

ORIGINAL

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

**Title:**           **BRIEFING ON 10 CFR 50.59 REGULATORY  
PROCESS IMPROVEMENTS - PUBLIC MEETING**

**Location:**       **Rockville, Maryland**

**Date:**           **Monday, March 10, 1997**

**Pages:**          **1 - 59**

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1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

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4 BRIEFING ON 10 CFR 50.59  
5 REGULATORY PROCESS IMPROVEMENTS

6 - - -

7 PUBLIC MEETING

8  
9 Nuclear Regulatory Commission  
10 One White Flint North  
11 Rockville, Maryland  
12

13 Monday, March 10, 1997  
14

15 The Commission met in open session, pursuant to  
16 notice, at 10:35 a.m., Shirley A. Jackson, Chairman,  
17 presiding.  
18

19 COMMISSIONERS PRESENT:

20 SHIRLEY A. JACKSON, Chairman of the Commission  
21 KENNETH C. ROGERS, Commissioner  
22 GRETA J. DICUS, Commissioner  
23 NILS J. DIAZ, Commissioner  
24 EDWARD McGAFFIGAN, JR., Commissioner  
25

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1 STAFF PRESENT AND PRESENTERS SEATED AT THE COMMISSION TABLE:

2 JOHN C. HOYLE, Secretary of the Commission

3 KAREN D. CYR, General Counsel

4 JOE CALLAN, EDO

5 THOMAS MARTIN, Director, Division of Reactor

6 Program Management, NRR

7 EILEEN McKENNA, Senior Reactor Systems Engineer,

8 NRR

9 FRANK MIRAGLIA, Deputy Director, NRR

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

[10:35 a.m.]

CHAIRMAN JACKSON: Good morning, ladies and gentlemen. The purpose of this meeting is for the Commission to be briefed by the NRC Staff on proposed regulatory guidance related to the implementation of 10 CFR 50.59 changes, tests, and experiments.

The Commission approved making publicly available the recent Staff paper addressing this subject, which I understand is also available today at the entrances to this meeting. The Commission is considering the Staff's request to seek public comment on the paper.

In the fall of 1995, I directed the Staff to perform a systematic reconsideration and reevaluation of the regulatory framework that authorizes licensees to make changes to their facilities without prior NRC approval.

Staff work to date is summarized in the paper, highlights of which will be discussed today. The paper proposes regulatory guidance that first reaffirms existing regulatory guidance; second, clarifies Staff positions in certain areas; third, establishes new guidance where none existed; and fourth, briefly discusses some policy issues related to potential rulemaking for 10 CFR 50.59.

As I stated last month at the Millstone Lessons Learned meeting, I believe an honest assessment from the NRC

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1 would indicate that the implementation of 10 CFR 50.59 has  
2 been long overdue for improvement.

3 That regulation, which was originally promulgated  
4 in 1962, is an important regulation, the applicability and  
5 use of which has expanded over the years. Recent lessons  
6 learned from Millstone and other reviews, coupled with the  
7 fact that the industry guidance document, NSAC 125, is being  
8 used by the nuclear industry to implement 10 CFR 50.59,  
9 while not having been formally endorsed by the NRC because  
10 there were certain differences between that document and 10  
11 CFR 50.59, indicate that the time is ripe to resolve the  
12 issues, to clarify guidance, and to get Commission policy  
13 input on any proposed rule change.

14 The Commission is very interested, therefore, in  
15 the proposed regulatory guidance and policy questions being  
16 presented in today's meeting. The Commission recognizes  
17 that the industry has in the past taken significant steps,  
18 as I have indicated, to formalize their own guidance for  
19 performing 50.59 evaluations.

20 The industry, for example, recognized early that  
21 plant changes should be evaluated against more than the  
22 final safety analysis report. However, it is clear that a  
23 consistent, thorough approach has not always been taken by  
24 all licensees.

25 Additionally, 10 CFR 50.59, as I have indicated,

1 has become more important over the years simply because of  
2 the expanding scope of the rule. Licensees are evaluating  
3 additional topics and significant plant changes under the  
4 provisions of this rule.

5 It is not too late to make the necessary  
6 improvements and to insure that NRC's program for assessing  
7 changes, tests, and experiments conducted under the rule is  
8 a more thorough and consistent program. However, the time  
9 to do it is now.

10 I understand that copies of the Staff's  
11 presentation are available at the entrances to the meeting,  
12 and if none of my fellow commissioners have any additional  
13 opening comments, Mr. Callan, you may proceed.

14 And I'd like to add a parenthetical comment, Mr.  
15 Callan. I believe the Commission will be well-served by any  
16 examples or insights that you may from the regional  
17 perspective with respect to any difficulties that the  
18 resident inspectors or region-based inspectors may face in  
19 this area. So we would appreciate any comments you might  
20 have as we go along.

21 MR. CALLAN: I will have plenty of examples,  
22 probably limited only by time.

23 Good morning, Chairman, and --

24 CHAIRMAN JACKSON: That's why we put it before  
25 lunch.

1 MR. CALLAN: The NRC Staff is here today to brief  
2 the Commission on the results of its review of  
3 implementation issues related to 10 CFR 50.59.

4 With me at the table are, to my right, Frank  
5 Miraglia, the Deputy Director of the Office of Nuclear  
6 Reactor Regulation; to my immediate left, Tim Martin, the  
7 Director of the Division of Reactor Program Management in  
8 NRR; and to his left, Eileen McKenna of his Staff.

9 Chairman, you covered in your opening remarks  
10 several of the points that I was going to make, so I will  
11 immediately turn the discussion over to Mr. Miraglia, who  
12 will now provide his opening remarks and then Mr. Martin  
13 will then discuss the details of the Staff review.

14 MR. MIRAGLIA: Thank you, Joe. Good morning,  
15 Madam Chairman, commissioners.

16 Just to set the stage a bit, on February 19th, we  
17 briefed the Commission on the Millstone Lessons Learned Part  
18 2, and if everyone recalls, there were six questions that we  
19 addressed that came from that lessons learned, two of which  
20 directly related to 50.59, the subject of today's meeting  
21 with the Commission.

22 As with the Millstone Lessons Learned, there are  
23 some short-term actions and long-term actions that we  
24 believe should be considered in order to move forward with  
25 the improvements in the 50.59 process.



1           The paper articulates the current Staff position  
2     and interpretations of 50.59. As you have indicated, Madam  
3     Chairman, for the most part, those Staff positions are  
4     reaffirmations or clarifications of longstanding  
5     interpretations, and in a few instances, they represent new  
6     positions.

7           Therefore, we believe it is an important first  
8     step in evaluating what changes need to be made in terms of  
9     rulemaking to get public comment on the proposed Staff  
10    position, and that's why the short-term recommendation is  
11    for receiving public comment on the Staff positions as  
12    presented in the paper.

13           A number of these questions have been addressed by  
14    the Commission in the past and, in addition, are related to  
15    some of the issues raised by NEI in their communications  
16    with the Commission in October regarding principles of  
17    conducting licensing basis reviews and for which the  
18    Commission responded in early February. So the positions  
19    then are consistent with communications with the industry  
20    and NEI, which are also a matter of public record.

21           With those opening remarks, I would like to have  
22    Tim walk us through the presentation and then we stand ready  
23    to receive any questions.

24           MR. MARTIN: Thanks, Frank. May I have the first  
25    slide, please?

1 [Slide.]

2 MR. MARTIN: 10 CFR, section 50.59 establishes a  
3 process for licensees to make changes to their facility or  
4 procedures described in the safety analysis report or to  
5 perform tests and experiments not described in the safety  
6 analysis report without prior NRC approval if those changes  
7 do not involve an unreviewed safety question or changes to  
8 their technical specifications.

9 Therefore, it establishes a regulatory threshold  
10 beyond which prior NRC approval is required before  
11 implementing a change or performing a test or experiment.

12 The purpose of this briefing is to present the  
13 results to date of the Staff's 10 CFR 50.59 action plan and  
14 recommendations for short-term improvements in regulatory  
15 guidance.

16 Clearly the 10 CFR 50.59 process has been a  
17 significant element for the framework for nuclear power  
18 plant regulation since promulgated in 1962 and provides  
19 licensees the needed structure and flexibility to make  
20 changes that do not erode the basis for NRC's licensing  
21 decisions.

22 Based on the Staff's review, we conclude that when  
23 properly implemented, the 10 CFR 50.59 process has been and  
24 continues to be successful in preserving the design basis  
25 and safety margins at operating plants.

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1           However, as a result of the Staff's analysis and  
2           experience, we have identified areas where implementation of  
3           the process would benefit from additional clarification or  
4           guidance. As a result, we conclude that existing regulatory  
5           guidance should be clarified to further reduce differences  
6           in interpretation of rule language and expectations of the  
7           process.

8           May I have the next slide, please.

9           CHAIRMAN JACKSON: Before you go, since we are  
10          talking about clarification, in the paper you submitted to  
11          the Commission, you discuss at least two other options when  
12          it comes to dealing with degraded or nonconforming  
13          conditions, and specifically, there's 10 CFR Appendix B, or  
14          section 16, the generic letter 9118, which explicitly deals  
15          with that subject.

16          Now, you don't have a viewgraph in here about  
17          that, but it appears that there is some blurriness in the  
18          boundaries between these different approaches or  
19          methodologies.

20          Can you expand for the Commission's benefit on  
21          what the various processes are, and do you think that  
22          licensees have a clear understanding from us as to when one  
23          is to be used versus another?

24          And then the related obvious question then is, is  
25          this part of what you're going to be addressing in talking

1 about clarification?

2 MR. MARTIN: Chairman, as one of the items on the  
3 implementation issues, that is a specific and, to be quite  
4 frank, a lengthy discussion of the handling of the discovery  
5 of degraded or nonconforming conditions, the applicability  
6 of 50.59 to that process, what guidance is out there in the  
7 form of the generic letter 9118, and how we believe that  
8 there may be some additional interpretations and guidance  
9 that we need to put out there.

10 If I can, I would like to hold off until that part  
11 since we have covered those major issues.

12 CHAIRMAN JACKSON: You're going to explicitly  
13 discuss these three?

14 MR. MARTIN: Yes, ma'am, I will.

15 CHAIRMAN JACKSON: Okay. I will hold off.

16 MR. MARTIN: May I have the slide, concerns about  
17 the 50.59 process?

18 [Slide.]

19 MR. MARTIN: The Staff's principal concern is that  
20 improper implementation of the 10 CFR 50.59 process could  
21 lead to a temporary reduction in the level of safety of a  
22 plant. Specific implementation problems can usually be  
23 placed in one of three bins.

24 First, the rule applies to facility or procedures  
25 as described in the safety analysis report. To the extent



1 the facility or procedures are not so described or are not  
2 perceived to be described, then the plan change may not be  
3 subject to the 10 CFR 50.59 process.

4 Second, questions of interpretation of the rule's  
5 language have led to ambiguity about when a change, test, or  
6 experiment requires an evaluation and when an unreviewed  
7 safety question is involved.

8 Third, because the rule as written addresses  
9 proposed changes, ambiguity exists as to its application to  
10 discovered conditions which are different from those  
11 described in a safety analysis report.

12 May I have the next slide, please.

13 [Slide.]

14 MR. MARTIN: Our proposed approach to resolution  
15 of these implementation concerns involves two parallel  
16 paths: first, by improving implementation of the rule as  
17 currently written by reaffirming existing regulatory  
18 positions and practices for which there is general  
19 agreement, clarifying existing regulatory positions where  
20 interpretations may vary, establishing new regulatory  
21 positions where none previously existed to assure uniform  
22 implementation expectations and enhancing NRC inspection  
23 guidance and oversight; second, by identifying additional  
24 opportunities for improving implementation of the 10 CFR  
25 50.59 process, such as through rulemaking.

1           Because the latter issues are inseparably linked  
2   to policy issues discussed in the Millstone Lessons Learned  
3   Report, Part 2, we intend to carefully examine the options  
4   for additional actions, evaluate the consequence, their  
5   implementation, and come back to the Commission with an  
6   integrated set of recommendations.

7           May I have the next slide, please?

8           CHAIRMAN JACKSON: Before you go, the ones that  
9   you're talking about that are under the heading of  
10  "enhancing implementation of the rule as written," are all  
11  of your recommended positions such that they can be  
12  implemented in the short term, and are any of them subject  
13  to back-fit consideration, or are they -- because they are  
14  implementation of existing rules, they are not?

15          MR. MIRAGLIA: In terms of some of the issues,  
16  Madam Chairman, where we feel that they're reaffirmations,  
17  the answer would be no. In terms of some of the  
18  clarifications, we need to put it through the process to  
19  make sure that it's not a new interpretation, and that could  
20  be done in the short term by generic letters or other kinds  
21  of communications and issuances, and that's true of also  
22  some of the new issues.

23          The longer term would be, given this experience  
24  and given those improvements, should we take the next step  
25  and codify all of that through a rulemaking process once we

1 take the short-term --

2 CHAIRMAN JACKSON: Is there concurrence between  
3 the Staff, technical Staff, and OGC with respect to that  
4 position?

5 MR. MIRAGLIA: I think in the short term with the  
6 guidance, the first step would be to get the public comment  
7 and that would establish the basis for issuing that in a  
8 generic kind of sense, but perhaps Karen would like to add  
9 to that.

10 MS. CYR: No. I think we're in agreement with the  
11 Staff on the approach they've laid out.

12 COMMISSIONER ROGERS: I think there is an issue,  
13 though, as to the separability of these policy issues from  
14 what you're proposing to do on the short term. It may very  
15 well be that some of your short-term proposals in fact  
16 represent policy issues that ought to be reviewed as policy  
17 issues.

18 So we'll have to see what this all amounts to, but  
19 I'm not so convinced that it's easy to separate short term,  
20 what you might call short term, from policy issues.

21 CHAIRMAN JACKSON: I think that what they're  
22 calling policy issues relate to policy issues related to  
23 rulemaking because all of them are policy issues in the end.

24 MR. MIRAGLIA: I think that that would be fair.  
25 In the terms of a generic communication, we would have to

1     come through process, would have to come to the Commission  
2     saying, this is the generic communication the Staff intends.

3             COMMISSIONER ROGERS: I understand that, but I  
4     think the question I'm raising is whether, by reaffirming  
5     something as a policy issue that later on in fact ought to  
6     be addressed through rulemaking and changed, it is something  
7     that we ought to be very mindful of that, that possibility.

8             CHAIRMAN JACKSON: Do you know enough at this  
9     point -- relative to the potential rulemaking, have you done  
10    enough of a consideration to say whether there's anything  
11    that you would be moving toward in that line that would  
12    conflict with what you're calling the shorter-term  
13    considerations?

14            MR. MIRAGLIA: I have not thought about that  
15    question. I'll give an answer. With all the considered  
16    thought that I've given it, probably not. I think if one  
17    goes back to the concerns about the 50.59 viewgraph, the  
18    issue of scope is one that we're leaving until later.  
19    That's clearly outside.

20            What the intent would be is that the  
21    clarifications in the short term that we would be providing  
22    would be to the scope of 50.59 as now described in the rule.  
23    So I don't believe anything in the short-term guidance is  
24    going to expand the scope. That question would be clearly  
25    later.



1           In terms of the ambiguity, we would try to be  
2 clarifying concerns relative to margin and consequences and  
3 changes in probability, again, to apply it to 50.59 as  
4 described. We are not intending to change the scope of  
5 50.59 within the context of the short-term lessons learned.

6           COMMISSIONER ROGERS: Well, I have to say that I  
7 think those are issues that are going to be policy issues.

8           MR. MIRAGLIA: Those latter two?

9           COMMISSIONER ROGERS: Yes.

10          MR. MIRAGLIA: Yes, and I think what we tried to  
11 present to the Commission here is what Staff practice has  
12 been and what the clarification has been and a  
13 reaffirmation. Certainly the Commission can provide us  
14 guidance in that area, either now or as for further  
15 briefings on that.

16          The clear intent of the Staff, Commissioner  
17 Rogers, is to put a reference out there that -- in terms of  
18 public comments so there could be an understanding of how  
19 it's being viewed and how we think is a fair implementation  
20 of the process within the scope of the rule as defined right  
21 now.

22          And I would agree, there are certain issues that  
23 are kind of hard to parse one to the other. I think we've  
24 tried to characterize long-term standard Staff practice,  
25 Commission practice in the past, and what we're saying is a

1 reaffirmation. Certainly if the Commission feels that we've  
2 gone further than that, we need to hear that from the  
3 Commission.

4 COMMISSIONER ROGERS: I don't want to delay the  
5 whole procedure here, but I do think in the first place, the  
6 SECY is an excellent piece of work and I think it really  
7 lays out the history and the issues, but when you read it  
8 very carefully, you see a lot of inconsistencies.

9 And so when you say, you know, we're going to  
10 reaffirm something, that reaffirmation is going to be  
11 dealing with some things that, in my view, have been dealt  
12 with in a rather inconsistent fashion and an unclear  
13 fashion.

14 CHAIRMAN JACKSON: Is that the clarification part  
15 of it, dealing with the inconsistencies?

16 MR. MIRAGLIA: I think that's what we felt we were  
17 trying to articulate, those various pieces, and I think if  
18 it would be helpful for the Commission to get more details  
19 as to what falls in what bin, we can endeavor to do that.

20 CHAIRMAN JACKSON: I think what's going to happen  
21 is, obviously, the Commission is going to be reviewing this  
22 paper, and depending upon its response to what you're  
23 calling a reaffirmation versus a clarification versus  
24 establishing some different regulatory position, therein is  
25 the guidance.

1           So we have the paper and so it's up to us to act  
2   on it.

3           MR. MIRAGLIA: That's fair.

4           MR. MARTIN: Chairman, in further amplification in  
5   response to your question, we have thought about whether  
6   this guidance that we're proposing would be sustained even  
7   with rulemaking.

8           Clearly, a number of the pieces of guidance we  
9   have there would be superseded by any rule change and  
10   abdicate the need for some of the clarifications that we put  
11   forward.

12           But a number of the guidance, we believe, would be  
13   sustained, would continue even after the rule would be  
14   modified, if that's the decision.

15           May I have the implementation issue slide?

16           [Slide.]

17           MR. MARTIN: Chairman, this is the meat of the  
18   presentation and the slide is short, but the discussion is  
19   long.

20           CHAIRMAN JACKSON: I was going to ask you for all  
21   your backup viewgraphs for all these bullets, but since I  
22   know you're going to talk very slowly and carefully.

23           MR. MARTIN: The 10 CFR 50.59 task group developed  
24   a compilation of guidance on a wide range of topics related  
25   to 10 CFR 50.59 implementation which was presented as an

1 attachment to our Commission paper.

2 Of the 22 implementation guidance issues  
3 identified, the five shown on this slide were the most  
4 significant or potentially controversial.

5 The first issue has potential impact on subsequent  
6 10 CFR 50.59 evaluations because the scope of the current  
7 rule is tied to as described in the SAR, or safety analysis  
8 report.

9 The question raised is whether licensees can  
10 remove information from the safety analysis report when not  
11 specifically linked to a change to the facility or  
12 procedures. Current regulations and regulatory guidance  
13 define information that must and should respectively be  
14 placed in the safety analysis report.

15 We recognize that current safety analysis reports  
16 contain information that may not be used in future safety  
17 evaluations in licensing decisions. Further, the content  
18 and level of detail of individual safety analysis reports  
19 differs considerably based in large part on the vintage of  
20 the original license.

21 However, there is no established policy or  
22 guidance on the question raised by this issue. Until the  
23 Staff develops guidance in this area, it is the Staff's view  
24 that licensees may not remove material from the safety  
25 analysis reports unless the material is changed as a direct



1 result of a change to the facility or its procedures.

2 The next three issues involve the determination of  
3 whether or not the proposed change, test, or experiment  
4 involves an unreviewed safety question. As a reminder, 10  
5 CFR 50.59(a)(2) states, "A proposed change, test, or  
6 experiment shall be deemed to involve an unreviewed safety  
7 question, one, if the probability of occurrence or the  
8 consequence of an accident or malfunction of equipment  
9 important to safety previously evaluated in the safety  
10 analysis report may be increased; or, two, if a possibility  
11 for an accident or malfunction of a different type than any  
12 evaluated previously in the safety analysis report may be  
13 created; or, three, if the margin of safety as defined in  
14 the basis for any technical specification is reduced."

15 It should be noted that a determination that the  
16 proposal involves an unreviewed safety question does not  
17 necessarily mean the proposal is unsafe or unacceptable. It  
18 only means that the licensee can't make the change or  
19 conduct the test or experiment until the NRC decides it's  
20 safe and approves the amendment.

21 The issue of margin of safety involves two  
22 questions: what is meant by "as defined" in the basis for  
23 any technical specification, and how do you determine  
24 whether the margin of safety has been reduced.

25 Technical specifications are derived from the

1 analysis and evaluation included in the safety analysis  
2 report. Technical specifications bases statements often do  
3 not present margins of safety; therefore, the Staff  
4 concludes the safety analysis report should be used as the  
5 basis for any technical specification.

6 It should be noted that industry guidance  
7 recommends that documents other than the tech spec bases be  
8 reviewed when text spec bases are not explicit. However, we  
9 should also note that this guidance has not been uniformly  
10 adopted by licensees.

11 The margin of safety is generally not explicitly  
12 defined in the safety analysis report or otherwise in  
13 documents; however, the safety analysis report does present  
14 limits within which the licensee proposes to operate the  
15 facility and which the NRC accepted during review of the  
16 licensing application.

17 Therefore, NRC's acceptance limits for approving  
18 the operation of the facility are the values the licensee  
19 proposed in the safety analysis report unless different  
20 values are explicitly established as the basis for the  
21 licensing action in the license, technical specifications,  
22 or the NRC safety evaluation report.

23 CHAIRMAN JACKSON: Let me ask you a question. If  
24 we do broaden this issue of the basis for any tech spec to  
25 include the safety evaluation report, do we run into any

1 problems with respect to enforceability?

2 MR. MIRAGLIA: I think in the long term, this is  
3 an issue that needs to be clarified and relates to some of  
4 the discussion we had a few weeks ago regarding commitments  
5 and what regulatory processes are required to change and to  
6 keep track of commitments in terms of a future fit and also  
7 a back fit. So there is that type of relationship.

8 I think what we're trying to say within the  
9 context here -- I think the intent is a little narrower;  
10 perhaps we can expand on that -- in order to define and  
11 answer the margin question, what we're saying is that the  
12 basis for determining margin should not just be the basis of  
13 technical specifications as defined in the regulation, but  
14 the basis is for significant licensing documents that would  
15 provide an answer to the question, what margins were there  
16 and what was approved. And I think it's a bit narrower in  
17 that kind of sense.

18 CHAIRMAN JACKSON: Again, is there concurrence  
19 between yourselves and OGC in terms of this broader  
20 definition of the basis for any tech spec, or is there some  
21 rulemaking space?

22 MS. CYR: No. I think the OGC supports the Staff.

23 CHAIRMAN JACKSON: Commissioner McGaffigan.

24 COMMISSIONER MCGAFFIGAN: I think this is on the  
25 same point. In the letter to Mr. Colvin, we talk about the

1 SER, the safety evaluation report. And on the end of a long  
2 paragraph, it says, "In order to be binding, these  
3 commitments must be reflected in supplements or amendments  
4 to the FSAR, tech specs, or license conditions."

5 If the SER has a higher limit than the FSAR and  
6 the licensee wants to use that higher limit for something,  
7 is that the sentence that tells them that in order to get  
8 the SER higher limit, that they had to somehow get it  
9 reflected in supplements or amendments to their FSAR?

10 Or how does that process work where there's a  
11 difference between the SER and the FSAR?

12 MR. MIRAGLIA: I think in terms of enforceability  
13 of commitments, if it's not in the FSAR or other appropriate  
14 licensing documents, such as condition of license or the  
15 like, then the licensing basis would prevail, and I think  
16 what -- if you look at the -- where we're talking about  
17 margins in this particular case, much of that is inferred  
18 when you read. We're not that clear as to what the margin  
19 and what the acceptability of margins are.

20 For example, the clearest case is where one says  
21 code and they're going to meet the code. Then it's -- but  
22 the code is cited, but even the margin's not inferred. You  
23 have to go back and find the trail. And I think we're  
24 looking at this as -- in this case as the SER providing  
25 guidance as to what is the scope of the margin type of



1 question and we weren't looking at it in terms of  
2 commitments to follow-up.

3 And these are ambiguities that need to be cleaned  
4 and cleared up. I think that in the previous briefing, we  
5 talked about what we were trying to do in terms of  
6 commitment, commitment tracking, and to follow those kinds  
7 of things.

8 So there is a nexus and a relationship to the  
9 short-term actions here and short-term actions that we  
10 discussed several weeks ago.

11 CHAIRMAN JACKSON: Commissioner Diaz.

12 COMMISSIONER DIAZ: The same point. Am I hearing  
13 -- maybe I'm not hearing right, but are you saying that the  
14 new guidance will say that if the safety evaluation report,  
15 the SER, has an acceptance limit that is higher than the  
16 licensee has in his SAR, that we will accept the higher  
17 limit as a -- you know, as a guide to changes? Is that what  
18 we're saying?

19 MS. MCKENNA: That's correct.

20 COMMISSIONER DIAZ: So we --

21 MR. MIRAGLIA: That would be an articulation that  
22 we haven't articulated. That's one of the -- that's a new  
23 interpretation that we have to put out there and get  
24 reaction to.

25 COMMISSIONER DIAZ: But is that fair? If we have

1 a guidance document that the licensee did use, used a lower  
2 level, we have a document that says, this higher level is  
3 acceptable, I think we should address whether we will accept  
4 the higher acceptance limit. I think that's really what we  
5 need to make clear.

6 MR. MARTIN: Commissioner, let me set it up for  
7 you, the problem we're trying to address. A licensee may  
8 propose an operating limit here. They know we have a  
9 standard review plan that would say we would have accepted  
10 anything up to here.

11 COMMISSIONER DIAZ: Right.

12 MR. MARTIN: But in reviewing the entire  
13 application, we may have decided that a lower limit is the  
14 right one. If we explicitly state that because it is below  
15 this lower limit, it is acceptable, then that was the basis  
16 for our licensing action.

17 Licensees would like to sometimes go all the way  
18 up to the standard review plan level and, in essence,  
19 violate the basis upon which we license that plant. And so  
20 we're saying that if there is no explicit articulation of  
21 what the Staff used as its basis for this, then it's what  
22 the licensee proposed to operate at, the SAR value.

23 COMMISSIONER DIAZ: I understand. And my question  
24 goes right at that issue, that I guess it's a new present  
25 knowledge and a new analysis, is that being considered if

1 actually the standard review plan established a higher limit  
2 and we license a lower limit? Would it be possible to  
3 consider that the higher limit is the one that should be  
4 applied?

5 MR. MIRAGLIA: Only if the SER said it was okay to  
6 go to the higher limit.

7 MR. MARTIN: Let's assume that we conclude that  
8 they are above our licensing limit. All they have to do is  
9 come into us and propose the change and get a license  
10 amendment if it's a safe thing to do.

11 So this only determines whether they've exceeded  
12 the regulatory threshold and have to get our buy-in before  
13 they can implement it. As long as it's safe, we could  
14 approve it.

15 COMMISSIONER DIAZ: Yeah, you could. The issue is  
16 that that requires a significant amount of work on the part  
17 of everybody, the licensee and us, and I was wondering  
18 whether there's been additional clarification of this issue  
19 or we are going to stick with our previous definition.

20 In other words, are we addressing the issue now  
21 whether --

22 MR. MIRAGLIA: I think there's a short-term fix  
23 that we're talking about, is just to clearly understand  
24 where we're at, and that it's going to take a longer period  
25 of time to evaluate these changes and the changes we

1 discussed in the past.

2 I think what we're trying to do is just establish  
3 the playing field and saying, here's our views and  
4 positions. Clearly, if the SER clearly spoke to a limit and  
5 it's in there, then that's one case.

6 I think what you'll find is that, in most cases,  
7 one can infer and it's not explicit, it's implicit. And in  
8 those cases, what the guidance would be, if you can't point  
9 to explicit material in the SER, as Mr. Martin just said,  
10 come to us and we'll evaluate the amendment and go on the  
11 basis.

12 It's clear that 50.59 is a regulatory threshold.

13 CHAIRMAN JACKSON: So let me make sure I  
14 understand something. Are you basically arguing the  
15 following way, that you have the standard review plan, the  
16 standard review plan is not plant specific?

17 MR. MARTIN: That's correct.

18 CHAIRMAN JACKSON: And, therefore, when you  
19 finally license the plant, you have to do plant-specific  
20 evaluations?

21 MR. MARTIN: That's correct.

22 CHAIRMAN JACKSON: And that plant-specific  
23 evaluation has things either documented in the safety -- the  
24 Staff's safety evaluation report, or it might not.

25 MR. MARTIN: That's correct.

1           CHAIRMAN JACKSON: And you're saying that if it  
2 does not, then what's been proposed and what's in the SAR is  
3 what governs?

4           MR. MARTIN: That's correct.

5           CHAIRMAN JACKSON: But if it has been explicitly  
6 stated in the SER, then that is what you say or want to say  
7 governs?

8           MR. MARTIN: Could be stated in the license or  
9 tech specs or the SAR.

10          CHAIRMAN JACKSON: I know, but explicitly stated  
11 somewhere. But you also want to include that explicit  
12 statement to be what's in the SER?

13          MR. MARTIN: I don't know that I understand.

14          CHAIRMAN JACKSON: Well, suppose something is not  
15 in the licensing, not in the licenses, not a license  
16 condition, but in fact it is something that's referenced in  
17 an SER. Are you saying that you -- that the Staff's  
18 position is that what's in that SER is what should govern?

19          MR. MIRAGLIA: If the SER had one limit and the  
20 SAR had another limit.

21          MR. MARTIN: Unfortunately, this is the way 50.59  
22 is written right now. If it is not described in the SAR,  
23 then the fact that we discussed it in the SER, it's still  
24 outside the potential scope of 50.59 controls.

25          CHAIRMAN JACKSON: Correct. So what is your fix

1 to that?

2 MR. MARTIN: The question that we ask in the  
3 policy area is: should we change the scope to encompass  
4 additional things beyond what is described in the SAR?

5 CHAIRMAN JACKSON: If that scope was the current  
6 licensing basis, would that address the issue?

7 MR. MARTIN: I believe it would; however, we have  
8 not done the integration of the issues that came out of  
9 Millstone and explored the consequences of that conclusion.  
10 So I am not yet ready to make a recommendation.

11 COMMISSIONER DIAZ: Following on Commissioner  
12 Rogers, this seems to be one of the crucial issues as far as  
13 implementation and is probably a policy issue that we should  
14 decide.

15 MR. MIRAGLIA: In the short term, I think what  
16 we're saying is that this is how we're looking at it, and if  
17 you want to take credit for something in the SER that's not  
18 in the SAR, you need to come for an amendment in the short  
19 term.

20 In the longer term, we'd have to decide how would  
21 we change that type of policy, and it's integrated and it's  
22 linked to commitments and other issues that we discussed, so  
23 that's why we need to take a step back and say, "How do all  
24 these pieces fit together?"

25 The scope of the FSAR -- I mean, the scope of the

1 rule is the FSAR.

2 CHAIRMAN JACKSON: So that's the scope of the  
3 existing rule. And what you're basically trying to say is  
4 that to reference anything else requires an explicit action?  
5 To do it in the broad-based sense requires a rule change?

6 MR. MIRAGLIA: And I think the other -- I think  
7 that's correct, and I think the other thing we're trying to  
8 illuminate is the question of margins and saying that, when  
9 one looks at the margins question, you need to look at the  
10 entire thing to come in and make the kinds of judgments. If  
11 they want to take credit for that, then the margins need to  
12 be examined.

13 CHAIRMAN JACKSON: Commissioner McGaffigan.

14 COMMISSIONER MCGAFFIGAN: I think two people are  
15 trying to -- Karen, do you want to go first?

16 MS. CYR: I just wanted to clarify something. If  
17 you're talking about the standard review plan, which is not  
18 referenced anywhere else, yes, then that's something new  
19 you're introducing. But if there is a number in the Staff's  
20 SER, then that's really the bases for the tech spec.

21 I was trying to clarify something that Tim said  
22 that I thought was -- that's what he said originally, and I  
23 thought he said something differently, and I just --

24 CHAIRMAN JACKSON: So the SER is part of the basis  
25 for the tech spec?

1 MS. CYR: Right.

2 COMMISSIONER McGAFFIGAN: I'd like to follow up  
3 because I think the key word or adjective or adverb that  
4 we're using is explicit versus implicit, explicitly versus  
5 implicitly. When one looks at an SER, and I haven't, is it  
6 clear when the Staff has explicitly set a different number  
7 between the FSAR and the standard review plan number?

8 Is it always clear or is it ambiguous? Would one  
9 have to induce implicitly that we meant to do that? How  
10 often are these documents ambiguous?

11 MR. MIRAGLIA: I would say then, in more cases,  
12 it's not as explicit as it should be. I think that's one of  
13 the lessons learned in how we're looking at stating  
14 commitments and evaluating SERs.

15 But there are cases where the differences are  
16 articulated. After a period of time, deviations from the  
17 standard review plan need to be documented. So there's a  
18 range.

19 In terms of one of the things that we have, the  
20 regulatory process has been an evolving one with time. In  
21 some of the evolutions, there were conscious decisions made.  
22 The variability FSAR is one where we have some plans with  
23 three or four volumes of SARs, and some are considerably  
24 more.

25 So I think there's a variability in the types of



1     SERs and what plants review the SRPs. The SRPs were not  
2     available prior to 1975, and many of the plants even -- that  
3     received licenses shortly after '75 were not reviewed  
4     against the SRP because it was an evolving kind of review  
5     plan at that point in time. So I think you would find that  
6     variability in the SERs as well.

7             MS. McKENNA: I just wanted to follow up on your  
8     comment about -- that's why -- the reason we're saying  
9     explicit, because if you can't -- if you have to go deduce  
10    it, you really should be falling back to what was in the SAR  
11    because, in essence, what you're really trying to find is  
12    what was reviewed by the Staff, defining unreviewed,  
13    unreviewed safety question.

14            If you can determine from the SER explicitly what  
15    the Staff considered their application against, we're saying  
16    that's what you can look to. But if you cannot explicitly  
17    figure out what that was, you need to fall back on what was  
18    in the SAR because that's what was on the record as to how  
19    they proposed to operate their plant, presuming, if we  
20    issued the license, that that was the basis on which we  
21    accepted it.

22            So that's where we came to the explicit statement  
23    kind of language.

24            CHAIRMAN JACKSON: Why don't you go on, Mr.  
25    Martin.

1           MR. MARTIN: Okay. Given the discussion, this is  
2 probably redundant, but it is still worth saying. The Staff  
3 concludes that a reduction in margin of safety has occurred  
4 and an unreviewed safety question is involved when a change,  
5 test, or experiment would result in no longer meeting a  
6 license-specific acceptance limit.

7           The issue of probability of occurrence or the  
8 consequences of an accident or malfunction of equipment  
9 important to safety both involve the question of what was  
10 meant by the phrase "may be increased."

11           Unfortunately, probabilities may not have been  
12 quantified during the original licensing action. Further,  
13 the methodology to quantify probabilities and uncertainties  
14 has improved substantially. Without these tools, the  
15 determination of whether the probability of occurrence may  
16 be increased would necessarily be qualitative.

17           The Staff interprets the phrase "consequence of an  
18 accident or malfunction" to mean radiological consequence.  
19 Further, given the rule language, the Staff position is that  
20 any increase or even uncertainty about a possible increase  
21 in the probability of occurrence or consequence of an  
22 accident or malfunction of equipment important to safety  
23 previously evaluated in the safety analysis report would  
24 involve an unreviewed safety question.

25           COMMISSIONER ROGERS: I think that's a fundamental

1 policy question, that interpretation. Because when the rule  
2 was written, as you just said, we were not talking about  
3 quantitative measures of probability. And now we have  
4 quantitative tools.

5 But to apply those now to a rule which was written  
6 with something totally different in mind seems to me is a  
7 very fundamental change, not a simple change at all, not an  
8 implementation change; a very fundamental change, as has  
9 been pointed out in this SECY.

10 So I think that's an issue of the type I'm talking  
11 about that I don't think, one, you just take that step  
12 comfortably, you say, well, probability, now we can measure  
13 it so we're going to start measuring it. And if it's an  
14 increase, however small, an increase is what the word said  
15 and we cannot -- we have to interpret it in that light.

16 I think you just have to go back to 30 years ago,  
17 try to figure out what was the intent. And the intent at  
18 that time, as far as I can see, was a more qualitative  
19 evaluation of probability than we are able to use today  
20 through PRA, but once you start doing that, you're in a  
21 totally different type of evaluation.

22 CHAIRMAN JACKSON: Well, it's the Commission's  
23 prerogative to decide if the interpretation of the rule as  
24 applied in '62 when it was promulgated is still relevant  
25 today, subject to the various kinds of considerations and so

1 on and whether there's some other way of interpreting  
2 increase in probability or increase in consequence. And  
3 that's precisely why the Staff was asked to bring the paper  
4 to the Commission, and so we're going to have to work our  
5 way through that in responding to this paper.

6 I mean, it's the Commission's prerogative to  
7 decide in any of these things what is policy and what is a  
8 change in that interpretation or implementation and what is  
9 not, and so, in that sense, I think this is a useful  
10 discussion.

11 MR. MIRAGLIA: I think -- and again, this may get  
12 to the area that Commissioner Rogers brought up in the  
13 beginning; some of these are hard to parse.

14 I think what we're trying to say here is we're  
15 going to interpret the rule very conservatively saying, if  
16 there's any chance of an increase, come to us, and that  
17 would mean qualitative or quantitative. That's where we  
18 were looking at the rule.

19 It's not an inference that you have to use PRA  
20 kinds of techniques. In fact, there is a -- what we tried  
21 to do in the Commission paper is point to the Commission,  
22 within the context of the PRA implementation plan, has asked  
23 the Staff to develop what areas and how to do it and to  
24 quantitate it.

25 So I think we were trying to look at it to say, we

1 were trying to be -- take the word "any" or "any increase"  
2 very literally and have more issues come to the Staff as  
3 opposed to not come to the Staff.

4 COMMISSIONER ROGERS: Yeah, I understand that, and  
5 I think if we're just talking about the single issue of  
6 whether the licensee has to come to the Staff or the  
7 Commission, that's not really what concerns me.

8 What really concerns me is the fundamental  
9 interpretation of any increase in probability, because now  
10 that can have application elsewhere in our regulations, not  
11 just here.

12 And so I think that that's the concern that I  
13 have, not that now people have to come to us. Well, if they  
14 do, so be it. That's not giving me any heartburn by itself,  
15 but what is giving me a lot of trouble is simply choosing to  
16 make that a new definition of increase in probability.

17 CHAIRMAN JACKSON: Commissioner McGaffigan.

18 COMMISSIONER McGAFFIGAN: I'd like -- we don't  
19 have to see a marker at the table, but can you all tell me  
20 anything about the history of this interpretation?

21 I recall from some previous briefing that the reg  
22 review group ran into this when they were looking at -- in  
23 the early '90s looking at items to proceed on and items not  
24 to proceed on in the large list that they looked at. This  
25 word "any" came up in that context and we ended up only

1 making regulatory changes that provided no change in safety,  
2 and there was a larger group of potential regulatory  
3 changes.

4 So I know it goes back at least to the early '90s  
5 and I wonder whether -- since this rule has been put on the  
6 book since '62, how has -- has the Staff interpretation  
7 changed on this over that period, to the best of your  
8 knowledge?

9 MR. MIRAGLIA: I think the issue has been looked  
10 at in a number of different contexts. I think what we are  
11 discussing here is within the 50.59 context, we describe and  
12 define a USQ, which is perhaps a narrower kind of thing, but  
13 the issue has come up.

14 In fact, the Commission, in dealing with the PRA  
15 implementation plan has just spoken to how to look at  
16 increases in terms of the probability and has given the  
17 Staff some guidance, and that's a refinement that reflects  
18 the evolution of the technology and the processes and the  
19 procedures.

20 I think we're trying to describe it in terms of  
21 the regulatory threshold. The issue came up in terms of the  
22 review group. It's come up in the marginal safety  
23 improvement program. I think one of the fundamental issues  
24 as to why we haven't fully endorsed the NSAC 125 document  
25 are these very, very issues, as to whether they are too

1 rigid of an interpretation and, given today's technology,  
2 how should we define it?

3 And we've taken the position that any change, any  
4 increase would --

5 COMMISSIONER MCGAFFIGAN: For at least a decade or  
6 --

7 MR. MIRAGLIA: I believe that's the case, although  
8 I think Commissioner Rogers raises an issue that perhaps I  
9 was coming at it from one direction, but Commissioner Rogers  
10 raises another one.

11 I think the intent is clearly within the language  
12 of establishing new thresholds for review by the agency  
13 before implementation, and I don't believe we were using it  
14 as a tool to foster new and improved and advanced PRA  
15 methods without -- and in front of the existing Commission  
16 guidance as to how we should do those and apply those. It  
17 should be in that context is what our intent was.

18 COMMISSIONER ROGERS: Well, you see, the problem I  
19 have here, and you put your finger on it because you said  
20 "in the context of," and that's what the problem is, that  
21 issues like this have been looked at in the context of a  
22 particular application.

23 Basically, we have not had a consistent point of  
24 view, and that I think when we go back to the point that  
25 Commissioner McGaffigan was talking about, whether -- when

1 we were considering tech spec changes and things like that  
2 and we didn't want to allow any increase in -- or decrease  
3 -- any decrease in safety, that was sort of an intermediate  
4 position. That was a clear one we could deal with right  
5 away. We postponed what would happen if there was a slight  
6 decrease and never dealt with it.

7 But I think that we're facing here the problem  
8 that we have had interpretations in the context of a  
9 particular question and they have not been entirely  
10 consistent. I think this is the time to get at these and  
11 try to establish what we mean by something when we say it.  
12 Does it mean the same thing in every different context? It  
13 should, in my view.

14 CHAIRMAN JACKSON: Go on.

15 MR. MARTIN: The last implementation issue  
16 involves the applicability of the 10 CFR 50.59 process to  
17 the discovery of degraded or nonconforming conditions.

18 CHAIRMAN JACKSON: This is my favorite topic.  
19 Before you get to that, let me talk about -- let me ask you  
20 a question in terms of difficulty in getting to the fourth  
21 bullet. Some of what we've said relates to this.

22 But I note in the Staff's paper, the Staff  
23 concludes that for those calculated in the SAR should be  
24 considered as the threshold for when an increase in  
25 consequences and thus an unreviewed safety question results.



1           Is the content of the SAR definitive enough  
2           currently for all analyzed accidents in those calculations  
3           for that to be the threshold?

4           MS. McKENNA: I hate to say all in anything. I  
5           think, in general, the FSAR would have the accidents  
6           evaluated and the consequences that resulted from them. I  
7           wouldn't say necessarily that all accidents.

8           A question came up. Sometimes if an accident, as  
9           an example, was a fuel handling accident, that was not  
10          considered originally in the FSAR and at a later time the  
11          Staff asked questions of the licensee about it, whether they  
12          would have put that information in the FSAR.

13          It may be a bit of an open question, but to the  
14          extent that the accidents are in the SAR, I think you will  
15          find what the accident was, some information about  
16          assumptions and some information about what the consequences  
17          of that accident are.

18          And what we're saying is that whatever that set of  
19          information is, that's what you look to to see whether the  
20          change that you're making is -- involves an increase in  
21          consequences.

22          MR. MARTIN: Madam Chairman, as a subsidiary  
23          issue, the tools for calculation of radiological consequence  
24          have also improved, and frequently we're finding that some  
25          of the requests for amendment are done with the new

1 techniques of calculation against a conclusion of a much  
2 less sophisticated calculation in the past, and we have had  
3 to go back and redo the calculations using the old tools and  
4 the new tools to check to make sure that it is in fact safe  
5 and stays within the envelope. But here's another case  
6 where technology has caught up with us.

7 CHAIRMAN JACKSON: So is it fair to say you're  
8 trying to trigger, let's call it, a review at the  
9 appropriate point in a consistent way of whatever the safety  
10 question is that allows you to do this kind of analysis,  
11 whether it ends up meaning you have been more conservative  
12 in some instances or not? I'm trying to understand where  
13 you want to go.

14 MR. MARTIN: Where I want to go, where we want to  
15 go is to end up where, if we have made a license decision  
16 based upon a certain issue, certain facts, and what is being  
17 proposed is less conservative than those facts, we just want  
18 a bite at the apple. We want a chance to review and  
19 approve.

20 And this establishes -- this process establishes a  
21 threshold where the licensee recognizes that they need to  
22 come to us and propose their change and we get to determine  
23 whether it's acceptable or not, so that we consistently  
24 review and approve the licensing basis for that plant.

25 MR. MIRAGLIA: I think what you said is a fair

1 summary, Madam Chairman, in the context of, there hasn't  
2 been consistency, and it's -- what we're finding in some  
3 cases, licensees may be taking those, and then we have to  
4 look at the 50.59 to find those.

5 What we're attempting to do with this articulation  
6 of the Staff position in terms of reaffirmations,  
7 clarifications, and new positions is to say, here's how  
8 we're going to be examining these things to get consistency  
9 across the board within the context of what the intent of  
10 50.59 as written and as it applies to the FSAR was, to  
11 provide flexibility within the context of 50.59, and that's  
12 all we were trying or attempting to do to articulate in  
13 these areas.

14 It's obvious, based on some questions, that  
15 perhaps we can be even clearer, but I think that was the  
16 intent of the position, was such that everyone understands  
17 that's what we're going to be looking at and we'll be asking  
18 questions as to 50.59, 50.59 evaluations with this clear  
19 laying out of the playing field, so to speak.

20 MR. MARTIN: The last implementation issue  
21 involves essentially two questions: When is a licensee  
22 expected to conduct a 10 CFR 50.59 evaluation, and what is  
23 required if the evaluation identifies an unreviewed safety  
24 question?

25 Degraded and nonconforming conditions involve the

1 discovery of situations adverse to safety or quality or  
2 safety -- of safety or safety supports, components or  
3 systems to meet requirements of regulations, conform to  
4 applicable codes or standard, or satisfy licensing and/or  
5 design basis.

6 The licensee is expected to promptly insure public  
7 health and safety. However, once that task is fulfilled,  
8 the licensee must determine whether the plant can continue  
9 to operate in conformance with its license, make the  
10 necessary reports, and implement prompt, corrective action  
11 per 10 CFR, Part 50, Appendix B, Criterion 16, to resolve  
12 the condition and prevent recurrence. The process we expect  
13 the licensee to follow is described in generic letter 9118.

14 Up to this point, there is no role for the 10 CFR  
15 50.59 process; however, the Staff has identified three  
16 situations under which the 50.59 process must be invoked.

17 First, when the licensee implements compensatory  
18 measures different than those described in the final safety  
19 analysis report to establish conditions for continued  
20 operation until a final resolution can be implemented.

21 Second, when the licensee intends to implement a  
22 final resolution different than as described in the FSAR.

23 And third, when the final resolution is not  
24 implemented at the first reasonable opportunity.

25 With regard to the second question raised by the

1 issue, the Staff position is that a plant currently  
2 operating with a condition involving an unreviewed safety  
3 question would not normally be required to shut down,  
4 provided that the licensee has determined that all necessary  
5 equipment is operable, that regulatory requirements are met,  
6 and that the licensee expeditiously submits its application  
7 for a license amendment. We're saying one to two days.

8           However, as a matter of regulatory prudence, the  
9 Staff would not allow a plant to start up with an unreviewed  
10 safety question unless the condition is corrected or the  
11 Staff has approved the change.

12           CHAIRMAN JACKSON: Now, if I understand, in a  
13 certain sense, wouldn't your previous point allow for a  
14 notice of enforcement discretion or enforcement discretion  
15 with an unreviewed condition?

16           MR. MARTIN: It could. There is a possibility for  
17 that, but even that -- if they are different than what is  
18 described in the FSAR and you have measures in place that  
19 are different, then we expect them to have evaluated those  
20 with the 50.59 process to determine if there is an  
21 unreviewed safety question involved, and if so, even though  
22 we might grant them enforcement discretion for a particular  
23 regulation or something of that nature, there's an  
24 enforcement action that we have to consider later on and  
25 there's also the question of whether we need to issue them

1 an amendment.

2 Next slide, please.

3 [Slide.]

4 MR. MARTIN: During the Staff's review of its  
5 experience with implementation of the 10 CFR 50.59 process,  
6 we identified two areas specific to the process where it was  
7 felt that rulemaking could be effective in further resolving  
8 some of the identified implementation concerns. Those two  
9 areas were the scope of the rule and the criteria that  
10 defines an unreviewed safety question.

11 The policy question associated with the scope of  
12 the rule centers on whether, in referring only to the safety  
13 analysis report, does the rule sufficiently include all  
14 information that should be subject to the regulatory control  
15 of the 10 CFR 50.59 process?

16 Adding to this issue is the concern that the  
17 requirements for periodic updating of the safety analysis  
18 report are not -- were not always implemented in a manner to  
19 insure the effects that all new analysis were included in  
20 the updated final safety analysis report.

21 The policy issue concerning the content and use of  
22 the final safety analysis report are discussed in further  
23 detail in the Millstone Lessons Learned, Part 2 report.

24 The policy question associated with the unreviewed  
25 safety question threshold is whether the definition should

1 be revised to, for instance, reduce ambiguity on when an  
2 unreviewed safety question is involved, facilitate the use  
3 of probabilistic safety analysis techniques, or eliminate  
4 the need for NRC review of negligible changes in probability  
5 or consequence as the industry has proposed.

6 As previously indicated, the Staff will be  
7 evaluating a number of policy issues identified during this  
8 and other lessons learned efforts in an integrated fashion  
9 to develop a sound set of regulatory proposals for  
10 presentation to the Commission.

11 May I have the next slide, please.

12 COMMISSIONER ROGERS: Just before you leave policy  
13 considerations, you didn't use the word, and it may be  
14 implicit in either the first or the second bullet, but I  
15 really think that a good deal of clarification is called for  
16 in what we mean by "margin."

17 The SECY offered a definition of margin in one  
18 place that I found rather difficult to agree with because it  
19 didn't seem to me that in fact it dealt with what -- the way  
20 the term is used in other contexts. So I think there's  
21 another issue, and that is, what do we really mean by  
22 margin?

23 And that's come up here of how do we define  
24 margin? What do we cite for something to give us a clue as  
25 to what is meant by margin? Well, if you have some numbers

1     that say this is the margin, then that's the margin.

2             But if you're trying to define margin, that's a  
3     different -- when you don't have those, then that's a  
4     different matter and I think that's something we've got to  
5     come to grips with because I don't think it's clear.

6             MR. MIRAGLIA: And I think it can reduce the  
7     ambiguity. It does include that issue in the broader sense  
8     because we discussed consequences, probabilities, and margin  
9     in that kind of context.

10            I think, again, what we were attempting to do  
11     would be to say that that's an issue that needs to be  
12     examined closely. And in terms of saying where should you  
13     look for margin and that description of margin, we were  
14     saying that the bases that should be looked at should be  
15     broader than just a bases of tech specs as defined in 50.36,  
16     but you should look for insights in other places in terms of  
17     establishing how could you point to explicit margin kind of  
18     statements.

19            So we were trying to narrowly focus to that kind  
20     of thing, but your questions are understood and that wasn't  
21     our intent. But perhaps we can make it even clearer than  
22     that.

23            MR. MARTIN: Can we have the last slide, please?

24            [Slide.]

25            MR. MARTIN: At this time, we recommend the



1 Commission approve issuance of the proposed regulatory  
2 guidance related to implementation of the rule to solicit  
3 public comment.

4 CHAIRMAN JACKSON: Let me ask you a question. Why  
5 not the entire paper?

6 MR. MARTIN: We certainly have no objection to  
7 releasing the entire paper. We had not completed our  
8 integration of the issues in the Millstone Lessons Learned  
9 report, Maine Yankee studies.

10 We need to think through the consequences of the  
11 proposals there and we did not want to foreclose any options  
12 for the Commission.

13 MR. MIRAGLIA: Clearly, I think three weeks ago I  
14 indicated the 50.59 issues can move in parallel, but there  
15 is a nexus to some of the other issues. Clearly, the scope  
16 issue, the scope of 50.59 beyond the FSAR is linked to some  
17 of the lessons learned from Part 2, and that has the nexus  
18 -- the content of the FSAR issue is another one that that  
19 raises through.

20 Clearly, as I indicated last time, we can move in  
21 parallel, but we need to keep an eye on those relationships.  
22 If subsequent decisions need to modify, then we'd have to  
23 codify.

24 And what we were thinking of doing is taking a  
25 step back and saying, what are the short-term activities

1 that we're proposing? What's the nexus of each of these  
2 activities to the other questions? And is there some way  
3 that makes more sense in an integrated way to stagger these  
4 things or have them related, or, if we do move in parallel,  
5 to know what -- how they impact on each other. If the  
6 Commission decides to put the policy questions out at this  
7 time, we would not object.

8 CHAIRMAN JACKSON: Would not public comment help  
9 to inform your process?

10 MR. MIRAGLIA: Given that all of the issues are  
11 out, including the Millstone Lessons Learned, perhaps so.

12 CHAIRMAN JACKSON: They're all out there?

13 MR. MIRAGLIA: They're all out there, yes.

14 CHAIRMAN JACKSON: What kind of time frame were  
15 you -- it seems like this whole business, you've been  
16 studying the issue now for over a year, and so the question  
17 is, maybe this is a way to spur you along.

18 MR. MIRAGLIA: Clearly the time frame in terms of  
19 the Staff position on 50.59, we asked for a 60-day comment  
20 period. In the memorandums that forwarded this paper and  
21 the previous paper to the Commission, we said 90 days  
22 subsequent to the Commission moving on the paper, we would  
23 come up with an integrated plan that we could indicate what  
24 actions we have taken and what are underway, how they relate  
25 to one another, and perhaps specific schedules for some of

1 the other actions. So that was the time frame we had been  
2 thinking and discussing.

3 CHAIRMAN JACKSON: I'm going to change the order  
4 so the newer commissioners don't always get left at the end,  
5 so Commissioner McGaffigan.

6 COMMISSIONER MCGAFFIGAN: I've asked the questions  
7 as I've gone along. I guess just on the timing.

8 If we go to rulemaking at some point to resolve  
9 these big issues, how quickly do you see that rulemaking  
10 moving forward in completing? Just sort of ballpark.

11 It's probably not in any six-month plan that you  
12 give us at the moment because it's a gleam in someone's eye,  
13 but --

14 MR. MIRAGLIA: I think what the intent,  
15 Commissioner McGaffigan, would be, in the 90 days, we would  
16 indicate where we are for the initiation in that process and  
17 how it could proceed. I think the nominal rulemaking  
18 process is -- is a two-year from start to finish. I'm  
19 getting some nods of the head.

20 CHAIRMAN JACKSON: Doesn't have to be.

21 MR. MIRAGLIA: It doesn't have to be, and we have  
22 looked at ways of expediting those kinds of issues.

23 CHAIRMAN JACKSON: But you would -- as a follow  
24 up, when would you come forward with the rule, if there were  
25 such?

1 MR. MIRAGLIA: Well, in terms of some of these, I  
2 think that based upon the public comment, and again, if we  
3 can clearly define what the -- what's within the scope in  
4 terms of policy, 60 days comment period, and we'd need some  
5 time to advance those in terms of moving ahead just on the  
6 50.59 piece without taking on the other issues of scope and  
7 commitments and all those kinds of things, we could probably  
8 move out faster than that, perhaps, what, next fall we say?  
9 Sixty days from today for comments?

10 COMMISSIONER McGAFFIGAN: Not to put words in your  
11 mouth, but late '99, we should hope for this to be resolved.  
12 Is that -- for rulemaking, if necessary, to sort of get to  
13 finality on --

14 MR. MIRAGLIA: Come with a proposed rule and then  
15 the proposed rule would have to go out for comment and go  
16 through that process.

17 CHAIRMAN JACKSON: You mean '99 for the rule to be  
18 done?

19 COMMISSIONER McGAFFIGAN: Right, yeah.

20 CHAIRMAN JACKSON: Not for the rule to be --

21 COMMISSIONER McGAFFIGAN: Late '99 for the process  
22 to end. That would be sort of ballpark, given past history.  
23 That sounds reasonable.

24 CHAIRMAN JACKSON: Commissioner Diaz.

25 COMMISSIONER DIAZ: This is a great opportunity.

1 Thank you.

2 CHAIRMAN JACKSON: No; thank me. I was doing that  
3 but I was trying to be nice.

4 COMMISSIONER DIAZ: I just wrote a series of  
5 things in here. Some of them are interesting. I think they  
6 all go to the heart of the problem. Quoting Chairman  
7 Jackson, she says, "the time is now to change this or to  
8 define it."

9 I think we heard from Commissioner Rogers and  
10 everybody else on the inconsistency and some lack of  
11 definition, and I put kind of a phrase in here, going back  
12 to my work, that really what we're trying to do -- if not,  
13 please tell me; we're trying to reduce the uncertainty in  
14 the application of these rules, having in mind the safety  
15 goals, and to apply some risk criteria to it.

16 Is that --

17 MR. MIRAGLIA: I think as a long-term, overall  
18 objective, I think the answer to that is yes, but to try to  
19 get something done in the short term, given the linkage of  
20 all the other policy issues that makes, that may be too big  
21 a goal to try to attempt.

22 COMMISSIONER DIAZ: And that was my next comment,  
23 is that, you know, to change this rule -- it really should  
24 be changed. It's 30 years old and we know a lot more now  
25 than we knew then. We really have to consider a lot of the

1 basic questions that we could comment about all of the time.

2 There is no doubt -- and I spent some time going  
3 to school this past weekend, and I went through the entire  
4 thing.

5 For example, tied into 50.59 is the definition of  
6 what a basic component is. That's in 50.2, define what a  
7 safety component is, and a safety component is a definition  
8 that is broad. It takes any, you know, structure, system,  
9 and component, and then you define specifically, what do you  
10 want those things to abide by. But, really, it doesn't say  
11 when.

12 Then we came and defined in '96 safety related.  
13 Safety related, the last three paragraphs are the same as  
14 basic component, but the first paragraph of safety related  
15 comes and tells you, this only applies to systems that will  
16 prevent or mitigate the consequences of events it postulated  
17 in the assigned basis.

18 I was joking this morning that you take that  
19 definition of safety related that says it's only those  
20 systems that are involved in a postulated event. We could  
21 probably rule out the reactor coolant pumps because they are  
22 not in the definition, but they are in the basic component  
23 definition.

24 That brings us back to where all these things  
25 start, okay, which is something we started very nicely and

1 abandoned through the years, and that was Appendix A and  
2 Appendix B. Appendix A and Appendix B are the nexus to  
3 50.59 and to the definitions of safety related.

4 Appendix A is the only component that I know in  
5 what we have written that defines what is important to  
6 safety. It's the only one, and they defined it in such  
7 broad terms at the time that it was almost unusable, and  
8 therefore we decided not to go by it.

9 But if you look at it, it clearly says those  
10 structures, systems, or components, okay, that are important  
11 to safety will be included. And which are those? Those are  
12 those structures, systems, and components that are necessary  
13 to provide assurance of adequate protection. It's very  
14 broad. No place else is that really defined.

15 Then Appendix B picks it up. Appendix B starts  
16 talking about safety related and then it goes on and talks  
17 about importance to safety, the fact. It's a very, very  
18 classic thing. Appendix B is to be applied to structures,  
19 systems, and components consistently important to safety.

20 Even in 1970, we were establishing that our  
21 regulation, our Q list, was to be graded to the importance  
22 to safety of the components. What was the problem? The  
23 problem is that we never redid, although we promised that we  
24 would do, Appendix A.

25 Appendix A should have included all those systems

1 and components that even were not part of your safety  
2 system, will have an impact. They should have clear  
3 definitions, and we promise in the rule we are going to come  
4 in and improve Appendix A, we're going to make it better,  
5 and we're going to make it what it should be: a guide. We  
6 never did.

7 We do patchwork like we could do now. I think the  
8 time is now. The time is now to put all of these things  
9 together so they mean the same thing, so they actually  
10 address the same issue, and the issues are very clear, okay?  
11 We need to have and maintain the level of safety while the  
12 licensee is able to operate according to his license, and we  
13 need to define that well so we provide him with the  
14 necessary vehicle so they can do their work.

15 And that can be done, but it only can be done if  
16 we integrate all these things. We cannot leave safety  
17 related. This afternoon, we're going to come safety related  
18 in 50.65. Read the definition, okay? It only applies to  
19 structures, systems, and components that are going to  
20 prevent -- or actually, they practically say are going to  
21 mitigate, okay, and dealing with postulated events.

22 In other words, leave the reactor coolant pump  
23 out. I'm sure you didn't mean that. I'm sure you didn't  
24 mean that. But if you are legalistic and you go through it,  
25 that's where you come out, and it is the time to put all of



1 these things together and say, do we really need to change  
2 50.59 or do we need to change Appendix A and Appendix B  
3 together? And I believe that that is what we should do. We  
4 should go that way.

5 In the short term, I think that zero increases,  
6 okay, are not what the rule meant. It also really clearly  
7 meant not significant increases, okay? But there is a range  
8 of safety here from zero to what is risk critical, and that  
9 is what the Staff should comment on.

10 CHAIRMAN JACKSON: Commissioner Dicus.

11 COMMISSIONER DICUS: No, thank you.

12 CHAIRMAN JACKSON: Commissioner Rogers.

13 COMMISSIONER ROGERS: I agree with Commissioner  
14 Diaz. Let me just say that I'm not going to add any details  
15 here. I think what we've heard is very well worth listening  
16 to, but I just wanted to say that I thought the SECY was an  
17 excellent job. It provides us with the basis for really  
18 looking at some of these questions, and I complement the  
19 Staff for producing such an excellent document.

20 I also raise the question that the Chairman has  
21 raised, why not circulate the whole document? It seems to  
22 me the policy issues are very critical. It would be very  
23 helpful to get public comment on those as soon as possible  
24 and I would certainly have no problem with circulating it in  
25 its entirety.

1           CHAIRMAN JACKSON: So this has all been structured  
2 to give me the last word.

3           On behalf of the Commission, let me thank the  
4 Staff for presenting to the Commission the results of your  
5 evaluation and recommendations for improvement in the  
6 regulatory guidance in this area.

7           The Staff's paper to the Commission and today's  
8 presentation have helped to illuminate the picture for the  
9 Commission on the various areas that are in need of further  
10 implementation, and I think net/net, the Commission is very  
11 interested in correcting the identified deficiencies.

12           As I stated at last month's Lessons Learned  
13 Commission briefing -- we've been having a lot of these --  
14 the industry and the NRC have recognized the importance of  
15 10 CFR 50.59 but yet have struggled with providing adequate  
16 guidance, and so we need clear guidance on a firm regulatory  
17 basis.

18           A 50.59 process that is not properly implemented  
19 could result in an unacceptable reduction in the level of  
20 safety at a plant. But conversely, it could be implemented  
21 in a way that would tie licensees' hands so much that they  
22 could never make any changes to the plants without coming to  
23 the NRC beforehand. And that's not our intent, but we have  
24 to be clear on what we mean by maintaining safety,  
25 appropriate safety levels.

1           So I commend you for the detailed presentation of  
2     the issues in the SECY paper. I tie this back to our  
3     previous briefing. If the Commission requires  
4     implementation of 50.71(e) as we discussed in the previous  
5     briefing so that FSARs are updated to correct past omissions  
6     of changes to the design bases and effects of other analyses  
7     that have been performed since the original licensing but  
8     have not been included in the updated FSAR, and include such  
9     information in the future, we will have a more complete  
10    description of the licensing and design basis information in  
11    the FSARs themselves, which is then controlled by 50.59.

12           The Staff should, in addition, consider additional  
13    information, what additional information is within the  
14    licensing basis, such as some commitments to the NRC that  
15    would not be included in these FSAR updates, how significant  
16    that information is, and provide recommendations for how it  
17    should be controlled.

18           The industry should be provided the opportunity to  
19    comment and to verify that the industry and NRC are  
20    accurately communicating with each other on implementation  
21    guidance for the rules and, as such, the Commission will  
22    soon decide on the publication of that paper, most likely  
23    the full paper, for public comment.

24           And since it's proposed that the -- part of the  
25    paper you were proposing for a 60-day comment period, we

1 would do the whole thing, but I believe it would benefit the  
2 Commission then to hear back from the Staff, again, in  
3 approximately 90 days.

4 And I would ask you to cull through the existing  
5 paper and to lift out all of the questions that would have  
6 to be addressed to promulgate appropriate changes to 50.59,  
7 but I'm going to make a comment to link to Commissioner  
8 Diaz's comments in a second, because I think the Commission  
9 wants to be clear to know exactly what the questions are.

10 If there have to be policy decisions, we should  
11 just give them in an expeditious manner and then you can use  
12 that as the basis for any rulemaking, coupled with the  
13 comments that you would garner in the comment period.

14 Referencing something that Commissioner Diaz said,  
15 there is a need more broadly for clarification. I can  
16 remember a year to a year-and-a-half ago talking about what  
17 the difference was between safety related, important to  
18 safety, safety significant, and risk significant. We have  
19 never cleaned that up, and people apparently have stepped up  
20 to the abyss, which is my favorite word, and stepped back.

21 And I think it's not going to all be done  
22 immediately as part of improvements to 50.59 itself because  
23 it is such an important rule, we need to get on with it.  
24 But I do think that you need to come back with an integrated  
25 plan in terms of how we can effect greater clarification

1 throughout our major rules with regard to these  
2 inconsistencies in definition.

3 I think we have an opportunity to do that now. I  
4 think this Commission is interested in it, and I think we  
5 would like you to do it in a timely manner.

6 So if there are no further comments, we're  
7 adjourned.

8 [Whereupon, at 11:57 a.m., the briefing was  
9 adjourned.]

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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 10 CFR 50.59 REGULATORY  
PROCESS IMPROVEMENTS - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Monday, March 10, 1997

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: David Lison

Reporter: Jody Goettlich



# **10 CFR 50.59 REGULATORY PROCESS IMPROVEMENTS**

**Office of Nuclear Reactor Regulation**

**March 10, 1997**

# **INTRODUCTION**

- **10 CFR 50.59 permits licensees to make certain changes without NRC approval**
- **It establishes a regulatory threshold on the need for prior staff approval**
- **Purpose of this briefing**



# **CONCERNS ABOUT 50.59 PROCESS**

- **Scope of rule is limited to facility or procedures as described in SAR**
- **Ambiguity exists about when a change involves a USQ**
- **Application to existing conditions**

# **APPROACH TO RESOLUTION**

- **Enhance implementation of rule as written**
  - Reaffirm, clarify, or establish regulatory positions
  - Improve NRC oversight and inspection guidance
- **Identify opportunities for improvement**
  - Integration of policy issues

# **IMPLEMENTATION ISSUES**

- **Deletion of Information from SAR**
- **Margin of Safety Interpretation**
- **Increase in Probability**
- **Increase in Consequences**
- **Degraded or Nonconforming Conditions**

# **POLICY CONSIDERATIONS**

- **Scope of Rule (Safety Analysis Report)**
- **Unreviewed Safety Question Threshold**

## **RECOMMENDATION**

- **Publish staff implementation guidance for public comment**

# **BACKUP SLIDES**

# **10 CFR 50.59**

## **§ 50.59 Changes, tests and experiments**

- (a)(1) The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.**

## **50.59(a) CONTINUED**

**(2) A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced.**



## **10 CFR 50.71(e)**

- (e) Each person licensed to operate a nuclear power reactor pursuant to the provisions of § 50.21 and § 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 FSAR contains the latest material 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 updated FSAR.**

## **10 CFR 50.71(e) CONTINUED**

**The updated FSAR shall be revised to include the effects of: all changes made in the facility or procedures as described in the FSAR; all safety evaluations performed by the licensee either in support of requested license amendments or in support of conclusions that changes did not involve an unreviewed safety question; 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 FSAR.**

**[50.71(e)(1) through (6) follow]**

## **10 CFR 50.2**

***Design Bases* means that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted “state of the art” practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a system, structure, or component must meet its functional goals.**

## **10 CFR 54.3**

***Current licensing basis (CLB)* is defined in Section 54.3 as “the set of NRC requirements applicable to a specific plant and a licensee’s written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modification and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 30, 40, 50, 51, 54, 55, 70, 72, 73, and 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications.**

## **54.3 (Current Licensing Basis) CONTINUED**

**It also includes the plant-specific design basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report (FSAR) as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports."**

## **50.34 (a)**

**(a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The minimum information to be included shall consist of the following:...**

**(4) A preliminary analysis and evaluation of the design and performance of structures, systems and components of the facility...including determination of (i) the margins of safety during normal operations and transient conditions anticipated... (ii) the adequacy of structures, systems and components provided for the prevention of accidents and the mitigation of consequences of accidents...**

## **50.34(b)**

**(b) *Final safety analysis report.* Each application for a license to operate a facility shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases and limits on its operation, and presents a safety analysis of the structures, systems and components as a whole, and shall include the following:...**

## **50.36**

- (a) Each application for a license authorizing operation of a production or utilization facility shall include in his application proposed technical specifications in accordance with the requirements of this section. A summary statement of the bases or reasons for such specifications shall also be included in the application, but shall not become part of the technical specifications.**
- (b) ... The technical specifications will be derived from the analyses and evaluation in the safety analysis report, and amendments thereto...**