limit)
Minimal reductions in margin from the limits should be allowed - to extent of precision of analysis	11-24
One commenter believes that approval should only be required if the limits would be exceeded, but that a change in the amount of "margin" to the limit might be established as a reporting criterion, as is done in 50.46 for PCT.	1-2
5. Evaluation Methods	
a. Some commenters stated that methods should not be controlled by 50.59 because the limits are conservative. These commenters stated that they should be allowed to use methods approved by NRC through SRP or other process without need for 50.59 or NRC approval. Allow licensees' design control QA to govern.	1-36, 17-31, 36-8, 38-22,39-37

<p>b. A few commenters stated that different methods should be reviewed/approved by NRC or meet applicable guidelines or standards; OR produce results that are consistent with licensing basis methods; OR changes to methods should be evaluated under 50.59 as a separate change.</p> <p>NEI states that input assumptions can be adjusted, but must be reviewed as separate changes</p>	11-25, 22-17
6. Other Comments	
<p>a. Two commenters proposed that there be alternate criteria for decommissioning reactors (fuel removed) - one states that fission product barriers not the issue, but would add environmental impact. Another suggested limiting the scope to systems related to spent fuel pool cooling or radiological waste.</p>	36-6, 46-3
<p>b. Part 72 parameters for "margin" should be those with potential to increase prob. or amount of offsite releases (containment of fuel: subitems-temperature, pressure)</p>	17-36, 22-31
<p>e. A few commenters said that as part of the final rule, the staff should state that basis for any TS is limited to bases section. In contrast, another commenter would modify the definition of SAR to include the TS and their bases, and then the "bases for any TS" are in the SAR, and the other criteria are enough.</p>	1-43, 27-10
<p>f. The discussion on margin could be used to provide guidance on NSHC "significant" reduction in margin</p>	1-33
<p><u>Summary:</u></p> <p>NEI proposed alternative of meeting design basis limits directly related to fission product barriers. Several commenters favored deletion of the concept instead. Many expressed second preferences, that is, they would support NEI's approach if deletion was not accepted or the reverse. Some commenters thought that evaluation methods should not be controlled by 50.59, others agreed with NEI proposal that methods must be either reviewed and approved by NRC or otherwise meet applicable standards.</p>	
<p><u>Resolution:</u> The staff proposal is discussed in the Commission paper. Guidance will be developed to ensure consistent implementation.</p>	

<p>b. A few commenters stated that different methods should be reviewed/approved by NRC or meet applicable guidelines or standards; OR produce results that are consistent with licensing basis methods; OR changes to methods should be evaluated under 50.59 as a separate change.</p> <p>NEI states that input assumptions can be adjusted, but must be reviewed as separate changes</p>	11-25, 22-17
6. Other Comments	
<p>a. Two commenters proposed that there be alternate criteria for decommissioning reactors (fuel removed) - one states that fission product barriers not the issue, but would add environmental impact. Another suggested limiting the scope to systems related to spent fuel pool cooling or radiological waste.</p>	36-6, 46-3
<p>b. Part 72 parameters for "margin" should be those with potential to increase prob. or amount of offsite releases (containment of fuel: subitems-temperature, pressure)</p>	17-36, 22-31
<p>e. A few commenters said that as part of the final rule, the staff should state that basis for any TS is limited to bases section. In contrast, another commenter would modify the definition of SAR to include the TS and their bases, and then the "bases for any TS" are in the SAR, and the other criteria are enough.</p>	1-43, 27-10
<p>f. The discussion on margin could be used to provide guidance on NSHC "significant" reduction in margin</p>	1-33
<p><u>Summary:</u></p> <p>NEI proposed alternative of meeting design basis limits directly related to fission product barriers. Several commenters favored deletion of the concept instead. Many expressed second preferences, that is, they would support NEI's approach if deletion was not accepted or the reverse. Some commenters thought that evaluation methods should not be controlled by 50.59, others agreed with NEI proposal that methods must be either reviewed and approved by NRC or otherwise meet applicable standards.</p>	
<p><u>Resolution:</u> The staff recommends acceptance of the NEI proposal. Guidance will be developed to ensure consistent implementation.</p>	



K. Safety Evaluation	
Comment	Commenter & Item Number
Support removal of the term "safety evaluation" in favor of simply "evaluation"	1-37, 17-32, 22-5, 39-38
<u>Summary:</u> There are 4 commenters commenting on this item; they all agreed with the staff's proposed change.	
<u>Resolution:</u> Retain in final rule - see also topic A.3 regarding changes to TS which refer to "safety evaluations"	

L. Reporting and Record Keeping - Update requirements (effects of changes)	
Comment	Commenter & Item Number
There should be no change in the requirements for summarizing individual 50.59 evaluations associated with the rule change	1-38
Proposes no changes to 50.71(e) because changes are captured by the existing requirements of 50.71(e) and that using NEI 96-07 guidance, changes in probability of equipment malfunction or accident probability are not quantifiable, such that 50.59 evaluation criteria is met only if there is no discernible change in probability.	17-3, 20-6 22-26-a 22-26-b 52-9 32-8
Disagree with any change in 50.71(e) - including the net effect of increases in probability and consequences adds burden on licensees	18-8, 21-1, 35-2, 36-5, 39-47, 44-6, 48-1, 51-2, 4-2, 38-23, 38-31, 39-15
Disagree with additional requirements because: 5. The provision for increasing consequences by a minimal amount is self-limiting. 6. Any changes to these parameters (sufficiently important, they should be captured in FSAR) would require corresponding changes to the FSAR, which would be "reported" in required FSAR updates,	43-5 57-3 1-23 33-2
No discussion on how to implement on this additional reporting requirement. The industry should be given an opportunity to work with the NRC to address the implementation concerns.	48-1 51-2
Agrees with the proposed language for 50.59(d)(3) clarifying that records of changes in the facility must be retained throughout any license renewal term.	22-25 17-34
The proposed additional reporting requirements should be the subject of a careful cost benefit analysis by the staff.  The staff proposes to require that effects of changes be reflected in the UFSAR including new analysis performed at the Commission's request. This requirement should be explicitly identified in subsequent Commission requests for analysis and factored into future 50.109 determinations.	57-3

**Summary:**

The majority of comments are against any additional reporting requirements and any change to 50.71(e), and endorse NEI 96-07 guidance. The basic arguments are:

- ▶ the provision for increasing consequences by a minimal amount is self-limiting; and that any changes to the parameters (important enough to be captured in FSAR) would require corresponding changes to the FSAR, which would be “reported” in required FSAR updates.
- ▶ any changes to 50.71(e) and additional reporting requirements could add burden on licensees.

**Resolution:** The staff accepts the comments about reporting of cumulative effects. Minor wording changes would still be proposed for 50.71(e) for consistent terminology - see also comments on Part 72 (topic M).

M. Part 72	
Comment	Commenter & Item Number
1. Misc. Sections (72.3, .9, .24, .56, .86, .212)	
a. 72.56 is not clear if it applies to site-specific licensees, general licensees, or both	17.II.M.12; 22.3.13
b. The requirements of 72.48 (e.g., records) should also be applied to general licensees performing 72.212 evaluations	22.3.7b
c. The NRC should create provisions for emergency and exigency processing of license amendments as allowed by 50.91(a)(5) and (6) in Part 72	22.3.15
2. 72.48 (Parallel to Items A and K above) - Structure	
a. Limit the scope of 72.48 reviews to important to safety SSCs vs all SSCs described in the SAR	7.2
b. 72.48 can be simplified by changing the definition of SAR and not referring to the "FSAR as updated"	7.8
c. Eliminate occupational exposure and environmental tests from (b)(2) to conform to 50.59. One commenter suggested that an environmental criterion may be appropriate for decommissioning reactors in 50.59, instead of other criteria such margin.	11.2.10c, 17.II.M.6; 22.3.5; 29.3b; 48.2.3, 36.6
d. The risk from casks is much less than from reactors; however, many of the proposed requirements are more restrictive than Part 50	17.II.M.1; 22.3.a
e. The environmental impact test should be retained for site-specific licensees	48.2.4a
f. Certificate holders cannot perform an environmental assessment test because they do not have an EIS to evaluate changes against	48.2.4b
g. General licensees should evaluate any environmental impacts against the reactor facility EIS under 50.59 not 72.48	48.2.4c
3. 72.48 (Parallel to Items B, C, D above) - Scope of Definitions	
a. The term FSAR is confusing given that no PSAR exists	7.1a

b. 72.48 process should evaluate changes made after the ISFSI license is issued but before the FSAR is submitted per 72.70	7.1b
c. switch the order of paras (a)(2) and (a)(3).	7.3
d. Discussions of interdependent changes should be eliminated from 72.48, even if NRC retains it in 50.59	7.5
e. Use "equipment important to safety" instead of SSCs (i.e. proposes to conform terminology with 50.59)	17.II.M.7; 22.3.6
f. The phrase "required to be included" should be deleted from 72.48(a)(3)(ii) and (iii) (see also topic B re 50.59)	29.1
g. Delete "an ISFSI or MRS" from the definition of FSAR for a GL because the FSAR only includes the cask.	48.2.1
h. Clarify the wording in paragraph (a)(2)(iii) on NRC prior approval. Sample language provided. (See also topic E.3)	48.2.2
4. 72.48 (Parallel to Item E above) - Criteria Reference as FSAR Plus Other Evaluations	
a. Eliminate para (a)(3)(iii) "evaluations"	7.10
5. 72.48 (parallel to Items F and G above) - More than Minimal Increase	
a. Require the linkage of changes with minimal increases	7.6
b. "more than minimal" is subjective. Provide regulatory guidance on this issue. (See also topic G.1)	29.2
c. The phrase "more than minimal" should be used instead of "significant" for occupational exposure and environmental impact tests	29.3a
6. 72.48 (parallel to Items H and I above) - Accident of a Different Type	
a. Add "significant" to para (b)(2)(v) and (b)(2)(vi) or "minimal increase in risk"	7.9
7. 72.48 (parallel to Item J above) - Margin of Safety	
a. Delete Margin of Safety	7.7, 11.2.11a; 48.2.5
b. Any parameters used in margin of safety should include only those with the potential to increase the probability or consequences of an offsite release (e.g., fuel and cladding temperature, cask temperature or internal pressure)	22.3.2a

c. Release/accident limits for Part 50 should also be used for Part 72	22.3.2b
8. 72.48 (Parallel to Item L above) - Records and Reports	
a. Reports should be submitted at the same frequency as 50.59 (24 months)	11.2.10b, 17.II.M.11; 22.3.12; 29.4
9. 72.70 SAR Updating Specific Licensees	
a. Clarify the format for SAR updates before the FSAR is issued.	7.1c
b. Requires more info than 50.71(e) does (i.e., proposes to conform to 50.71(e))	11.2.10d, 17.II.M.5, 17.II.M.9e; 22.3.4
c. the change from “ <b>contain</b> all the changes necessary ...” to “ <b>describe the effects</b> of all the changes necessary ...” is excessively burdensome and was not properly accounted for in the backfit and paperwork reduction analyses	17.II.M.2; 22.3.1
d. Use the 24 month update frequency of 50.71	17.II.M.9a; 22.3.9a
e. The requirement to update the SAR every 6 months before fuel is loaded is overly restrictive.	17.II.M.9b; 22.3.9b
f. FSAR submittal 90 days before loading may not allow time for inclusion of 72.48 changes found during pre-op testing.	17.II.M.9c; 22.3.9c
g. Does the preload SAR requirement apply to general licensees	17.II.M.9d; 22.3.9d
h. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included in 72.70	11.2.10e, 17.II.M.10; 22.3.10
i. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1
j. Clarify that this section only applies to site-specific licensees	48.2.6
10. 72.216 SAR Updating - General Licensee	
a. Requires more info than 50.71(e) does (i.e., conform to 50.71(e))	11.2.10d, 17.II.M.5; 22.3.4; 48.2.7
b. The impact of this requirement has not been addressed in the paperwork reduction, backfit or reg analyzes	17.II.M.8a; 22.3.7a

c. An implementation schedule for this section should be provided	17.II.M.8b, 22.3.8
d. Use the 24 month update frequency of 50.71	17.II.M.9a
e. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included	11.2.10e, 17.II.M.10
f. Guidance on timeliness of reviewing 72.48 changes sent by the GL to the certificate holder should be provided.	17.II.M.13a; 22.3.14
g. Site-specific licensees should also be informed of GL or CoC holder 72.48 changes	17.II.M.13b
h. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1
i. The provision on replacement pages should apply to generic FSAR changes only.	48.2.8
j. Instead of sending FSAR changes to the CoC holder send the summary of 72.48 changes. Also require this within 30 days, not the annually	48.2.9
k. Revise the wording on FSAR revision numbers, it is confusing	48.2.10
11. 72.244 through 72.248 - SAR and Amendments for Certificate Holders	
a. Requires more info than 50.71(e) does (i.e., proposes to conform to 50.71(e))	11.2.10d, 17.II.M.5; 22.3.4
b. Clarify that the updated FSAR need not be limited to the most current design	11.2.11b
c. Use the 24 month update frequency of 50.71	17.II.M.9a; 29.5
e. The 6 month cutoff date in 50.71(e) for updating the FSAR should be included	11.2.10e, 17.II.M.10
f. Guidance on timeliness of reviewing 72.48 changes sent by the certificate holder to the GLs should be provided.	17.II.M.13a; 22.3.14
g. Site-specific licensees should also be informed of GL or CoC holder 72.48 changes	17.II.M.13b

h. the change from “ <b>contain</b> all the changes necessary ...” to “ <b>describe the effects</b> of all the changes necessary ...” is excessively burdensome and was not properly accounted for in the backfit and paperwork reduction analyses	22.3.1
i. If no 72.48 changes occur in a year, a letter stating no changes were made to the FSAR is adequate - see 50.71(e)(2)	22.3.11; 32.II.M.1
j. Instead of sending FSAR changes to the GL send the summary of 72.48 changes. Also require this within 30 days, not the annually	48.2.9
<p><u>Summary:</u></p> <p>Comments relate to following areas:</p> <ul style="list-style-type: none"> <li>-clarification of requirements relative to the three types of entities (site-specific licensees, general licensees and certificate holders</li> <li>- consistency of the proposed requirements between 50.59 and 72.48 (and other provisions such as for updating requirements)</li> <li>- consistency of existing requirements in 72.48 with comparable requirements in Part 50, and commenters views that Part 72 is more restrictive even though the risks are less.</li> </ul>	
<p>Resolution: Staff intends to provide any necessary clarifications in the rule language or supplementary information. In the Commission paper, the staff has made a recommendation on how to proceed with existing requirements and consistency issues. Staff notes that some of the requirements in Part 72 are more restrictive in certain respects (e.g. release limits) because other Part 50 requirements were not imposed (offsite emergency planning).</p>	



N. Other Request for Comment Issues	
Comment	Commenter & Item Number
1. Scope	
a. Include vendor topical reports (or develop parallel process).	1-12,17-13
b. NEI proposals on scope could allow reduction of some defense-in-depth requirements. Reliance solely on analytical bases is not robust or resilient approach.	1-16
c. Agree with NEI recommendation for follow-on rulemaking to determine appropriate, risk-informed scope.	5-2, 22-27,50-2
d. USAR is good choice for scope - any decision to increase or decrease scope should heavily weigh the practicality of implementing and enforcing any new screening criteria.	52-10
e. Could limit scope of required evaluations by designating which parts of the SAR are subject to 72.48 (or 50.59) - would allow information to remain in SAR and not require evaluations of programmatic material	7-1
f. Commenter suggests that for decommissioning reactors, scope of rule could be limited to changes that affect SSC related to spent fuel pool cooling and radiological waste.	46-3
2. Backfit Issues	
a. NRC underestimates the impact rule change will have on NRC licensing reviews.	1-41
b. NRC underestimates the cost to utilities of additional submittals to NRC.	1-42
c. Even prospective application of the rule may require a more detailed backfitting analysis.	16-2
d. NRC has not adequately addressed backfit burdens for Part 72 licensees	17-30, 22-30

Summary and approach to resolution:

No summary is provided because of the range of topics.

Comments will be considered in different ways - for example, scope issues will be examined in contemplated risk-informed changes to Part 50. Backfit issues will be considered during preparation of final regulatory analysis for final rule (staff notes that analysis for Part 72, although not ready at time of SECY-98-171, was included in the published documents for review).

O. Implementation Comments	
Comment	Commenter & Item Number
1. Guidance	
a. NRC and NEI should work together to provide examples that do and do not meet the evaluation criteria.	1-4, 17-5
b. Provide examples of changes for which it is appropriate or inappropriate to consider as integrated changes.	1-8
c. Provide examples of cases where activities normally viewed as maintenance would require 50.59 evaluation.	1-9
d. Provide detailed guidance on treatment of nominal values contained in SAR.	1-10,17-12
e. Provide clear and specific examples for "margin of safety" issue.	1-34
f. Commenter provides checklist for guidance document.	3-14
g. NRC should endorse industry guidance via RG prior to effective date of amended rule. Hold workshop to run test cases.	5-3, 22-45, 38-1, 52-11
h. Update NUREG-1606 with Section II of supplementary information or endorse NEI 96-07	7-4
i. Provide guidance that clarifies methods for implementation appropriate to non-power reactors.	19-1
j. NRC needs to either update or supersede (listed) guidance documents to the industry to ensure consistent guidance remains.	38-32
k. Revision of the rule not required, just issue RG, one commenter suggests that NRC just endorse NEI 96-07. Another commenter suggests revising rule to match NEI 96-07.	1-1, 2-1,17-1
l. Publish guidance concurrent with rule for format and content of license amendments when 50.59(c)(2) not met e.g., should proposed FSAR change be included, how should updating be conducted while pending)	39-10
2. Timing of implementation of rule	

a. NRC should define implementation period to allow utilities to revise their 50.59 processes (and changes to NEI 96-07)	1-3, 17-4, 57-2
b. Rule changes should expressly be limited to prospective application	16-1
c. Ensure that final rule is within bounds of proposed rule or provide opportunity for public comment on any portions of final rule that have substantially changed from proposed rule.	16-4, 32-1
3. Enforcement	
a. Staff should not issue NOVs for violations of existing rule language that will be changed under proposed rule	22-29, 39-48, 54-1
b. Only take enforcement during interim rulemaking period for deviations from NEI 96-07	17-3
c. "Grandfather" policy should be applied to past evaluations done in good faith using industry guidance unless willful violation	22-47, 39-48
<u>Summary:</u> Several comments were submitted that suitable guidance was needed to support the final rule, both as industry implementation guidance (endorsed by NRC), and inspection guidance.	
<u>Resolution:</u> The staff agrees that guidance is needed and has provided a recommended implementation and enforcement strategy in the Commission paper.	

P. Other Issues	
Comment	Commenter & Item Number
1. SIMPLER PROCESS: Create a more streamlined process than license amendments for changes that don't meet 50.59 evaluation criteria but which would not otherwise require NRC approval. License amendment process for changes not affecting TS or license is not necessary.	1-5, 22-28, 16-3, 27-1
2. RISK INFORMED REQUIREMENTS	
a. Proposes that a reasonable approach to risk-informed 50.59 would use CDF and LERF as well as risk insights for improving deterministic criteria.	1-40
b. Additional, longer-term rulemaking should address risk-informed changes	17-2, 55-2
c. Differences in acceptance criteria used for Chapter 15 analyses and PRA's should be understood and considered in determining acceptance criteria or defining "accident" in any risk-informed rule	17-26
d. Risk-informed approach to 50.59 should consider (1) some role for determining acceptability of changes based on CDF or LERF, (2) risk insights for improving the deterministic evaluation criteria that would have to remain a part of 50.59 to address non-severe accident impact.	17-31
e. Ensure that risk-informed 50.59 does not become added regulatory layer.	17-31,
f. Eliminate the requirement that licensees independently assess the impact of a change in the facility on the probability and consequences of a malfunction of equipment important to safety in those circumstances where a licensee has incorporated the possibility of equipment malfunction in a probabilistic assessment of the probability and consequences of the accidents that the malfunction would affect.	27-5
3. OTHER DEFINITIONS	

a. NRC should define terms "important to safety" and "design basis" particularly with respect to equipment for which probabilities and consequences of malfunctions have previously been evaluated in the FSAR. One commenter suggested substituting "safety-related" for important to safety.	3-5, 38-18, 52-7, 57-1
b. Define "design bases" in terms that are not subject to varying interpretations.	18-20, 55-1
4. CHANGES TO OTHER RULES	
a. Consider 50.59-like process for Part 71	5-4,22-32, 29-1
b. Modify 72.48 to allow changes in a dual-purpose cask without prior NRC approval under Part 71 and Part 72 (transportation and storage)	11-15, 32-14
c. Revise 76.68 concurrently with 50.59	6-1
d. Clarify acceptance limits of 10 CFR 51.52 re burnup assumptions for transport of spent fuel and clarify if this is subject to 50.59.	1-35
e. Incorporate all substantive provisions (e.g., definitions) in proposed revisions to 50.59 into ABWR design certification rule.	11-16,25-3

**Summary and Resolution:** No summary is provided because of the variety of comments. Several of the areas raised by these comments are considered as outside the scope of the proposed rule. Comments will be forwarded to staff responsible for the areas mentioned, and will be considered in future staff actions. See also recommendations in Commission paper.

**ATTACHMENT 2: RECOMMENDED (DRAFT) FINAL RULE  
LANGUAGE FOR 10 CFR 50.59 AND RELATED PROVISIONS**

## **PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES**

1. The authority citation for Part 50 continues to read as follows:

**AUTHORITY:** Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, and 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Section 50.37 also issued under E.O. 12829, 3 CFR 1993 Comp., P. 570; E.O. 12958, Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. Section 50.59 is revised to read as follows:

§ 50.59 Changes, tests and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Facility as described in the final safety analysis report (as updated)* means:

(i) The structures, systems, and components (SSC) that are described in the final safety analysis report (FSAR) (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.



**(3) *Final Safety Analysis Report (as updated)*** means the Final Safety Analysis Report (or Final Hazards Summary Report) submitted in accordance with § 50.34, as amended and supplemented, and as updated per the requirements of § 50.71(e) or § 50.71(f), as applicable.

**(4) *Procedures as described in the final safety analysis report (as updated)*** means those procedures that contain information described in the final safety analysis report (as updated) regarding how structures, systems, and components are operated and controlled (including assumed operator actions and response times).

**(5) *Tests or experiments not described in the final safety analysis report (as updated)*** means any activity where any structure, system, or component is utilized or controlled in a manner which is either:

- (i) Outside the reference bounds of the design bases as described in the final safety analysis report (as updated) or
- (ii) Inconsistent with the analyses or descriptions in the final safety analysis report (as updated).

**(b) Applicability.** This section applies to each holder of a license authorizing operation of a production or utilization facility, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required under § 50.82(a)(1) or a reactor licensee whose license has been amended to allow possession but not operation of the facility.

**(c)(1)** A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

- (i) A change to the technical specifications incorporated in the license is not required, and

(ii) The change, test or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A licensee shall obtain a license amendment pursuant to § 50.90 prior to implementing a change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);

(vii) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to §50.90 after the last update of the final safety analysis report pursuant to § 50.71 of this part.

(4) The provisions in this section do not apply to changes in the plant or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d)(1) The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test or experiment does not require a license amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility must be maintained until the termination of a license issued pursuant to this part or the termination of a license issued pursuant to 10 CFR part 54, whichever is later. Records of changes in procedures and records of tests and experiments must be maintained for a period of five years.

3. In § 50.66, introductory paragraph (b), paragraphs (b)(4), (c)(2), (c)(2)(i), (c)(2)(ii), and (c)(3)(iii) are revised to read as follows:

§ 50.66 Requirements for thermal annealing of the reactor pressure vessel.

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(b) Thermal Annealing Report. The Thermal Annealing Report must include: a Thermal Annealing Operating Plan; a Requalification Inspection and Test Program; a Fracture Toughness Recovery and Reembrittlement Trend Assurance Program; and Identification of Changes Requiring a License Amendment

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(4) Identification of Changes Requiring a License Amendment. Any changes to the facility as described in the final safety analysis report (as updated) which requires a license amendment pursuant to § 50.59(c)(2) of this part, and any changes to the technical specifications, which are necessary to either conduct the thermal annealing or to operate the nuclear power reactor following the annealing must be identified. The section shall demonstrate

that the Commission's requirements continue to be complied with, and that there is reasonable assurance of adequate protection to the public health and safety following the changes.

(c) ★ ★ ★

(2) If the thermal annealing was completed but the annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications, shall also be identified.

(i) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to Technical Specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(ii) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to the Technical Specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

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(iii) If the partial annealing was not performed in accordance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program, the licensee shall submit a summary of lack of compliance with the Thermal Annealing Operating Plan and the Requalification Inspection and Test Program and a justification for subsequent operation to the Director, Office of Nuclear Reactor Regulation. Any changes to the facility as described in the final safety analysis report (as updated) which are attributable to the noncompliances and which require a license amendment pursuant to § 50.59(c)(2) and any changes to the technical specifications which are required as a result of the noncompliances, shall also be identified.

(A) If no changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may restart its reactor after the requirements of paragraph (f)(2) of this section have been met.

(B) If any changes requiring a license amendment pursuant to § 50.59(c)(2) or changes to technical specifications are identified, the licensee may not restart its reactor until approval is obtained from the Director, Office of Nuclear Reactor Regulation and the requirements of paragraph (f)(2) of this section have been met.

4. In § 50.71 paragraph (e) is revised to read as follows:

§50.71 Maintenance of records, making of reports.

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(e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 or § 50.22 of this part shall update periodically, as provided in paragraphs (e)(3) and (4) of this section, the final safety analysis report (FSAR) originally submitted as part of the application for the operating license, to assure that the information included in the report contains the latest information developed. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The submittal must include the effects<sup>1</sup> of: all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2) of this part; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request. The updated information shall be appropriately located within the update to the FSAR.

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<sup>1</sup> *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.”

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5. Section 50.90 is revised to read as follows: [same as proposed rule]

§ 50.90 Application for Amendment of license or construction permit.

Whenever a holder of a license or construction permit desires to amend the license (including the Technical Specifications incorporated into the license) or permit, application for an amendment must be filed with the Commission, as specified in § 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

**PART 52 - EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS; AND  
COMBINED LICENSES FOR NUCLEAR POWER PLANTS**

6. The authority citation for Part 52 continues to read as follows:

AUTHORITY: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5546).

7. Appendix A to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 as follows:

Appendix A - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

*VIII. Processes for Changes and Departures*

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**B. Tier 2 information**

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a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would—

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(8) Result in more than a minimal change in a method of analysis described in the plant-specific DCD that is used to establish design basis values.

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d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

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*X. Records and Reporting*

A. Records.

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3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

8. Appendix B to Part 52 is amended by revising Section VIII.B, paragraphs 5.a,b,d, and Section X.A.3 to read as follows:

Appendix B - Design Certification Rule for the system 80+ Design

*VIII. Processes for Changes and Departures*

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B. Tier 2 information.

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a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2\* information, or the technical specifications, or otherwise requires a license amendment as defined in paragraphs B.5.b and B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would—

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;



(4) Result in more than a minimal increase in the consequences of a malfunction of a SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(8) Result in more than a minimal change in a method of analysis described in the plant-specific DCD that is used to establish design basis values.

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d. If a departure requires a license amendment pursuant to paragraphs B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

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#### *X. Records and Reporting*

##### *A. Records.*

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3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

### **PART 72 - LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE**

9. The authority citation for Part 72 continues to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as

amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

10. Section 72.3 is amended by revising the definition for independent spent fuel storage installation or ISFSI to read as follows:

§ 72.3 Definitions.

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*Independent spent fuel storage installation or ISFSI* means a complex designed and constructed for the interim storage of spent nuclear fuel and other radioactive materials associated with spent fuel storage. An ISFSI which is located on the site of another facility licensed under this part or a facility licensed under part 50 of this chapter and which shares common utilities and services with such a facility or is physically connected with such other facility may still be considered independent.

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11. In Section 72.9, paragraph (b) is revised to read as follows:

§ 72.9 Information collection requirements: OMB approval.

(a) ★ ★ ★

(b) The approved information collection requirements contained in this part appear in §§ 72.7, 72.11, 72.16, 72.19, 72.22 through 72.34, 72.42, 72.44, 72.48 through 72.56, 72.62, 72.70 through 72.82, 72.90, 72.92, 72.94, 72.98, 72.100, 72.102, 72.104, 72.108, 72.120, 72.126, 72.140 through 72.176, 72.180 through 72.186, 72.192, 72.206, 72.212, 72.216, 72.218, 72.230, 72.232, 72.234, 72.236, 72.240, 72.244, and 72.248.

12. In § 72.24, paragraph (a) is revised as follows:

§ 72.24 Contents of application: Technical information.

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(a) A description and safety assessment of the site on which the ISFSI or MRS is to be located, with appropriate attention to the design bases for external events. Such assessment must contain an analysis and evaluation of the major structures, systems and components of the ISFSI or MRS that bear on the suitability of the site when the ISFSI or MRS is operated at its design capacity. If the proposed ISFSI or MRS is to be located on the site of a nuclear power plant or other licensed facility, the potential interactions between the ISFSI or MRS and such other facility—including shared common utilities and services—must be evaluated.

13. Section 72.48 is revised to read as follows:

§ 72.48 Changes, Tests and Experiments.

(a) Definitions for the purposes of this section:

(1) Change means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) The facility or spent fuel storage cask design as described in the Final Safety Analysis Report (FSAR) (as updated) means:

(i) The systems, structures, and components (SSC) that are described in the FSAR (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(3) *Final Safety Analysis Report (as updated)* means:

(i) For site-specific licensees, the Safety Analysis Report for a facility submitted in accordance with § 72.24, as amended and supplemented, and as updated in accordance with § 72.70;

(ii) For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and

(iii) For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted in accordance with § 72.230, as amended and supplemented, and as updated in accordance with § 72.248.

(4) *Procedures as described in the Final Safety Analysis Report (as updated)* means those procedures that contain information described in the FSAR (as updated) regarding how SSCs are operated and controlled (including assumed operator actions and response times).

(5) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any activity where any SSC is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the FSAR (as updated) or

(ii) Inconsistent with the analyses or descriptions in the FSAR (as updated).

(6) *Facility* means either an ISFSI or an MRS.

(b) This section applies to:

(1) each holder of a license issued under this part, and

(2) each holder of a Certificate of Compliance (CoC) issued under this part.

(c)(1) A licensee or certificate holder may make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures

as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining either (A) a license amendment pursuant to § 72.56 (for specific licensees) or (B) a CoC amendment pursuant to § 72.244 (for general licensees and certificate holders) if:

(i) A change to the technical specifications incorporated in the specific license is not required; or

(ii) A change in the terms, conditions, or specifications incorporated in the CoC is not required; and

(iii) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A specific licensee shall obtain a license amendment pursuant to § 72.56 and a general licensee or certificate holder shall obtain a CoC amendment pursuant to § 72.244, prior to implementing a change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the frequency of likelihood of a malfunction of a system, structure or component (SSC) important to safety previously evaluated in the FSAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR;

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated);

(v) Create the possibility for a accident of a different type than any evaluated previously in the FSAR (as updated);

(vi) Create the possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the FSAR (as updated);

(vii) Result in the design basis capability for any SSC directly related to maintaining the integrity of the physical barriers intended to contain radioactivity (including mitigation systems), or any system necessary to support the functions of these SSC, being exceeded or altered; or

(viii) Result in more than a minimal change in a method of analysis described in the final safety analysis report (as updated) that is used to establish design basis values.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include evaluations performed pursuant to this section and analyses performed pursuant to §§ 72.56 or 72.244 after the last update of the FSAR pursuant to §§ 72.70, or 72.248 of this part.

(4) The provisions in this section do not apply to changes in the facility or spent fuel storage cask design or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d)(1) The licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee and certificate holder shall submit, as specified in § 72.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report shall be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility or spent fuel storage cask design shall be maintained until:

(i) spent fuel is no longer stored in the facility or using the spent fuel storage cask design, or

(ii) the Commission terminates the license or CoC issued pursuant to this part.

(4) The records of changes in procedures and of tests and experiments shall be maintained for a period of five years.

(5) The holder of a spent fuel storage cask design CoC, who permanently ceases operation, shall provide the records of changes to the new certificate holder or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

(6)(i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 30 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 30 days of implementing the change.

(iii) A certificate holder shall provide a copy of the record for any changes to a spent fuel storage cask design to any general or specific licensee using the cask design within 30 days of implementing the change.

(iv) A licensee or certificate holder receiving a record of such changes shall review the record within 60 days for applicability to its facility or cask design, respectively.

14. Section 72.56 is revised to read as follows:

**§72.56 Application for amendment of license.**

Whenever a holder of a specific license desires to amend the license (including a change to the license conditions), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

15. Section 72.70 is revised to read as follows:

**§ 72.70 Safety analysis report updating.**

(a) Each licensee for an ISFSI or MRS shall update periodically, as provided in paragraphs (b) and (c) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) The licensee shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after issuance of the license.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the license approval and/or hearing process.

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The update shall include the effects<sup>1</sup> of:

(1) All changes made in the ISFSI or MRS or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the licensee either in support of approved license amendments, or in support of conclusions that changes did not require a license amendment in accordance with § 72.48(c)(2);

(3) All final analyses and evaluations of the design and performance of structures, systems, and components that are important to safety taking into account any pertinent information developed during final design, construction, and preoperational testing; and

(4) All analyses of new safety issues performed by or on behalf of the licensee at Commission request. The information shall be appropriately located within the updated FSAR.

(c)(1) The update of the FSAR shall be filed in accordance with § 72.4, on a replacement-page basis;

(2) The update shall include a list of effective pages, indicating the current revision for each page;

(3) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both);

(4) The update shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 72.48, but not previously submitted to the Commission;

(5) The update shall reflect all changes up to a maximum of 6 months prior to the date of filing; and

(6) Updates shall be filed every 24 months from the date of issuance of the license.

(d) The updated FSAR shall be retained by the licensee until the Commission terminates the license.

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<sup>1</sup> *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.



16. In § 72.80, paragraph (g) is added to read as follows:

§ 72.80 Other records and reports.

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(g) Each specific licensee shall notify the Commission, in accordance with § 72.4, of its readiness to begin operation at least 90 days prior to the first storage of spent fuel or high-level waste in an ISFSI or MRS.

17. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

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(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, 72.240, 72.244, and 72.246.

18. In § 72.212, paragraphs (b)(2) and (4) are revised to read as follows:

§ 72.212 Conditions of general license issued under § 72.210.

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(b) ★ ★ ★

(2)(i) Perform written evaluations, prior to use, that establish that (A) conditions set forth in the Certificate of Compliance have been met; (B) cask storage pads and areas have been designed to adequately support the static load of the stored casks; and (C) the requirements of § 72.104 have been met. A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

(ii) The licensee shall evaluate any changes to the written evaluations required by this subparagraph using the requirements of § 72.48(c). A copy of this record shall be retained until spent fuel is no longer stored under the general license issued under § 72.210.

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(4) Prior to use of this general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c)(2) of this chapter. Results of this determination must be documented in the evaluation made in paragraph (b)(2) of this section.

19. In § 72.216, paragraph (d) is added to read as follows:

(Proposed rule is withdrawn)

20. Section 72.244 is added to read as follows:

§72.244 Application for amendment of a certificate of compliance.

Whenever a certificate holder desires to amend the CoC (including a change to the terms, conditions or specifications of the CoC), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.

21. Section 72.246 is added to read as follows:

§72.246 Issuance of amendment to a certificate of compliance.

In determining whether an amendment to a CoC will be issued to the applicant, the Commission will be guided by the considerations that govern the issuance of an initial CoC.

22. Section 72.248 is added to read as follows:

**§ 72.248 Safety analysis report updating.**

(a) Each certificate holder for a spent fuel storage cask design shall update periodically, as provided in paragraph (b) of this section, the final safety analysis report (FSAR) to assure that the information included in the report contains the latest information developed.

(1) The certificate holder shall submit an original FSAR to the Commission, in accordance with § 72.4, within 90 days after the spent fuel storage cask design has been approved pursuant to § 72.238.

(2) The original FSAR shall be based on the safety analysis report submitted with the application and reflect any changes and applicant commitments developed during the cask design review process. The original FSAR shall be updated to reflect any changes to requirements contained in the issued Certificate of Compliance (CoC) and information contained in the NRC staff's safety evaluation report (SER) for the cask design. However, the entire CoC and SER need not be directly inserted into the FSAR.

(b) Each update shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the certificate holder or prepared by the certificate holder pursuant to Commission requirement since the submission of the original FSAR, or as appropriate the last update to the FSAR under this section. The update shall include the effects<sup>1</sup> of:

(1) All changes made in the spent fuel storage cask design or procedures as described in the FSAR;

(2) All safety analyses and evaluations performed by the certificate holder either in support of approved CoC amendments, or in support of conclusions that changes did not require a CoC amendment in accordance with § 72.48(c)(2); and

(3) All analyses of new safety issues performed by or on behalf of the certificate holder at Commission request. The information shall be appropriately located within the updated FSAR.

(c)(1) The update of the FSAR shall be filed in accordance with § 72.4, on a replacement-page basis;

(2) The update shall include a list of effective pages, indicating the current revision for each page;

(3) Each replacement page shall include both a change indicator for the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion actually changed, and a page change identification (date of change or change number or both);

(4) The update shall include (i) a certification by a duly authorized officer of the certificate holder that either the information accurately presents changes made since the previous submittal, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 72.48, but not previously submitted to the Commission;

(5) The update shall reflect all changes up to a maximum of 6 months prior to the date of filing;

(6) Updates shall be filed every 24 months from the date of issuance of the CoC; and

(7) The certificate holder shall provide a copy of the updated FSAR to each general and specific licensee using its cask design.

(d) The updated FSAR shall be retained by the certificate holder until the Commission terminates the certificate.

(e) A certificate holder who permanently ceases operation, shall provided the updated FSAR to the new certificate holder or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

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<sup>1</sup> *Effects of changes* includes appropriate revisions of descriptions in the FSAR such that the FSAR (as updated) is complete and accurate.

## **ATTACHMENT 3: OTHER RULE LANGUAGE CHANGES AND ISSUES**

## OTHER RULE LANGUAGE CHANGES AND ISSUES

In addition to the topics discussed in the paper, the staff is providing this discussion of other aspects of the rule that have resulted in changes to the rule language, or that were requested by the Commission. In addition, the staff notes that the comment discussion in Attachment 1 to the paper contains more details on suggested rule language changes and other issues brought forth by the comment letters.

### Definitions

A number of comments were received on the definitions, and as a result, certain clarifying changes were made as reflected in the attached draft rule language. One of the more significant changes to definitions was that for "change." This definition is discussed in more detail below.

#### **Change to the facility as described in the final safety analysis report (as updated)**

In the proposed rule, NRC recommended that the word "change," as written in the existing requirements, be understood to mean the modification of an existing provision (e.g., systems, structures, or components (SSCs); procedures; design requirements; analysis methods or parameters); additions (e.g., new SSCs or procedural steps); and removals from the facility (physical removals or retirement in place or non-reliance on a system to meet a requirement). Further, the supplementary information for the proposed rule stated that changes to evaluative methods, acceptance standards, or other information for an SSC described in the FSAR is also a change to the facility as described. Therefore, the proposed rule included definitions of "change" and of "facility as described in the safety analysis report (as updated)," as well as for procedures as described.

Several commenters stated that revisions were needed to the proposed definitions to allow greater use of screening of proposed changes, that is, for licensees to determine that certain proposed changes to the facility do not require evaluation against the regulatory criteria in § 50.59. Otherwise, the commenters were concerned that even such additions as identification tags or light bulbs might require evaluation under the rule. Thus, they proposed that the definition of "change" be modified by the addition of the highlighted phrase: "a change is a modification, addition or removal *that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.*" This approach would allow certain changes to be made without requiring the review and documentation process for a § 50.59 evaluation.

In practice, the industry uses a two-step process in reviewing changes to its facilities. Step one is a review of the proposed change to determine if it meets the "scope" criteria for review (contained in proposed rule § 50.59(c)(1)), otherwise known as a "screening review." If the change falls within these definitions, an evaluation against the criteria in § 50.59(c)(2) would be performed. The staff recognizes that many of the changes being made at a facility are such that a licensee could readily determine that the change does not affect the facility, and would never involve any of the evaluation criteria, and, thus, could be screened out, provided the rule language accommodates such an approach. The suggested rule language would codify screening of changes in the regulations. Such clarifications to the definitions would significantly reduce the number of evaluations that need to be performed and therefore would reduce

licensee burden. There is some potential for changes to be mistakenly screened out as not affecting functions and, thus, as not requiring an evaluation. Since the rule does not explicitly require documentation of screening, opportunities to correct such errors may be limited. In practice, records of screenings are typically prepared and maintained, as discussed in NEI 96-07. Accordingly, the staff views the potential for undetected errors to be small, and the rule change would provide much greater flexibility and reduce the licensee burden for preparing evaluations for changes that do not warrant such review. Staff also believes that staff burden to inspect and review § 50.59 evaluations would be reduced, thereby allowing staff to focus attention on more significant changes. This approach will require some revisions to existing guidance such as NEI 96-07 especially with respect to how to appropriate screen changes that may affect functions.

Staff recommends adopting the NEI proposal in this area to codify the use of a screening process. Staff plans to supplement existing staff guidance and NEI 96-07 guidance to provide greater assurance that screening activities will be appropriately conducted and documented.

#### **Definition of accident, or design basis accident of a different type**

The proposed rule included as a criterion for prior approval if a change, test, or experiment would "create the possibility for a design basis accident of a different type than any evaluated previously in the final safety analysis report (as updated) or in evaluations...." The FR notice suggested a definition of "accident" and requested comment as to whether a definition was needed and on the language offered in the notice. Most commenters stated that a definition of "accident" was not needed in the rule but could be discussed in guidance. A few commenters offered alternative definitions for "accident" or more specifically, "accident of a different type." Several agreed with the premise that only "design basis" accidents were to be considered, distinguishing these from the spectrum of accidents typically considered in a PRA and from incredible accidents that might be created as a result of a change. Minor changes to NEI 96-07 may be useful to clarify understanding of accident of a different type.

Staff does not recommend adding a definition of "accident" or using the terminology of "design basis accident of a different type" in the rule. The staff concludes that a suitable definition for accident previously evaluated in the FSAR, that would be included in guidance, is the following:

*Accident previously evaluated in the FSAR (as updated)* means an accident described in the final safety analysis report (as updated) including accidents such as those traditionally found in Chapter 15 of the final safety analysis report, and those accidents described in the final safety analysis report dealing with floods, fires, seismic events, other external hazards, water-solid over pressure, anticipated transient without scram, and station blackout.

#### **Consequences of an accident or malfunction of equipment important to safety previously evaluated in the FSAR (as updated) are more than minimally increased (§§50.59 (c)(2)(iii) and (c)(2)(iv))**

In addition, the proposed rule included language that would permit a minimal increase in consequences. To assist in implementation, the supplementary information for the proposed rule included options for guidance to explain how "a minimal increase" should be applied. One of the options offered by staff was that minimal increases would correspond to a fraction (i.e.,

10%) of the difference between the FSAR calculated value and the applicable acceptance guidelines (regulatory values or Standard Review Plan values as applicable).

During the comment period, NEI proposed that the staff's guidance be modified such that there is no more than a minimal increase in (radiological) consequences if the increase is less than or equal to 10 percent of the difference between the FSAR calculated values and the guidelines established in the regulations (e.g., Part 100 or Part 50 General Design Criterion 19), but also if the increase did not exceed any other acceptance guidelines (if applicable). While NEI acknowledged staff's concerns about changes being made without review that would approach the regulatory guidelines, it also believes that the guidelines in the SRP that establish acceptance criteria of "small fraction of Part 100 limits" for particular events already provide sufficient regulatory control such that licensees should not be restricted from increases up to these values. Some commenters thought 20% was a more reasonable fraction of the difference to specify as minimal. Still other commenters favored allowing increases up to regulatory limits (without use of a term such as minimal increase), believing that the "consequences previously evaluated" includes the limits that were used as the basis for the licensing determination.

The staff agrees that establishing controls on the margin to the SRP guidelines is not necessary, and, thus, proposes to revise its guidance on interpretation of "minimal" increases to make this clarification. The staff's proposal will require some revisions to NEI 96-07 to explain the use of differences to regulatory guidelines, and the role of other guidelines such as SRP values.

Thus, the staff would agree that there is no more than a minimal increase in consequences if the increase is less than or equal to 10% of the difference between the calculated value and the regulatory guidelines, or as long as the SRP guidelines are met, with the clarification that the SRP guidelines form a basis of minimal increase for all facilities, not just those that were specifically reviewed against its guidelines. This clarification will be discussed in the implementation guidance.

#### **Reporting and Recordkeeping Requirements (§ 50.71(e))**

For reporting, the NRC proposed to revise the reporting requirement in § 50.71(e) to require licensees to provide information to enable the staff to monitor potential cumulative impacts for "minimal" increases. Specifically, the proposed rule would interpret the phrase "effects of" to include, for purposes of the FSAR update report, the effects on probabilities and consequences.

This proposal elicited strong opposition. Many commenters stated that this proposal would significantly increase licensee burden, that it was not necessary since the rule would limit the amount of change to "minimal" increases that were insignificant with respect to the licensing basis, and, therefore, that the proposal should not be implemented. As noted by many of the commenters, assessments of probabilities are generally qualitative and would thus be difficult to report on with respect to cumulative effects. Where analyses are revised to document the effects of changes (involving consequences, or "margins"), the existing language would require the FSAR to reflect the effects of these changes. Further, the way that "minimal" is defined prevents even multiple changes from exceeding limits. The staff recommends acceptance of these comments and proposes to drop the rule language that would require explicit documentation of cumulative effects as part of the update requirements.