UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
***
BRIEFING ON 10 CFR PART 70
PROPOSED RULEMAKING,
"REVISED REQUIREMENTS FOR DOMESTIC
LICENSING OF SPECIAL NUCLEAR MATERIAL"
***
PUBLIC MEETING
***
Nuclear Regulatory Commission
Room 1F-16
One White Flint North
11555 Rockville Pike
Rockville, Maryland
Tuesday, August 25, 1998

The Commission met in open session, pursuant to notice, at 10:00 a.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:
SHIRLEY A. JACKSON, Chairman of the Commission
NILS J. DIAZ, Member of the Commission
EDWARD McGAFFIGAN, JR., Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:
JOE CALLAN, EDO
TOM BAER, NFS
JACK ALLEN, Westinghouse
CHARLIE VAUGHAN, GE
JOHN C. HOYLE, Secretary
KAREN D. CYR, General Counsel
JAMES TAYLOR, Executive Director for Operations
DR. CARL PAPERIELLO, NMSS
ELIZABETH TEN EYCK, NMSS
RICHARD MILSTEIN, NMSS

P R O C E E D I N G S

[10:00 a.m.]

CHAIRMAN JACKSON: Good morning. Today we are going to be focusing on the staff's proposed revisions to 10 CFR Part 70, and we have several industry representatives who have come to provide their views regarding the proposed changes to Part 70.

Following their presentation, the staff of the NRC will brief the Commission on the details of its proposal for revising the requirements for the domestic licensing of special nuclear material found in 10 CFR Part 70.

The process to revise Part 70 began in 1993, and various aspects were presented to the Commission for resolution in 1996 and 1997. Today, my colleagues and I look forward to hearing from all presenters to assist us in resolving issues associated with the draft rule that is presented in SECY 98-185.

And so unless my colleagues have any remarks they would like to add at the moment, Mr. Fertel, I assume you are going to lead off. If you could introduce your colleagues.

MR. FERTEL: I will. Thank you, Chairman Jackson, and good morning, Commission McGaffigan, Commissioner Diaz.

I am Marvin Fertel of the Nuclear Energy Institute, and I am certainly pleased to be here today to

represent not only NEI, but all of the fuel fabrication and enrichment companies that operated facilities licensed under 10 CFR Part 70.

With me at the table this morning at Dr. Tom Baer, who is the VP for Safety and Regulatory Activities at Nuclear Fuel Services; Mr. Charlie Vaughan, who is the Manager for Strategic and Regulatory Planning at General Electric; and Mr. Jack Allen, who is the Plant Manager for the Westinghouse Columbia facility. And I think with the expertise sitting with me here, hopefully, we will be able to answer any questions that you might have from a safety, regulatory, or operational perspective as this dialogue goes on.

I would also like to point out that there are representatives from all the fuel fabricators and enrichers present today in the audience.

On behalf of the Nuclear Energy Institute's Facility Operations Committee, I would like to thank you for the opportunity to appear before you again to discuss the ongoing rulemaking to amend 10 CFR Part 70.

As you are aware, we have been working for several years, and Chairman Jackson mentioned 1993, which makes it at least five years right now, with the NRC staff to develop a set of modifications to Part 70 which would improve the regulatory process and enhance protection of the public

health and safety at our facilities without imposing unnecessary burdens on industry or the NRC.

Prior to receiving SECY 98-185, the staff's most

recent draft rulemaking package, we believed that we were making reasonable progress in closing the gap between the staff's perspectives and our own. We had planned to present to you today a sense of significant progress and to identify those few important issues which remain for resolution.

We have not yet fully digested all of the detail in the very extensive rulemaking package. It is voluminous and involves many new and complex concepts such that making it difficult for us at this time to make informed judgements as to its implications in a single rulemaking.

For example, within the SECY there are new requirements and criteria governing worker safety, new reporting requirements, new design criteria for new processes or facilities, new provisions for the conduct of preliminary ISAs, new procedures for licensee changes, and new criteria related to criticality safety. Any of these concepts in and of itself could justifiably be the subject of an individual rulemaking proceeding.

We have, however, performed a sufficient review of SECY 98-185 to conclude that much of the progress we thought had been made was illusory. That, (2), the rulemaking package, particularly the draft standard review plan, is a

significant departure from how we understood our rulemaking petition was being dispositioned. (3) If implemented using the proposed SRP, the rule will focus many industry and staff resources away from significant safety issues. And (4), the package deviates from the guidance provided with the Commission in its August 22, 1997 SRM.

We cannot hide our sincere disappointment with the package we received. To understand our concern, it is important to recount some of the history of our interactions on this issue.

CHAIRMAN JACKSON: Let me stop you for a moment, Mr. Fertel.

MR. FERTEL: Yes, Chairman.

CHAIRMAN JACKSON: Can you be more explicit in terms of what respect or respects do you feel the proposed rule differs from the guidance?

MR. FERTEL: Yes, I can. And I will in here, but the primary area where it does that is the staff has included a significant amount of prescriptive, programmatic safety criteria.

CHAIRMAN JACKSON: Is that in the rule or in the documents?

MR. FERTEL: It is in the SRP. It is the Standard Review Plan.

CHAIRMAN JACKSON: Standard Review Plan.

MR. FERTEL: Yes.

CHAIRMAN JACKSON: Yes.

MR. FERTEL: It is not in the rule itself, but it is in the SRP. And that is the one major area where we think it deviates. We think that another area is they are

consistent with the guidance offered by the Commission, though we request that the Commission, maybe after we finish, consider whether or not you want to offer them new guidance in a couple of areas. So they are not totally inconsistent with the guidance in the SRM, but they clearly are, in our opinion, on the imposition of major programmatic safety requirements.

CHAIRMAN JACKSON: And you are going to talk in more detail about those?

MR. FERTEL: Yes.

CHAIRMAN JACKSON: Okay.

MR. FERTEL: The last time we appeared before the Commission, on July 2, 1996, we expressed strong concern regarding the existing draft Part 70 revisions, as well as the draft standard format and content guide and the standard review plan.

One of our most significant comments was that the rulemaking package, including the format and content guide and the SRP contained a large number of new programmatic criteria. Those documents contain new guidelines for NRC

review and approval of our various safety programs in areas such as quality assurance, maintenance, training and criticality safety.

Many of those guidelines went well beyond existing programs and were not, in our view, justified on the basis of health and safety. Up until our July 2nd meeting with you, the industry had argued that no changes in Part 70 were necessary. On July 2nd we modified our position and embraced the staff proposal to require the performance of integrated safety assessments. I think they call them integrated safety analyses now.

We concluded that by adopting the ISA, the safety basis of the facilities would be more clearly defined. The licensee's and the NRC's attention would be focused on the most important safety issues, and it would provide for implementation of a graded risk-informed, performance-based safety program.

In embracing the ISA concept, however, we urged the Commission to eliminate the references to these new multiple safety programs as premature and unnecessary. We believe that a rule should be written to require the performance of ISAs and to require licensees to modify their plants and activities to address any vulnerabilities identified as a result of those ISAs.

Our rulemaking petition proposed to implement this

approach, but we concluded that promulgation of a wide range of new prescriptive safety program criteria would not be part of the rulemaking package.

In SECY 97-137, the staff discussed its proposed disposition of our rulemaking petition and stated that, "In response to licensees' concerns, staff is now proposing that, rather than require multiple safety programs,

licensees have the flexibility to determine, based on the ISA results, the specific elements of the safety programs that would be needed."

The Commission's SRM dated August 22, 1997 approved the staff proposal to revise Part 70, as requested by the NEI petition, with the modifications described in SECY 97-137. On that basis, we assumed that the current rulemaking package would focus on the ISA and on the need to address vulnerabilities identified in the ISA, but would not contain a wide range of new prescriptive safety program criteria.

CHAIRMAN JACKSON: What are you calling -- are you calling -- what are you calling -- give us some examples of what you are calling --

MR. FERTEL: In the SRM itself, Chairman Jackson, there is at least the expectation, from the experience that we have in dealing with the regulatory process, that if I identified a particular high risk safety system in my

facility, that as the reviewer here looked at what I should be doing for it, they would, in QA-1, which is what they are including in the SRM and the SRP, they would require me to use a systematic approach to training, which may or may not be appropriate or that case. And they would basically have prejudged the nature of the QA, the training program and other programs that I should be using for a high risk system.

What we would have expected, and I think that maybe the staff would say this would still happen, but these are the words that they have in the SRP.

CHAIRMAN JACKSON: I guess what I am really trying to make sure I understand is, are you -- is your fundamental point that there are a number of additional prescriptive requirements in the standard review plan that go beyond the ISA? Or are you talking about the ISA itself. I just want to be clear.

MR. FERTEL: We are talking about prescriptive program requirements in the standard review plan that would be applied if my ISA identified a high risk system, or process, or activity. So we are actually okay, in general, on how the staff wants to do ISAs. We have a problem with whether the ISA goes in the license or not. But as far as how to actually do an ISA, I think that that is an area where the industry and the staff have made very good

progress and are, basically, in very good agreement.

It is when I finish doing it and I determine that this class is a high risk class, and I am now sitting down to say, okay, am I treating it correctly within my plant operation and program space as far as the way I am training Charlie to operate it, or I am looking at the QA program that I am putting on it. We would say we ought to look at that, we ought to come up with what makes sense, and it may or may not be a systematic approach to training approach in

this case. It may or may not be in QA-1. It likely wouldn't be in our mind in many cases.

But right now, if I look at the SRP, the test, the hurdle, would be, okay, how are you applying in QA-1 to that particular class? How are you applying your systematic approach to training to that class?

CHAIRMAN JACKSON: So, I mean is the problem having to do with the degree of prescription in terms of how to resolve a vulnerability or address a vulnerability?

MR. FERTEL: I think that is an appropriate and correct characterization of the problem.

CHAIRMAN JACKSON: Okay.

COMMISSIONER McGAFFIGAN: Just to follow-up on that, going back to this point as to whether the ISA is in the license or not, it also is who is in charge of the process of figuring out how to respond, right? You don't

want us second-guessing every judgment, as I understand it, or every engineering change that you make that might be above a 50.59 threshold. And so it is a question of, if it is not in the license, if you do the ISA, you respond to it, you are responsible for doing that much, but if -- but we are not second-guessing every judgment you make in response to your ISA.

MR. FERTEL: Yeah, I think that's accurate, too, Commissioner, that we don't want you second-guessing. Now, we certainly do want you to approve those particular actions that you should approve and we are not at all opposed to license conditions that would make all the ISA information available. I think the problem with the ISA and the license is it is adding, you know, thousands of pages of material, and, in many cases, lots of material that -- you know, how do you sort through to find out what is important as part of your license, and it is an administrative nightmare for handling. These facilities, when you go visit them, thousands of pages.

CHAIRMAN JACKSON: Well, let me just understand. Is the rub, with respect to this specific issue, an administrative one, or is it that you are concerned that it triggers requirements? Because, presumably, if you have to do an ISA, you know, as a condition of getting a license, and it has to be maintained in some way, and has to be

updated and so on, because if it is not, it is useless, all of that is going to occur anyway. And if there are thousands of pages associated with it, there are thousands of pages associated with it.

But, so I guess I really want to understand, is the fundamental rub an administrative issue, or it is that you are concerned about requirements that may be triggered as a consequence?

MR. FERTEL: It is both. And administrative is probably making it sound too trivial. It is not so much administrative and Xeroxing another thousand pages, because

that certainly can be done. What it is, is if I am going to keep it up to date as part of my license, and every time have to make a decision whether it is a license amendment, whether or not that is really important or not, if I am going to have to implement a 50.59 equivalent process for these facilities, which they have never had, nor seem to need, am I creating something that, again, diverts, in this case, relatively limited resources at these facilities?

CHAIRMAN JACKSON: No, I understand the point you are making. But are you -- you are not arguing that it should not be updated?

MR. FERTEL: Absolutely not. And we are not arguing that it shouldn't be available. We think it definitely should be available.

CHAIRMAN JACKSON: And so the real question has to do with mechanism?

MR. FERTEL: Yes.

COMMISSIONER DIAZ: It can be docketed but it is not part of the license, that is what you are saying? It can be an available --

MR. FERTEL: Certainly available, and certainly used. And we don't have any problem with using it, even in enforcement space, correctly. We are just trying to keep it simple.

CHAIRMAN JACKSON: Well, as simple as the complexity of it allows. All right. Okay.

MR. FERTEL: Let me see, I'll pick up somewhere and skip a couple of things.

Okay. In addition to the problem that we have raised with the apparent imposition --

CHAIRMAN JACKSON: Excuse me.

COMMISSIONER McGAFFIGAN: There was one other question I meant to ask on this slide that you were on, the history of interactions. In 1996, in July of '96, it sounds like at that point there was a standard review plan that you all had access to and that you didn't like, and there was a Commission, before my time, and you had discussion.

There are now, in this SECY document, you have seen the new standard review plan, and apparently, that,

again, is causing great concern.

What, in that intervening two-year period, what was the nature of the interaction on the standard review plan? Did it evolve? Did you all have some insight into it?

You know, as a general matter, I'll tell you where I am coming from, in the reactor space, we seem to work best when these guidance documents are discussed back and forth between NEI and the staff in public. FSAR update, we now are relying on 98 -- NEI 98-03 as the basis for, hopefully, resolution there. We are hoping to do similar things in other reg. guides.

But in this case, from '96 to a few days ago, or a

week ago, had you seen the SRP?
MR. FERTEL: We hadn't. From '93 to '96 there was a lot of interaction between the industry and the NRC on development of the standard review plan that evolved to that point. NRC held a number of open meetings where the industry came in and made presentations on draft sections of the SRP. And I think during all those meetings, there was a consistent drumbeat, at least from our side, that you are getting too prescriptive and back off. And what came out in the '96 time frame, when we appeared before the Commission, was, well, we hadn't won those arguments and it was still there.

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From '96 till now, the real focus of the discussion has been on the other issues of where should -- How do you do an ISA? What do we think about, you know, what is an ISA? And, again, there was very good agreement that has been reached there. What type of criteria should you have for the radiation side? And I think there has been very good agreement there.

And we didn't get very good agreement on where the ISA should go, whether it is in the license or not, but there was a lot of discussion. We had a lot of discussion on the applicability of the backfit rule. We did not see the SRP until this SECY was released, nor did we discuss it.

CHAIRMAN JACKSON: Let me make sure I understand, though, you know. So that you have had open interactions.

MR. FERTEL: Very much so.

CHAIRMAN JACKSON: It is just that the open interactions have no focused on the SRP.

MR. FERTEL: That's correct.

CHAIRMAN JACKSON: Okay.

MR. FERTEL: And it may have been erroneous on our part to assume that the SRP was going to end up absent some of these things. And I think maybe that was why the visceral reaction when we saw it was not good.

CHAIRMAN JACKSON: Okay. So, I mean -- because there is an implication that there was a deliberate attempt

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to keep you from seeing the SRP.

MR. FERTEL: I have no basis for that, that was just the process.

CHAIRMAN JACKSON: It is just the process that you --

MR. FERTEL: Yes.

CHAIRMAN JACKSON: You were interacting.

MR. FERTEL: Very much so.

CHAIRMAN JACKSON: It is just that the SRP was not the focus of most of those interactions, is that correct?

MR. FERTEL: Yes.

CHAIRMAN JACKSON: You were going to make a comment.

DR. BAER: No, that was correct.

CHAIRMAN JACKSON: Right. Okay.

MR. FERTEL: Yeah. In addition to the problem that we do have with the programmatic requirements, which are related to the SRP, we continue to have disagreements with the staff on the proposal on whether to include the ISA results in a license, their opposition to the inclusion of an immediately effective backfit provision and the inclusion of consequence criteria that focus on purely chemical hazards, and we are going to talk some more about all of these.

Based on that, we have concluded that the proposed

rulemaking package is substantially the same as the prior draft to which we objected back in 1996, even though, again, I would say that on the ISA, we are clearly in much more agreement than we ever were, and even in the radiation criteria.

As the Commission is moving to improve and simplify its regulatory process overall, we believe the proposed Part 70 rulemaking package would significantly increase both complexity and burden on the licensee, and the NRC. It would do so for facilities that have an excellent safety record, and really pose extremely low public health and safety risk. And we believe there is simply no need for dramatic change in the Part 70 regulations.

ISAs should be conducted and licensees should be required to correct any vulnerabilities that may emerge. The ISAs should be kept up to date, and the NRC should --

CHAIRMAN JACKSON: Let me ask you a question. What would be the basis of that requirement?

MR. FERTEL: We would support a license condition that says I must have an ISA. We would support a license condition that tells us that we must keep it up to date. We would support a license condition that says it must be available for inspection and review by NRC.

CHAIRMAN JACKSON: You are taking all of this down, right?

[Laughter.]

COMMISSIONER McGAFFIGAN: That much -- do you need a new rule for? Or could we, under the existing Part 70, just say these license conditions will be expected when somebody renews a license? And just put them into a document that says when you review future --

CHAIRMAN JACKSON: It is not an explicit regulatory requirement, so you would have a question in terms of --

MR. FERTEL: You would have that question. I mean, not wanting to beat it to death, but I mean the staff has been imposing those as conditions of every license renewal. So Chairman Jackson is correct, but, clearly, the process works in other ways.

And, again, I think, Commissioner McGaffigan, a simple rule would probably legitimatize what is going on in practice, which, in most cases, we are honestly willing to

support.
COMMISSIONER DIAZ: Is this -- it would work something like, you know, the maintenance rule in a certain way, maintaining configuration control, but without having to keep, you know, the process at every step, very, you know, scrutable, but you have to comply with it, you have to make sure that information is available so the staff can check that you actually --

MR. FERTEL: I think that is not a bad analogy, Commissioner Diaz.
MR. VAUGHAN: No, in fact, that is very good, because at the operating level, the operator has to understand what the configuration is to manage their operation. And we have indicated time and again that, at the sites, that information would be available for the NRC either to review or inspect, or whatever their desire is.
COMMISSIONER DIAZ: So those requirements express for your facilities -- that requires that you maintain, according to the ISA, the configuration management would actually maintain the safety aspects of your facility and be scrutable.
MR. FERTEL: Yes, very much so. Again, I don't think in philosophy, we are really at odds with even the staff. I think that it is in implementation mechanisms and processes, and I think that the Commission is offering suggestions that are very consistent with ways that we would think you could implement. Because we are not arguing against any sort of accountability here, or using the ISA appropriately. That is not in debate on our side.
CHAIRMAN JACKSON: Okay.
MR. FERTEL: In support of the proposal that the staff has put out, they discuss incidents, many of which have been, in our opinion, mischaracterized at operating

facilities, and all of which have occurred years ago.
Maybe most important is they don't adequate account for the changes that have occurred in the intervening years. While the Part 70 regulations themselves have not substantially changed, the rigor of their implementation has substantially increased. And I think this goes to Commissioner McGaffigan's statement that, in essence, a lot of this is already happening, though maybe the rule doesn't give it all the regulatory legitimacy it should have.
A wide range of NRC staff initiatives undertaken under the existing rules, including enhanced criticality, safety reporting, more rigorous inspections and updated guidance on management oversight and chemical safety have increased the NRC's focus on chemical hazards, fire protection and nuclear criticality safety. These are the concerns which originally prompted calls for amending the regulations.
Beyond this, during the last license renewal

cycle, most Part 70 licensees agreed, as a condition of their license, to perform an ISA on a set schedule. The acceptance of an ISA condition demonstrated that both the NRC and the NRC recognize the valuable tool an ISA can be.

Furthermore, industry initiatives have resulted in a fuel fabrication industry that is safer than it was ten

years ago. Those initiatives include improvements in the level and quality of documentation of nuclear criticality safety analyses, improved configuration management programs and better unusual event identification and root cause analysis.

Together, the staff and industry initiatives have resulted in better understanding of plant safety bases and more rigorous application of programs important to safety within the current Part 70 regulations.

COMMISSIONER DIAZ: Excuse me. The term "safer" just caught my eye and ear. Would you elaborate on that? How much safer is safer? Can you give me a ballpark?

MR. FERTEL: It would have to be qualitative. I think that in almost all the facilities, Commissioner Diaz, what has happened is the rigor at look root cause analysis has gotten much better. The configuration management control systems have gotten much better.

The implementation of 91-01 as a reporting mechanism has helped share across the industry, maybe more effectively, information. So it is more of a qualitative, because we are not quantifying.

And I think, you know, my background is much more reactors than the Part 70 licensees, and it took me a while, sitting with my friends here, and various meetings, to understand the nature of their risk, and they very different

than reactor risks. It is really hard to cause something off-site. So when we are talking safer, it is safer in avoiding any type of event, not a health and safety threat.

COMMISSIONER DIAZ: Besides the difference in the absolute, you know, between reactors. And is this -- have the improvements in the fuel facilities comparable, start with, you know, lower safety regs to those that have been made in the reactor side?

MR. FERTEL: I would tend to say yes. I mean there's a lot more rigor at the reactor sites and things like PSAs, and, you know, just the nature of the beast that you are working with. And event here, you know, it's hard to say as, you know, the bar keeps getting raised.

COMMISSIONER DIAZ: Okay.

MR. FERTEL: I don't know if anybody here at the table, Jack, or Tom, or Charlie, would like to say something.

DR. BAER: Commissioner, it is very difficult to have a dramatic improvement in something that is already at a safety level where incremental changes cause, on a percentage basis, large amounts. At our facility, there are

essentially no accident sequences that would produce a significant off-site impact. So we are already starting below the limits that have been set in the regulations.

COMMISSIONER DIAZ: I understand that. I was

referring to the fact that if configuration management and all of the other processes have increased in quality and effectiveness, you know, as they have in reactors, that even your very safe levels will be at a much higher level of safety. And I was questioning what those improvements are, and I am really not familiar.

MR. VAUGHAN: I think from the operating plant standpoint, I can't compare it to rectors because I don't -- you know, I am not qualified to do that, but in our businesses, I think the lessons that we have learned in the last few years, and have tried to implement, one of those is the lesson of configuration management. And you have to have configuration management to keep your programs in tune. And we have made lots of changes in that regard. And, also, kind of as a spin-off of that, or a result, there has been a lot of improvement in the internal documentation that describes your basis for safety and what is important to assure that those protective measures are in place.

I believe the next milestone, if you want to go farther than what we have pretty much done voluntarily, is --

CHAIRMAN JACKSON: Let me take you up on the issue of voluntarily. The question is what drove the changes. And I mean it seems like I heard a combination of things, industry initiatives, more rigorous implementation of the

existing Part 70, and lessons learned on both the industry and the agency side in terms of learning from incidents and so on that occurred over the years. And so it strikes me that it seems to be a kind of a potentiating thing, that not all of these were just totally voluntary from the beginning.

MR. VAUGHAN: Yeah, you are correct. There's a lot of interaction. But we learned a number of lessons from what was happening at our plant, and there was a sensitivity driven by the NRC to those kinds of things. So it was clear that we needed to learn the lesson. And the inspection program continues to point out places that we miss the mark, and we take that very seriously and learn from those, too. So it is an interactive process.

COMMISSIONER McGAFFIGAN: Could I ask what has the trend been in 91-01 reports? In the 96 document, attachment, there apparently was a downward trend, and I was wondering whether that had continued in 97, in 91-01, you know, the reports that you all voluntarily, or whatever, submit in response to the information notice.

MR. ALLEN: I would say that from the Westinghouse experience, that they are increasing, that there is more involvement, more reporting as we have gone through various situations, and I think it is because of the interactions,

that it has not truly been voluntary in some respects and it has been interactive. So there's -- I would say that it has

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been an increase.

COMMISSIONER McGAFFIGAN: But does 91-01, I have not honestly read the bulletin, does it -- are these precursor type reports that you have to report on, or does that mean the number of precursors is increasing? Or does it just mean that you are getting down and finding more?

MR. ALLEN: I think it is the latter, in the case -- I think we are being more deliberate about the license requirements, understanding the license requirements, the timing of reporting and the specifics. In some cases it goes to the point of the prescriptiveness of some of the requirements that we are talking about. I think that is what has driven a lot of the reporting.

I would just like to also comment that in the case of our customers and the quality requirements, there are -- in QA-1, there are iSA requirements. It is not prescriptive, and yet we have enhanced our quality systems and work closely with our customers, and you have in regulating them, done the same.

And so back to what Commissioner Diaz was talking about, in terms of an improvement in safety, I would say that the improvement in safety that we have seen is commensurate with the enhancement in the product quality. And so we have seen that kind of level of improvement that has been generated. And so those are the two points I would

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make relative to prescriptive improvements.

MR. FERTEL: Tom, do you want to say anything in response to Commissioner McGaffigan's question on 91-01?

DR. BAER: It's not a fair comparison for at NFS, because two years ago we were not operating. Today we are operating. We have made a couple of 91-01 reports. We don't believe that it is an indication of precursor. It means it is because we are looking very closely at the operations and what we have. And we have used the 91-01 process to help us identify things, and that view, that process has helped us to be more rigorous in our own approach.

CHAIRMAN JACKSON: Let's go on.

MR. FERTEL: I think just the last point which is relevant to maybe the discussion we just had is that all the NRC license performance reviews at the fuel fab facilities over the last couple of years have confirmed the safety of the operations there, and I think that it is an evolving and maturing thing as maybe you do reporting under 91-01.

Clearly, we endorse safety enhancements that are achievable at reasonable cost to the industry and the NRC and which are commensurate with the safety benefits. We don't believe that costly major regulatory changes are required and we have said that since 1996. And we view the new programmatic criteria set forth, primarily in the draft

SRP, as costly and unnecessary. And on that basis alone, we have a problem with supporting going forward with the rule as currently written, if it is supported by that SRP.

CHAIRMAN JACKSON: So it is really the SRP that is the big rub?

MR. FERTEL: That is clearly the eye-opener when we began to look at it, in all honesty, and we talked about this yesterday a bit, that the package is really pretty voluminous. And we have problems with the regulation of purely chemical hazards, which we will talk about a bit, and we think we should have some discussion on, and we have the problems that we carried over on how the ISO -- ISA, I'm sorry. I am thinking of the system operators these days. The ISA, whether it is in the license or not.

But the thing that caught our attention was the imposition of what looked like just a monstrous set of programs that, again, may or may not be appropriate. And that's only a question. We are not saying we would never do those. What we are saying is they shouldn't be just prescriptively imposed.

We believe that our approach -- sorry.

CHAIRMAN JACKSON: Oh, no, no.

MR. FERTEL: We believe that our approach provides the necessary improvements to the regulatory process contained in the staff proposal, at far less cost. We are

concerned that the cost estimates contained in SECY 98-185 substantially underestimate the burden on both industry and the NRC.

Our basis for that concern is the experience of at least one licensee, and keep in mind, there aren't very many in this particular community, where as much as 70 percent of the ISA is completely and where there is actual cost data available. The cost greatly exceeds the regulatory analysis estimate.

We also base our opinion on experience in recent license renewal proceedings in which the staff has prematurely, and maybe inappropriately, applied the guidance set forth in the draft SRP as licensing standards. Aside from our concern with the rulemaking itself, this is a practice which we would strongly disagree with, and one which highlights, in our opinion, the need for a backfit provision, which Tom will talk about in a minute.

What I would like to do now is have Tom Baer talk about some of the specific issues that we had thought we would be raising before you today until we saw the SRP, which sort of changed our tack a little bit, but it is probably the ones that the staff also felt that we and they were in somewhat disagree on coming into this meeting. And I think that while there is that disagreement, those discussions have been constructive, though maybe not

conclusive.

DR. BAER: Good morning, Chairman Jackson, Commissioner McGaffigan, Commissioner Diaz. The first topic I will be discussing is the inclusion of the ISA results in our licenses.

After extensive discussion with the staff, we have not been able to reach agreement on the inclusion of ISA results in the license. The staff believes that the results or output from the ISA process should be physically incorporated into the Part 70 facilities licensees. The draft proposal is not appropriate because it creates an excessive burden in managing extensive information, much of which is commercially sensitive, requires significant administrative support and focuses significant NRC and licensee resources away from safety at the facilities.

CHAIRMAN JACKSON: Let me ask you this, if the ISA were to be docketed, had to be maintained, were used as part of regulatory decisions, tell me where the cost comes in so I can really understand between whether it is in the license or not in the license.

DR. BAER: It is back to what can we change once something is in the license.

CHAIRMAN JACKSON: Okay.

DR. BAER: So if I go to make minor changes in my plant --

CHAIRMAN JACKSON: So it is the change process and how onerous it is if it is in the license.

DR. BAER: It essentially eliminates our ability to make minor modifications to the plant.

CHAIRMAN JACKSON: So let me understand. So the point is really it is the change process for it if it is in the license versus not being in the license. Is that what you are basically --

DR. BAER: That is a major part of it, yes, ma'am.

CHAIRMAN JACKSON: Okay. Okay.

DR. BAER: It is not necessary because the information is available at the plants in the proper context. The information is not necessary for the NRC to exercise enforceable authority.

CHAIRMAN JACKSON: Let me ask you this, if the ISA were available in the plants, but not to the licensing staff, which is here, how would the process work in terms of if there were some need to evaluate it relative to some change in the license or change in the plant?

DR. BAER: We have had several visits from the licensing staff to come to our facility and have looked at the detailed documents we have provided.

CHAIRMAN JACKSON: So you are talking about not docketing it at all.

DR. BAER: Not docketing the entire ISA, but,

certainly, we would consider docketing, certainly, a summary, docketing the results. The summary information would certainly address those items that are safety

significant, but a complete ISA addresses literally thousands of scenarios, many of which are not safety significant.

COMMISSIONER McGAFFIGAN: Could I -- I am just trying to tie down. The staff and the SRP talk -- shows a model license application and the level of detail that they expect encapturing the results of the ISA. And you don't want to do that in the license and have that incorporated in the license. But what they describe in the SRP in the way of results, is that level of detail that you would imagine docketing? Or is that -- is that excessive, what they are asking for in the SRP even to be docketed? I am trying to tie down --

DR. BAER: The level of detail that they ask for in the example is beyond what most licensees had anticipated docketing.

COMMISSIONER McGAFFIGAN: Okay.

MR. ALLEN: I would also add that another part is, in addition to the change process, the commercial sensitivity of some of the information. Each of us runs different processes.

CHAIRMAN JACKSON: I understand.

MR. ALLEN: So what we are down to is writing two versions, one for public consumption and one for the license. And so that becomes an onerous part of the management of it.

MR. FERTEL: Just maybe to add one point, Chairman Jackson. You had mentioned in a change process, how would the licensing staff, if they didn't have it, do things. I don't think anybody envisions not submitting sufficient information on a change that requires NRC approval to the licensing staff, but you would submit the information that was relevant to that change as part of whatever ISA analysis you may have done, et cetera.

CHAIRMAN JACKSON: Now, is there a need, though, to have clarification on that as part of either, if it is not the SRP, the rule itself? Because I do know there is, you know, a historical issue having to do with back and forth requests for additional information. The staff feels it needs certain things. The licensee either doesn't have it or doesn't want to submit it, and that causes a kind of do loop. And so then, you know, either this Commission or a successor Commission could be sitting around hearing complaints about RAIs back and forth.

And so, you know, you try to fix one problem and you end up with another one. And so there really needs, to me, to be some clarification on this issue of how you handle

what is needed to make these kinds of decisions.

I appreciate what you talk about in terms of commercial sensitivity and what may be in the public domain particularly. But I do believe this issue of what information the licensing staff would need, you know, should

the need arise, and how that is to be obtained is a non-trivial issue, because you don't want to -- because you -- and so at the same time I am appreciative of this issue of not having an overly onerous change process. But there has to be some middle ground, you know, somewhere between the two extremes, because the NRC staff does have to have information to do its job.

DR. BAER: Yes. And we recognize that and we want them to have all the information necessary to make good decisions.

MR. ALLEN: And, in fact, have participated in this process where each of our sites has been visited to discuss the content, format and the process for handling ISAs. So we have been very interactive and just would like to extend that to resolve these issues.

MR. VAUGHAN: Chairman Jackson, I just wanted to say that I think you are on a very important point there. And there probably does need to be some clarification. It seems that the NRC needs to relook at what tasks they are giving the licensing people versus what tasks they are

giving their inspection people, because it seems like programmatic approval might come at the licensing stage and then confirmation and confidence is developed through inspection. So I think you hit on a very good point there.

CHAIRMAN JACKSON: Well, that's true except when they are changes to the licenses because of major changes to a facility. And that -- I mean so it is not that the licensing staff acts once and then from then on it is strictly inspection. You know, and I don't know, you all know more about the facilities than, obviously, we do. But at some point, you know, there are issues that do propagate back into licensing space. And so -- and that is really what we are talking about here.

Yes.

COMMISSIONER McGAFFIGAN: I am going to stay on this theme of changes that require our approval. At the moment is it clear in Part 70 what changes at the facilities --

CHAIRMAN JACKSON: Do require.

COMMISSIONER McGAFFIGAN: -- do require our approval? And then, how big a difference would it be compared to the proposed rule, which as I understand it has a 50.59 type provision where we would capture all these results of our ISA, and then if it is more than minimal increase in safety or any new event, you all would have to

come in for a license? I am just trying to understand, whatever the credere are today, how many amendment change requests do we get? And under the new rule, how many change requests are we likely to get?

MR. VAUGHAN: Part 70, now, I don't believe addresses that particular subject, but --

CHAIRMAN JACKSON: Should it?

MR. VAUGHAN: In our licenses, we have sections in our license that address that. The only problem that we see there is the fact that the conditions are not always the same, and maybe they shouldn't be. But I mean there's a variation.

COMMISSIONER DIAZ: We agree with that.

CHAIRMAN JACKSON: Well, but that is the question. I mean if it is license-specific, should it be? And if it shouldn't be, should that be something that is addressed here in terms of how, you know, what triggers?

MR. VAUGHAN: I personally I think you can handle it either way you want to. You sometimes have a little bit more flexibility -- I mean you regulate a number of different licensees, not just us, and so if you look at the larger picture, it might be better off to do it in licenses, because that way you could tailor it to the particular kind of license you are working with. On the other hand, if you want to treat everybody exactly the same, then you write it

into the regulation.

COMMISSIONER McGAFFIGAN: One of the problems we run into reactor space, as you know -- or you probably don't know, is treating everybody exactly the same sometimes gets us into trouble, because we are alleged to be ratcheting people down to the worst performers.

CHAIRMAN JACKSON: Yes, but at the same time, treating everybody not the same also gets us into trouble.

COMMISSIONER McGAFFIGAN: Right. Right.

CHAIRMAN JACKSON: We are alleged to be inconsistent and so that's --

COMMISSIONER McGAFFIGAN: It depends which stakeholder you are listening to at the particular time.

CHAIRMAN JACKSON: It depends on the particular situation.

COMMISSIONER McGAFFIGAN: But, okay, back to my question. You all have license conditions. In the license conditions at the moment, you know when you have to come in for a license amendment. That is fairly clear from the license condition, not the rule, when you have to come in and say this is a change that requires NRC approval, is that correct?

MR. VAUGHAN: We feel like it is, yes.

COMMISSIONER McGAFFIGAN: Okay. How many do you have today and how many do you envision you would have to

have under this 50.59 rule, or like rule that we are building into the new rule? I mean how -- you if you make changes in your facility every year, how many would likely have to come to us under the new rule?

MR. VAUGHAN: I am not sure, because there is not exactly -- it is not like a routine thing, it is just when a change comes up, and sometimes you will have several in one year, and then you may go the better part of a year without anything significant. So it doesn't seem to have a pattern.

But under the new approach, if you go down to the level of requiring the ISA in the license and all of the items relied on for safety in the license and all of that, we, at our facility, process, and I imagine the others are about the same, process about 800 facility change requests a year. So 800 times in a year you are going to have to make this decision about whether you have to come get an amendment or not. And the requirements, as are being proposed, are tight enough that some amount of that 800 are going to have to come to the Commission. So -- and I just can't you how many that is.

COMMISSIONER McGAFFIGAN: But just to get back to the moment, there's 800. I am trying to tie down the changes, 800 a year approximately. At the moment there is some significance test in your license condition and you recognize it when you see it. I mean you don't have an

elaborate process to decide whether each of these 800 changes require an NRC -- whether there is unreviewed safety question that would then require a license amendment with us, but you know it when you see it, so it must be a very small subfraction, a handful per year, zero, it sounds, some years, of the 800 that fit the criterion in your license amendment.

You are saying the new rule will impose a process where you have to look at each 800 document why you didn't -- why it is not an unreviewed safety question and why it doesn't breach this minimal threshold.

MR. VAUGHAN: Right. Right.

COMMISSIONER McGAFFIGAN: And then a much larger fraction, you are judging will have to come to us for prior approval.

MR. VAUGHAN: Right. If my memory serves me right, for example, we have had two such cases that we had to come to licensing in the last year.

COMMISSIONER McGAFFIGAN: Two out of 800, approximately.

MR. VAUGHAN: Yes.

COMMISSIONER McGAFFIGAN: Okay.

MR. ALLEN: But there is a rigorous process. There is a very deliberate process in each of our facilities for managing those process changes. And so there is a

scrutiny of those 800 and it is a documentation process, and it undergoes a formal review. So I don't want to leave you with the thought that there is not that type of scrutiny in our facility.

CHAIRMAN JACKSON: Right. But I am guess what I am trying to understand is the -- are you saying that the way the rule, as it is currently structured, that it would end up causing you to have a more onerous process for, you know, deciding when to come -- whether something has to come to the NRC?

MR. ALLEN: I don't think it would be more onerous

in deciding what to come. I think it would be more decisions to come for a formal license change as opposed to the process.

CHAIRMAN JACKSON: I see. So it is changing a threshold?

MR. ALLEN: That's correct.

CHAIRMAN JACKSON: Okay.

DR. BAER: The draft proposal, we believe does little to improve facility safety, places NRC prescriptive requirements on the licensee, and would require major license -- major amendments to our license by requiring that potential accidents, items relied upon to prevent or mitigate such accidents, and the measures to assure that those items are available and reliable, all to be included

in the license.

We agree that all of this information resulting from the conduct of the ISA process must be retained, used by the licensee to manage the facility, and made available for NRC licensing reviews and inspections.

The proposed requirement to which we object is to include all of this detailed information in our license applications and, ultimately, our licenses. The staff's approach would dramatically expand the description of the plant site, facilities, equipment, processes and controls. Including this level of detail in our licenses is not necessary for the staff to conduct effective inspection and enforcement activities. To our knowledge, the NRC has never required this type of information to cite violations when they are warranted.

Furthermore, it would represent a significant administrative burden for the licensees and the staff, producing little measurable improvement and safety, and diverting finite resources away from safety programs.

Our concerns in this regard are heightened by our initial review of the staff's example of an ISA submittal included in SECY 98-185, which suggests a level of detail beyond what we had anticipated or believe to be appropriate. The Commission should recognize that most of the Part 70 licensees already have committee to performing ISAs and have

those efforts well underway. Substantial rework would be required if the staff's approach was adopted.

The staff's objectives can be achieved without incorporating the detailed ISA results into the licenses. Under NEI's approach, the regulation would require that we include in our licenses, binding commitments to prepare and maintain the ISAs, identify potential accidents, identify the items relied on for safety, and maintain controls to assure that those items are available and reliable. Through these simple license conditions, the NRC would have the ability to inspect and verify that ISAs are properly performed and updated as facility changes are made, items relied on for safety are identified, and appropriate

measures are maintained to ensure the availability and reliability of such items.

Under our approach, the ISA results and documentation would be fully available for NRC staff licensing reviews and inspections. Enforcement action could be taken for non-compliances with the rule, including failure to perform an adequate ISA, failure to make necessary plan or program changes or failure to maintain those changes.

Thus, the benefits of the proposed amendments to Part 70 can be realized if the rule requires the simple license commitments we have proposed. We believe this

approach is moving toward the Commission's risk-informed, performance-based regulations.

Now, turning to the backfit rule. Our next concern involves the application of the backfit provision. In NEI's rulemaking petition, we propose that a backfit provision be included in Part 70 and that it should apply as soon as the other Part 70 rule changes become effective.

The staff has proposed only to consider including such a provision in Part 70 several years from now, after the ISAs are complete, the results are incorporated into our licenses and experience is gained with implementation of the ISA requirement. Under this approach, a wide range of costly new requirements, many of which are set forth in the draft SRP, could be imposed without any site-specific consideration of whether they are needed for compliance or are justifiable on a cost benefit basis.

The staff previously proposed delaying the effectiveness of a backfit provision in another context, the certification of the gaseous diffusion plants under 10 CFR Part 76. We have provided the history of the NRC's decision-making process on that provision on our White Paper on the Part 70 regulation.

We call to your attention to that history because we believe that it clearly shows that the Commission directed the staff to apply Part 76 backfit provision as

soon as Part 76 became effective, but the staff ha not done so. The NRC certification of the gaseous diffusion plants, without the benefit of a backfit rule, has resulted in millions of dollars in plant program and procedure changes at these plants, many of which may not have been justifiable under the backfit rule. That experience strongly suggests to us that inclusion of an immediately effective backfit provision in Part 70 is essential and is consistent with past Commission directives. The addition of the new programmatic criteria beyond the content of the rule clearly demonstrates the need for an operative backfit provision.

The next issue I will discuss --

CHAIRMAN JACKSON: Yes, go ahead.

COMMISSIONER McGAFFIGAN: Could I ask on this, because I am one of the problems for you all on backfit? I

took down fairly carefully something Mr. Fertel said a few minutes ago, that the industry supports safety enhancements achievable at reasonable cost. My problem with the backfit rules is they proliferate in our legislation, Part 76, Part 50, is that that isn't the test. It isn't safety enhancements achievable at a reasonable cost. There is a first -- that is in there, but first you have to have, and I am reading it, a substantial increase. So a small increase for a minimal cost or a trivial cost, under the backfit rule, as I read it in Part 50 or Part 76, even, although you

say it has been waived there, I am not allowed to do that. Small -- because it has to be a substantial increase in safety in order to even consider it.

So I am open to backfit it if it were the Marvin Fertel backfit, supporting safety enhancements achievable at reasonable cost. But the backfit where you start with this test that there has to be a substantial increase, not just a good increase or whatever, that's where -- that's the problem I am having with backfit. Because as I said in my vote, and you know, you have seen my vote on the previous paper, that substantial increase test, at times, I think, prevents us from doing reasonable things at trivial cost. And so, you know, if you are open to the wording of the backfit rule, then you may find a somewhat more responsive Commissioner. But this one you shouldn't blame the staff for because I am at least one of the people who has --

CHAIRMAN JACKSON: Guilty.

COMMISSIONER McGAFFIGAN: -- urged the staff to go in this direction.

[Laughter.]

CHAIRMAN JACKSON: Guilty as charged.

MR. FERTEL: Maybe, Commissioner McGaffigan, we should look at it maybe in three tests. I mean there is clearly the test of, is it a safety enhancement that is required from the standpoint of satisfy either regulatory or

true, you know, risk standpoint? And I don't think there is any question that NRC can impose that and licensees should fulfill their obligation there.

I think then there is sort of the fork in the road that you are going down, which is I am an operator and there are some relatively inexpensive enhancements I can make that get me some good, though not maybe not substantial, safety improvement. I think that operators will do that if they make sense, and it shouldn't be a regulatory imposition. Because, again, we are -- in a reactor space now, we are looking very hard at how should we do assessment of reactors in a way that really builds risk-informed information into it and creates some sort of assessment process where you really do have different areas of regulatory involvement, including some areas of just regulatory oversight and no imposition potentially.

I think that that is, again, where you want to

stay out of areas where, gee, NRC thinks this is a good thing, but it really isn't a substantial increase for the dollars. I think that that is a point where it is beyond the regulatory requirement for protection of public health and safety. It may be something the operator wants to do and should do, and maybe we would find they would do it more often if they didn't think it would become a regulatory requirement.

So I mean I think my advocacy would be to apply the backfit provision systematically, the way the rule says it should be applied, and you may find this sort of gray area in between true regulatory requirements and true backfit requirements being done maybe more at the prerogative of licensees in some cases, or not, but still not diminishing safety. I mean you are still well above the safety threshold from a regulatory standpoint, or a safety margin from a regulatory standpoint. So I guess I would maybe argue that you could get more of what you want if the backfit provision was implemented in a more rigorous way, as currently written in 51.09.

COMMISSIONER McGAFFIGAN: Okay. Well, I think there is more than a semantic issue there, and we can continue the discussion.

CHAIRMAN JACKSON: Why don't we move along?

DR. BAER: The next issue that I will discuss this morning involves the proposed consequence criteria. We are pleased that SECY 98-185 includes criteria which generally agree with those we had proposed in our petition. The ISAs would evaluate potential event sequences against such criteria and identify the items relied on to provide reasonable assurance that such criteria will not be exceeded.

However, the SECY appears to be proposing specific

consequence criteria governing concentrations of various non-radiological chemicals that have nothing to do with the safety of nuclear materials. This suggests to us that licensees could be cited with violations for exceeding purely chemical exposure levels.

As we read the proposed rule, if the established chemical exposure levels are exceeded, a licensee would be required to institute controls to prevent or mitigate those exposures. In fact, the proposed rule will require reporting of purely chemical exposures to the NRC.

While purely chemical exposure levels can be used in the ISA process for determining whether those exposures could affect the safety of license materials, they should not themselves be used as consequence criteria. The proposed rule would establish an unnecessary system of dual regulation between the NRC, EPA and/or OSHA.

CHAIRMAN JACKSON: Well, you know, as you point out here, that NRC and OSHA operate under a MOU.

DR. BAER: Yes.

CHAIRMAN JACKSON: And so I will ask the staff, in terms of their criteria, how that plays off against the MOU and whether, in fact, it has caused a problem. Does OSHA regularly inspect your facilities?

DR. BAER: We, at our facility, have been inspected within the last year by the Tennessee OSHA.

CHAIRMAN JACKSON: Okay.

COMMISSIONER McGAFFIGAN: I might just follow up. You say here in your viewgraph it conflicts with the NRC/OSHA MOU. That isn't as clear to me, as I read the MOU. We are not supposed to -- it says NRC inspectors are not to perform the role of OSHA inspectors. But then it also says that they are going to be trained in order to enhance the ability of NRC personnel to identify safety matters under OSHA per view. OSHA will provide NRC regional personnel with basic chemical and industrial safety training. And then it says that they will -- that NRC/OSHA joint team assessments are going to be carried out. Each agency will make its best efforts to support such assessments at about 20 facilities once every five years.

As I understand it, we obviously do that. OSHA, because of budged constraints, oftentimes doesn't. So what we have here is an awkward situation where we have some responsibility under a MOU. We are not OSHA, but we have some responsibility to identify issues. And OSHA doesn't have the capability to, or the personnel resources to inspect as often. So how much of that should be capture or not capture in our regulatory space in order to be honorable under the MOU is the issue.

So it wasn't -- it isn't as clear to me that it conflicts with the MOU. It may be an effort by staff to

carry out de facto what has been going on under the MOU.

MR. FERTEL: I think that we would appreciate the fact, to some degree, NRC's in-field folks are eyes and ears for OSHA and that is why the training is going on, and that probably makes good sense in this cooperation and avoidance of duplication of effort by federal agencies. That's good.

I think the concern that we have is the way both the rule is written, in this case, as well as the SRP information. It appears that NRC is going to regulate and enforce pure chemical hazard requirements. Not chemical hazards that relate to nuclear materials. We understand that that --

CHAIRMAN JACKSON: Dr. Paperiello is shaking his head no.

MR. FERTEL: I hope he is shaking it that -- he is shaking no, that they don't intend to do that. I would love to be corrected on this.

[Laughter.]

MR. FERTEL: I can't see Carl.

COMMISSIONER DIAZ: But let me understand, in the relative worth of each item, how big is this issue compared

to the ones we have been talking about? I mean is the inspection and reporting of chemical hazards as important to you as what you have been talking about? Or is it a relatively small issue compared to the rest?

CHAIRMAN JACKSON: Do you want us to fix this, but have the ISA in the license?

[Laughter.]

MR. FERTEL: Can I get a few more choices?

[Laughter.]

MR. FERTEL: I want to know all the options before I choose. I think, Commissioner Diaz, let me try and answer this maybe a little bit differently than you posed the question. I think this is almost a no-brainer for the Commission. Because it is outside of the purview, and I would assume that Karen would offer whatever legal opinion she would have on it. But I think that pure chemical hazard is truly outside the purview of the NRC's regulatory requirements, so it ought to be an easy one, not requiring trade-off with some of the others.

And, again, if Carl was shaking his head no, I would love to stand corrected on this and have him say that was not the intent.

CHAIRMAN JACKSON: Not wanting to cut you off, but we have used most of the time, and we will have the panel to hear from.

DR. BAER: I have got a third of page, and then back to Marv for about a page.

Finally, I would like to point out that the proposed rulemaking package contains a number of new

concepts that were not part of previous discussions and not part of the staff's proposed disposition of our rulemaking condition as approved by the Commission. These concepts include, among others, the introduction of design criteria for new Part 70 facilities or for new processes at existing facilities. It requires new reporting requirements and a new provision for the conduct of preliminary ISAs prior to construction of new facilities or processes. These new concepts, among others, warrant careful review before they are included in a proposed rule.

Now, I will turn the floor back over to Mr. Fertel.

MR. FERTEL: The facility operations committee and the facility operators would like to move forward with a rulemaking that would aid in further enhancing both the Part 70 regulatory process and in assurance of adequate public health and safety at the facilities.

SECY 98-185, however, with all of its complexities, does not provide the basis for doing so, nor does it meet all of the guidance in your 1997 SRM. NEI requests that the NRC reconsider our petition and adopt a rule that requires licensees to conduct ISAs using accepted techniques, where I think we do have agreement; requires

licensees to document the results of those ISAs and to make those results available for NRC review and inspection; and

directs licensees to identify and correct vulnerabilities identified through the ISA process; and ensures that controls established those vulnerabilities are maintained.

We continue to believe that this simple approach, coupled with an immediately effective backfit provision, and we will have more discussions with Commissioner McGaffigan, would provide a sound a cost effective basis for further enhancing safety at licensed Part 70 facilities. And the SRP should not be adopted in its present form, nor used on an ad hoc licensing and inspection basis in the interim.

We recognize that the staff proposal does comport with some of the guidance provided by the Commission in the 1997 SRM. In this regard, we ask that the Commission consider issuing new guidance to the staff that reiterates your direction regarding the elimination of new prescriptive programmatic requirements, that addresses the regulation of pure chemical hazards, and that you reconsider your position on the ISA and the license, and the timing and implementation of the backfit provision.

We, again, appreciate the opportunity to appear before you today. We remain committed to working with the staff and the Commission towards resolution of the issues we have raised and we would be pleased to answer any other questions you have.

CHAIRMAN JACKSON: Well, you know, Commissioner

McGaffigan has advertised his position on the backfit issue. I am going to advertise something to you, and this has to do with this issue of documenting or docketing of the ISA and what results are available for NRC review and inspection. I do not believe it is acceptable to try to fix one problem, and this is separate than -- I mean, because I think the issue can be addressed separately or, you know, we can deal with the issue whether the ISAs, the full ISAs need to be a license. But it is not that you solve it by saying, well, we have it hear, and if you want it, come and get it, kind of thing. And so I think you need to think through whether there is some middle ground with respect to this issue of how much information and where it is. Because, again, we don't need to have it be overly onerous for you, but, at the same time, the agency has to be able to have what it needs to have for its decision making. And so I am just saying that is my point of view. Yes.

COMMISSIONER McGAFFIGAN: I would like to ask a question about this preliminary ISA concept. As I understand it, and, obviously, I have only heard about it in the last few weeks myself, this is partly motivated by the potential for some DOE facilities to come under our purview, the tank waste remediation project up at Hanford, the MOX facility if it comes under our regulatory purview, et cetera.

And, indeed, I know in the text of something I have seen, I think a White Paper, you all say that this is not a problem for your facilities. But there is some historical evidence that is a problem for DOE. There's a famous Rocky Flats plant that closed before opening because it was misdesigned from a criticality perspective.

So how -- you know, the problem we have is that Part 70 may be a document that will be used, if it is revised, for both the existing well-established facilities that you all represent and how a framework for dealing with these complex DOE facilities, where some of these criticality issues are going to be much for difficult. And so the preliminary ISA, you know, may force them to think through in DOE space, and their contractors, some issues where there is, as I say, there's at least some historical evidence that DOE didn't do well. How do you respond to that?

MR. FERTEL: Well, again, I think in the regulatory space that you are looking at, Commissioner, what you ought to do is maybe separate the two. For one thing, these licensees have been licensed by NRC for 30 years now probably. And while they didn't have an ISA for all that time, you know, they were licensed. They have all gone through license renewal, one is completing it now, and NRC found fit to find them safe to keep operating.

The ISA, by its nature, is living document. I am not quite sure I even know what a preliminary ISA is, to be completely honest with you, given the living nature of the document. So you would do the best job you can with the best information available, and you would continue to use that document, both at the plants and in regulatory space.

If there's unique aspects of the DOE situation, I guess my encouragement would be write a separate section, even if it is under Part 70, that allows you to make that distinction and impose different sets of steps in the process maybe for DOE facilities coming in. But maybe you can't mix it all together in the same bowl, you know, right now.

MR. ALLEN: I think just to add quickly to this, and it is scary to me because I have seen, within our own facility, the escalation of administering these requirements. But in one of our discussions over the last several days, I heard a number where a process change in a facility was proposed to have several thousand pages of documentation and approximately six man-years' worth of work to be required for that process change, and it now almost four-fold the number of people and ten times the amount of documentation. And that is scary for a process change.

So I think what we are really suggesting is that we need to work together through this so that we don't

create a Rocky Flats similar situation, but we recognize

that the ongoing nature of our facilities, which have been licensed for 30 years, really needs to be taken into account. So I would just echo what Marvin has said and recognize that we want to work through this together.

MR. VAUGHAN: Yeah, a couple of more points on that, if I can. One thing is we have been licensed for 30 years, but up until recently we had to redemonstrate safety at every five year renewal. Now, I know the five years got a little longer, but at a relatively frequent periodic cycle, we had to completely redemonstrate safety for our facilities.

The other thing is our facilities have to operate and operate efficiently and cost effectively, and so, therefore, when we consider modifications or changes to the facility, we have to be satisfied that we are protecting the stockholders and that the mission we are on is one that will proceed successfully. So there are some differences between our segment and DOE, for example.

CHAIRMAN JACKSON: Well, let me make one comment, which actually may sound like it agrees with Commissioner McGaffigan.

[Laughter.]

CHAIRMAN JACKSON: But let me assure you it is purely coincidental. You know, I appreciate what you are

saying about the fact that your facilities have operated 30 years. And that, you know, what we put into place ought to make sense relative to the safety of those facilities.

At the same time, at any given time, the Commission has a responsibility to decide what the baseline needs to be. And so it is not a linear no-threshold model that everything goes to zero. You know, there will be some baseline. It has to be risk-informed, et cetera. So that's number one.

Secondly, and this is where I touch base with what Commissioner McGaffigan talked about within the context of DOE, but let's leave DOE aside. I mean at the moment you have your 30 year old facilities. The real question becomes, you know, one could say, will there never be another fuel facility created or licensed? And what then, in terms of kind of a regulatory framework should exist that allows us to deal effectively and fairly with you, but that doesn't necessary require us to go down a new rulemaking path each time there is potentially a new facility being potentially licensed? And so I think that is the kind of the issue, to me, at the heart of it.

And whether -- and I appreciate what you say, that perhaps for DOE, if we go down that path, there may be a need to have some segregation of some of the kinds of requirements. But there always is this embedded issue of

what kinds of regulatory fabric can be the living regulatory fabric that allows us to accommodate existing facilities, but that doesn't always make us have to create a new rule if

there is a new facility. But I understand the point you are making.

Commissioner Diaz.

COMMISSIONER DIAZ: Just a comment. This is not advertising, there might be another exception.

I am concerned about the fundamentals of what we are talking, and let me see if I understand it. There seems to be agreement on the ISA. Everybody seems to like the ISA. And if that is true, I think the bottom line is make this living ISA a functional document that allows you to manage your plant according to the safety requirements that the Commission imposes. That means some communications, some ability for us to determine that you are carrying out your configuration management with adequate intrusion but not maximum intrusion. And the problem is how we do that.

And I think one of the issues that has been raised is how much you put as part of the license or not. And I think that is what we need to get, you know, real clear feedback from you and from the staff, because I think that is the bottom line.

CHAIRMAN JACKSON: Thank you very much.

MR. FERTEL: Thank you very much.

CHAIRMAN JACKSON: We will now hear from the NRC staff. Mr. Callan, why don't you begin?

MR. CALLAN: Good morning, Chairman, Commissioners. With me at the table this morning are Elizabeth Ten Eyck, who is the Director of the Division of Fuel Cycle Safety and Safeguards; Carl Paperiello, who is the Director of NMSS; and Richard Milstein, the Project Manager for the Part 70 effort.

Elizabeth Ten Eyck will be our primary briefer, but before I turn the discussion over to her, I would like to have Carl Paperiello make a few opening comments.

DR. PAPERIELLO: I want to -- I would like to just talk about the process, and Liz will talk about the rule.

The staff is extremely sensitive to the release of pre-decisional information without explicit Commission direction. So in all our interactions with the industry on the rule, we never gave them text. We came -- we talked about everything and what was in it, but they were never given text. And a lot of the discussions were on the rule and very little on the --

COMMISSIONER McGAFFIGAN: Can I --

CHAIRMAN JACKSON: Let him finish his sentence. Let's go.

DR. PAPERIELLO: It was not on the standard review plan. And I want to step back. Standard review plans,

traditionally, have been not constraints on licensees but constraints on individual reviewers to ensure uniformity of the process. Because we do that, prescriptiveness creeps in, because we are putting the constraints on what the reviewer is allowed to accept to ensure that reviews done by

different reviewers achieve the same result.

It was clear to me when I took over NMSS, where we had very poor standard review plans, that we had to update them, and also they were de facto constraints on the applicants. So I made the decision that in the future all NMSS standard review plans would be issued in draft and we would get public comment on them.

Now, for those standard review plans for which there is not an associated rulemaking, they are old rules and things like that, that is an ongoing process. We have been revising all of these things and getting public input. When we had a standard review plan provided as part of the rulemaking, it still is pre-decisional, and without explicit Commission direction, we have never put these out in the public domain for comment, and that is where we stand right now.

We changed in Part 35, based on the proposal we made to the Commission, everything was done on the web. In the future, since NMSS is now responsible for all its rulemakings, we will probably always propose to you, that is

the way we do, but the situation we have right now, this is the first time this standard review plan went out for, you know, for the review. I guess there's -- well, I am bothered by the bit of an implication that there was bad faith on the part of the staff, and we didn't try to do that.

CHAIRMAN JACKSON: Let him finish that paragraph, then it's all yours.

COMMISSIONER McGAFFIGAN: I am not --

CHAIRMAN JACKSON: Are you done?

DR. PAPERIELLO: Yes.

COMMISSIONER McGAFFIGAN: -- accusing bad faith. What I believe is, though, that we would be better served. I mean I have actually been citing, as Joe Callan knows, to Joe, why can't we -- why can't NRR be more like NMSS in the way we did Part 35, the way the decommissioning guidance was out on the web, even as we were voting on it and giving you final guidance on how to deal with the decommissioning guidance for the decommissioning rule.

And I think that that is a better process. I think it leads to better results. And so if your intention in the future is to use that process, that is fine. I didn't imply -- these gaps occur all the time around here. It happens in reactor space all the time, where we go pre-decisional and we can't talk about it until it is before

the Commission, and we end up having train wrecks. And we would be better off having the documents -- we are not, to my knowledge, we are not having any train wrecks in Part 35 partly because we have --

CHAIRMAN JACKSON: Right. But I think you are both right. Okay. But I think we ought not to spend our time talking about what did or didn't happen. I do not

believe the staff operated in bad faith. You realize that the staff has traditions in terms of how it operates that are based on previous Commissions and how they wanted to do things. If this Commission wants to do things differently, then it has the prerogative to do that and to give the staff that guidance. And so, you know, I think you have a situation where the Commission made a deliberate decision, together with the staff, on Part 35.

Perhaps it should have thought more broadly at that time on other rulemakings. It did not. We are where we are. It is out for public comment, and that is the opportunity to make changes as appropriate, and I think that is where we ought to take it up and not spend more time talking about the process, you know, other than how we might change in on a go forward basis, and talk about the content of the rule. Okay.

MS. EYCK: Thank you. Good morning. We would like to discuss our Part 70 activities included on the

viewgraph and overview. Since members of the Commission have changed since we first started this effort, we would like to provide a small background of how we got to where we are today. We will identify some of the weaknesses in the current Part 70. We will discuss the approach that we have taken in developing this rulemaking package. And we will describe the major elements that are contained in the proposed Part 70.

Next slide, please. I'm sorry, we can -- yes, next slide.

For background, in 1986, a worker was killed at Part 40 license facility based on a chemical hazard, hydrogen fluoride, that resulted from the result of UF6. And in 1991, we had a near criticality accident at a licensed -- a Part 70 licensed facility. And after that, staff and other activities and other organizations started to reexamine the fuel cycle safety program to identify weaknesses with the program.

A review by the House Committee on Government Operations criticized NRC for being a paper tiger, too narrowly focused on radiological hazards and not enough on non-radiological hazards such as chemical and fire. And quoting from their report, they made a comment that said, "The Committee must conclude that deficiencies in NRC's regulatory program for the licensing and inspection of fuel

facilities were also a major contributing factor to the accident." This is the death of the individual at Sequoia Fuels.

"In fact, NRC acknowledges a number of shortcomings in its regulatory program with respect to chemical and other toxic hazards at fuel cycle facilities in its own lessons learned report."

It also stated that, "It is the view of the Committee that NRC must assume regulatory authority over

chemical hazards when they cannot be separated from or could potentially affect licensed radioactive material."

So it was just not the staff that was finding fault with our regulatory program, there were outside entities that also were.

COMMISSIONER McGAFFIGAN: Having come out of the Congress, one of the great things Congress sometimes does is give you report language and no authority, and it can lead you astray. This issue that Mr. Fertel brought up, he believes that the rule that is proposed to us in the chemical area goes beyond our regulatory authority in that it doesn't just deal with those cases where it affects us, but deals with things that are properly in the purview of EPA or OSHA, or their state counterparts. How do you respond to that?

MS. EYCK: Well, I am prepared to discuss that in

greater detail when we talk about the specific elements of the rule. But we have, basically, followed the OSHA MOU as far as focusing on what our responsibilities are. We have expanded to also address potential impact on the public, besides just the worker, and that is a little bit of an expansion, but we feel that, from our responsibilities from protecting the worker and the environment around, that this was appropriate. But we can discuss that in a little bit more detail when we get there, if you would like.

At that time -- and NRC formed a task force to also evaluate its regulatory program and their findings were documented in NUREG-1324, proposed method for regulating major fuel facilities. At that time the staff also initiated a team assessment program to look for weaknesses in the implemented programs at licensed facilities.

However, in November of 1992, the Commission directed the staff to upgrade the regulatory base for assuring the adequacy of licensee performance rather than trying to depend upon inspections to inspect safety into the licensed facility programs.

After a reorganization in 1993 that combined fuel cycle safety and safeguards programs, and Commission approval of an action plan to improve the fuel cycle regulatory program, staff started to rewrite -- or, initially, to revise the regulatory base, and then later,

after Commission approval, to rewrite the regulatory base, because of the conditions of Part 70 and the weaknesses.

COMMISSIONER McGAFFIGAN: NUREG-1324 has been referred to by NEI, and they quote senior Commission officials at the time, as it is a "blue sky" document. What would the ideal be if it weren't constrained by anything? But they said it is not a road map for going forward. And I don't know whether Commissions ever took a point of view on 1324 in a SRM or whatever, but the plain words in 1324, as described by the author, seemed to imply that he or she did it without a lot of constraints.

MS. EYCK: It was a staff effort to review the regulatory program, and they did include a lot of recommendations on how to improve it. Our proposed rulemaking does not endorse all of the proposals that were in NUREG-24. We are just showing that there was a staff effort at the time to identify where there were areas that needed improvement. Upgrading the regulatory base was one. Having some type of a hazards analysis to have a basis for risk was another one. So there were a number of areas -- addressing chemical hazards was another one. So what the staff basically did was look the evaluations of the programs by all the different entities and just came up with recommendations on ways to improve it. But this rulemaking is not a mapping of all of the recommendations that were

contained in that document. It is only a recognition that it was recognized by both NRC and outside entities that improvements were necessary in the fuel cycle safety program.

Basically, we were asked by the Commission to upgrade the regulatory base and we started that effort. Industry was initially opposed to any changes in the regulatory base, and staff then conducted a number of public meetings to try to discuss our proposed approach with them and to explain what we were looking for in both the rule and the standard review plan.

In a Commission meeting in 1996, industry, while not endorsing the staff's proposed approach in Part 70, did support the conduct of an ISA, as they had mentioned earlier here. The Commission at that meeting also encouraged the industry that if they did not support the staff's proposed approach, that they would propose their own program. And in September 1996, as was mentioned earlier, the Nuclear Energy Institute, on behalf of the fuel cycle industry, did submit a petition for rulemaking.

In SECY 97-137, the staff proposed a resolution to that petition. Staff agreed in principle, since it did include the conduct of an ISA with the industry approach, but they did not agree in total and suggested some proposed modifications.

In August of 1997, the Commission approved the staff's proposed approach and directed the staff to proceed with rulemaking, and you now have that rulemaking before you.

Next viewgraph, please. The current Part 70 has a number of weaknesses, and among the more significant if the fact that it is not based on a specific risk-informed approach. Protection against an inadvertent criticality is not specifically required. The primary --

COMMISSIONER McGAFFIGAN: Could I stop you on that point? Because, again, you and NEI just are on -- they say that 70.22(a)(8), and I have looked at it, specifically requires procedures to, quote, "avoid accidental

criticality." I mean what -- so if we have a rule that says you are to, quote, "avoid accidental criticality," why isn't that protection against inadvertent or accidental criticality?

MS. EYCK: Well, we feel that the procedures to avoid it is not as strong a basis as for them to evaluate the risk from all of the areas of criticality and implement procedures to protect against it. And that is what we are looking at, is a risk-informed approach that does protect, or does specifically say that they must protect against criticality.

Where it is included is in just a little -- in the

content of an application that just says that it should address procedures, that criticality should be avoided. We feel that that is an insignificant reference to a safety issue that is as important as nuclear criticality.

Okay. An analysis to identify the hazards such -- of an ISA and the identification of items relied on for safety is not required.

The current two part license format only requires in Part 2, at the time of a license submittal or a renewal, that the operator discuss their safety program. There is no commitment to notify NRC of any changes they would to that program. And over time, the safety basis, or the safety discussion is not representative of the total of the licensee's programs. Just as was mentioned earlier, that they -- when they go through license renewal, they have to come back and totally rejustify, or discuss their safety basis. That is because that it has eroded over time and there is no requirement for them to keep NRC up to date on that. That is why we are proposing that NRC would have that type of a program where we would have a current safety basis.

And we also found in the rule --

COMMISSIONER DIAZ: Excuse me. In Part 70 there is also kind of a weakness in that when you get to time, you know, timely renewal.

MS. EYCK: Timely renewal. Yes, that is an issue. We didn't raise that here, but that is an issue. And the fact that there is no time restraints on the licensee on when they -- except that they have to submit their renewal before the license expires. There is then no timeliness on when all that action has to be completed. So we end up with no sense of urgency on, when we ask them for additional information, to answer questions that were not addressed in their application, for them to respond with anything. So that is a problem. But I think we have got a solution to that in the fact that if we do incorporate the ISA as a safety basis, we have a living license. And so when it comes to license renewal, it is almost a pro forma activity, because we already have in-house their current safety basis. So I think that we have come up with a solution to that, but

it is a problem with our current program.
COMMISSIONER DIAZ: But if there is a significant safety issue, let's just assume, in the in between, what process do we have to address it so it won't linger on?
MS. EYCK: I was going to plan to address that in more detail later on --
COMMISSIONER DIAZ: No, no. Okay.
MS. EYCK: -- the specific elements. If we could wait until just then.
COMMISSIONER DIAZ: Fine. Sure.

MS. EYCK: Okay. And also activities such as QA and maintenance are not required. Now, the industry has addressed the SRP and they say that it includes a number of these programs. It was never our intention to require all of those programs to be applied across the board. The SRP basically says that in items that are relied on for safety, you have to ensure measures to make sure that they are available and reliable. And if one of those measures happens to be something like maintenance, then the reviewer would go to the section that includes criteria for maintenance and what would be an acceptable maintenance program. Is it a preventive maintenance program? What should they look for?
So there is no intent for all of the programs to be in the ISA. The ISA is a guidance document. It doesn't provide -- it doesn't issue requirements or anything. All it does is when the licensee proposes such a program, this is a section that allows them to go and look based on existing guidance or, you know, basic -- what can I say, you were talking about earlier, --
DR. PAPERIELLO: Consensus standards.
MS. EYCK: Consensus standards to what would be viewed as an acceptable program. We can get in more in this. I didn't want to get off --
COMMISSIONER DIAZ: I was going to say, if the ISA

is a guidance document, what should be a part of the license?
MS. EYCK: The SRP is a guidance document. I'm sorry.
COMMISSIONER DIAZ: Oh, I'm sorry.
MS. EYCK: If I said ISA --
COMMISSIONER DIAZ: You said ISA. Okay.
COMMISSIONER McGAFFIGAN: Let me just take the one example that they talked about in their testimony. If you are a license examiner and the QA program is required, the SRP says that ANSI -- this consensus standard, ANSI QA standard is an acceptable way to meet the rule, they said that they don't believe that that is necessarily going to be required for even the high risk items identified in the ISA.
If a reviewer comes -- you know, is reviewing an application and comes across this and they don't want to use ANSI QA and they justify using a lower standard, how much

are we going to grind on whether that different standard is acceptable?

MS. EYCK: Well, the SRP is just one way of meeting our requirements. They can -- they are more than welcome to justify other ways of doing it. And the guidance document doesn't say that they have to have a QA-1 program. I think it says something like that they may refer to in QA-1.

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What is in the SRP would be for a high risk criteria. If it is a lower risk, based on their ISA, then lower requirements would be acceptable in meeting the QA. You know, we are just looking at it. We are trying to give the reviewer some guidance. We are trying to standardize, as Carl has mentioned earlier, the licensing review process, and this document is just guidance as far as what way --things that would be acceptable.

COMMISSIONER McGAFFIGAN: But if I am reading it, and from industry, I know from reading the document that if I come up with this ANSI QA, it is going to be a no-brainer for the staff, they will go on to the next page. If I am trying to justify something else, it is going to take some time and I am going to have to provide some degree of detail to justify it, and he or she is going to ask a bunch of questions on it. And so, de facto, I think what they are worried about is if you say this -- if it is the only way mentioned for a high risk item, --

MS. EYCK: No.

COMMISSIONER McGAFFIGAN: It is not. Okay.

MR. CALLAN: Commissioner, you point is correct, that the SRP in both reactor space and Part 70 space does provide, if you will, the path of least resistance for a licensee, and to deviate from it does usually involve more resources and time. And it does -- we know our processes do

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ensure that the SRP provides a de facto set of expectations as well. And so I think that needs to be said.

MS. EYCK: And it is. Okay. In resolving these NEI petition, the staff recommended that the Commission endorse an approach that the proposed risk-informed rulemaking be based on the performance of an ISA, which is a type of a hazard analysis similar to that developed and used by the chemical industry.

The conduct of an ISA and the identification in the license application of items relied on for safety and measures to ensure their continuous availability and reliability is deemed by the staff to be the foundation of the proposed risk-informed approach.

Licensees will be provided to make changes based on the results of the ISA on their safety program without NRC prior approval. The process would be that they could make those changes if they have already addressed it in the ISA and it doesn't introduce any additional problems, and then periodically, maybe every six months or every -- send

NRC a change page to their summary submittal of the ISA so that NRC would have a current copy of their summary of their ISA.

It is only changes that would be new processes or major changes that would require an amendment to come and actually change the license.

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COMMISSIONER McGAFFIGAN: I am sorry to keep asking, but that, the 50.59 criterion you have in the rule, I am not sure it is only major changes. It is more than minimum changes, right? It is changes, and there's a big -- you know, in my dictionary there is a big gap between minimum and major or significant, and if it is only the significant -- they are saying, one of the people who talked, that at his plant there's 800 changes a year, and zero to 2 or so come before you at the moment under the license conditions that that plant operates under. And the fear is that that under this new rule, with the 50.59 provision, and the word minimal in it, that a far larger percentage of those 800 will come to us, which will consume his resources, and consume resources that perhaps you don't have to then provide approval for the changes. So how do you respond to that?

MS. EYCK: Well, first off, only the changes that we will be interested in are ones that introduce new high or intermediate risks. The graded approaches, we will be focusing only on the higher risk items. They can make all kinds of changes to their process if, through their ISA, it doesn't introduce any of these types of risks, which I will describe in a little bit more detail in a minute. So it isn't all these 800 changes.

First off, if the change doesn't -- is covered by

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the ISA, then they don't have to submit to us. You know, they can make that change and then just submit us a summary change page. If it does introduce some change that they have to change their ISA, that is when they would have to come forth and we would review the change and the impact on their licensing program.

CHAIRMAN GLEIMAN: Mr. Milstein, do you want say something?

MR. MILSTEIN: No, I was just nodding in agreement.

CHAIRMAN JACKSON: Okay.

COMMISSIONER McGAFFIGAN: What number do you expect to receive of changes that would be determined to be above this, you know, the equivalent of an unreviewed safety question threshold and, therefore, would require a change in the ISA which is now, you know, the rule in the basis of the plant and then how long do you -- how many resources do you require to process all of those license amendments?

MS. EYCK: First off, I don't think I am the person to ask what changes they would make in their process that would increase the risk. I think that the industry

would be in a much better position to characterize the various types of changes they make and how these 800 changes, how significant they are.

But I would say that we don't have a whole lot of

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resources in the fuel cycle program, as you understand. So I would expect the very minimal types of changes would come to us to have that type of review. But there are some changes like when they significantly change their process from a wet to a dry, that we would expect to see an amendment.

There's processes where they are doing new type of work, which the licensees are doing now. And we would expect if it a new type of a process that isn't covered by their ISA, that they would come to us for a review.

COMMISSIONER McGAFFIGAN: It strikes me that you may be in violent agreement on what the goal is, in terms of the number of items that you want to be reviewing, and that may already be captured by the license conditions that are in the existing licenses. But there is real fear that the words will -- that are in the rule at the current time may not get the result that you just described.

CHAIRMAN JACKSON: Mr. Milstein.

MR. MILSTEIN: Again, later on you will see the categorization of risk that we are talking about. But many of these risks, many of these changes I think will fall below that threshold. And they won't even come to the threshold of actually having to be considered as affecting the ISA. So I don't -- I really don't know the answer to the question, but I suspect that it may not be -- many of

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them may fall below that threshold and won't even have to be considered at all.

CHAIRMAN JACKSON: Go ahead.

MS. EYCK: Also, a graded risk-informed approach for reporting of events will also be established and requiring particularly the reporting of loss or degradation of items relied on for safety. A qualitative backfit mechanism to enhance regulatory stability would also be considered by the Commission after licensees have conducted and implemented an ISA and have provided NRC with the details of that safety basis to use as a baseline for determining incremental risk in a backfit analysis.

In the case of Part 76 that was mentioned and the industry, and the millions of dollars that have had to be spent on modifying systems, the initial premise was that the DOE orders and rules were comparable to the NRC requirements. And when the backfit provision was implemented, it was with the understanding that we would receive an acceptable safety basis because they had been operating for this long period of time. But, in reality, what happened, we got a safety basis that had a lot of weaknesses. And the corrections that were made in the systems that were upgraded were to come up to DOE

requirements, not that they were required for NRC requirements.

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It's also important to note that in the areas where they didn't have an appropriate safety basis, we had a compliance plan, and they were required to do certain things in that compliance plan to bring their safety basis up to an acceptable level. Those are the things that they did that were not under backfit. Because backfit assumed an adequate safety basis, and they did not have it at the GDPs. And that was why changes were required, not because the staff was not implementing the backfit provisions.

Next slide, please. This viewgraph contains a list of items that are really the major elements that we have included in Part 70 that I would like to discuss in greater detail now.

Next slide, please. An important element in the proposed rulemaking package was the identification of specific consequences against which licensees must provide adequate protection. The consequence criteria are not new, but are based on existing radiological and chemical standards developed previously by NRC, other government agencies and professional societies.

The consequences which are applicable to both workers and members of the public are categories according to their level and severity of consequences in two categories, high and intermediate. Because accidents at fuel facilities could result in human exposure to both

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radiological and chemical hazards, the proposed rule adopted criteria that address both types of consequences. It also codifies the MOU that we established with OSHA to address chemical hazards affecting workers.

Next slide, please.

COMMISSIONER McGAFFIGAN: As you saw, the NEI slide said that this conflicted with the OSHA MOU. I tried to ask whether you were trying to implement the OSHA MOU. I guess your answer is you are trying to implement the OSHA MOU. But the --

MS. EYCK: If you will turn to the next slide.

COMMISSIONER McGAFFIGAN: Okay.

MS. EYCK: If you have the next slide, we can see what our consequences and how they implement the OSHA. The OSHA one is primarily focused on worker protection. And we adopted the standards that deal with the consequence of both workers and members of the public. On the viewgraph, the consequences that are identified as high include accidental exposure to the worker or a member of the public to high levels of radiation and hazardous chemicals. It also includes, as you will see, the occurrence of a nuclear criticality.

The consequences identified as intermediate include accidental exposure of the worker and the members of the public to moderate levels of radiation or chemical

hazards. It also includes environmental contamination. Now, this is one area that -- in our original proposal to you, we didn't include environmental contamination. But as we looked at all of the rules, the requirements that we have to meet for the Part 70 license, the NEPA requirements regarding exposure on contamination were one of the things that we thought was important so we included that and we felt that it would fit in in the intermediate, as an intermediate hazard.

COMMISSIONER McGAFFIGAN: Could I ask, maybe this really goes to the General Counsel, who presumably signed off on this paper. Is there a problem here with us trying to enforce other agencies' authorities through our rulemaking? I know the Congress has recently criticized us the in the case of uranium mill facilities for trying to enforce, at least one committee of Congress, trying to enforce the in-ground aspects, that the state or EPA are supposed to enforce, in our licensing and rulemaking process.

MS. CYR: Well, I think with respect to the chemical hazards, and I think you have -- in the MOU, there are sort of like four categories of hazards that are described there, and it says three of them are clearly ones that are within our scope of what we view as within the -- they are, in a sense, a mixed -- the chemical hazard is, in

a sense, either inextricably linked with the use of the material or it is associated with assurance of safe utilization and use of the material.

For instance, like on the plant conditions, if you had a chemical hazard that would somehow impact your ability to get in and deal with the radiological safety of the plant, that then you could look at the chemical hazard in that context. But strictly chemical hazards that did not, in a sense, have those attributes were not ones that we would be looking at.

And so I think if you read the staff's framework in that context, I think using chemical hazards within those categories of kinds of activities, that's okay.

Again, under NEPA we have obligations, in a sense, to look for the -- look at the impacts of the various activities that we license and try to minimize those impacts in terms of taking into account those impacts in the context we license and look at those hazards.

So, I think, again, there is a basis there to look at and to try to achieve, in a sense, the most environmentally benign process we can in the context of looking at the license and trying to look at alternative ways of dealing with things in the context of licensing. So, again, I think there, again, in terms of how it is tied to the processes that were licenses, we have a basis to get

in and look at those activities.

But if you are looking at, again, just a free-standing requirement that is not driven by a process or a licensing activity that we are looking at, that that might be problematic. But I think --

COMMISSIONER McGAFFIGAN: It strikes me that it sounds like there is a gray area there and the counsels need to talk to each other.

CHAIRMAN JACKSON: Well, the question is whether there could be more clarity of language.

MS. EYCK: And within each category, the radiological and chemical criteria for a given level of severity do not necessarily represent equivalent levels of health effects. However, they do represent current regulatory practice.

Next slide, please. To achieve an acceptable level and to minimize the regulatory burden, the proposed rule revision requires licensees to provide a graded level of protection to sufficiently reduce the likelihood of accidents commensurate with their consequences. Thus, the occurrence of a high consequence event should be highly unlikely, and the occurrence of an intermediate consequence event should be unlikely. The terms are defined in the SRP with criteria for judging the likelihood of potential accidents.

Next slide, please. The proposed rule requires licensees or applicants to perform an ISA. We have defined an ISA as a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, to identify the potential accident sequences and their likelihood and consequences. And, finally, to identify the items that are relied on for safety to protect against the hazards that are identified.

Licensees must demonstrate, based on the performance of an ISA, their ability to provide an adequate level of protection against accidents that could occur at their facilities.

Next slide, please. We agree with NEI that the performance of an ISA to identify items relied on for safety and the implementation of measures to ensure the continuous availability and reliability of these measures are important items towards increasing the confidence in the margin of safety at these facilities.

However, without incorporating the summary of the ISA in the license, and the identification of items relied on for safety, and commitments regarding how they will maintain these items available and reliable, NRC would not have a safety basis for regulatory decisions that would be available for public scrutiny.

CHAIRMAN JACKSON: So let me make sure I heard.

Did you say you were requiring the summary of the ISA?

MS. EYCK: Just a summary of the ISA, not the ISA. Only a summary. And this has been contention between us and

industry -- I shouldn't say contention -- an item of disagreement on what is the appropriate -- what is appropriate to include in the summary. And we have been kind of talking back and forth from each other. So I have asked the staff, and it is a part of this package, to put together what we would consider a summary submittal, and what it would include.

Now, obviously, this is a guidance -- in the guidance area, and it is something that we have a strawman now to talk specifically about whether what industry feels is an over-requirement versus something that, you know, we feel is important to have. So we have something concrete to talk about. You know, I agree that it may not be perfect. But we are working towards trying to get a consensus of what would be appropriate to include in a summary.

Now, the industry has indicated today that what we have included was above their expectations on what they had to provide. So I think we have got, you know, some area to work in there. But we do think that it is important to just have a summary. And here, again, this is only what they would be updating, is our summary. It wouldn't be the entire ISA. They could make changes to their ISA, whatever,

as long as it didn't affect the summary of the accidents and consequences and measures and items relied on for safety.

CHAIRMAN JACKSON: So you are saying you have started down a path to try to resolve this?

MS. EYCK: Well, I have started with the point that we have a draft document that it gives our perspective. We feel that it is a very good document, that when the rule goes out for public comment, people will have something there to review and to give us feedback on whether they think that what we are asking for is appropriate or inappropriate.

CHAIRMAN JACKSON: So you have included it in this package?

MS. EYCK: It is in the rulemaking package, yes.

COMMISSIONER DIAZ: It might not be an easy answer for this, but can we have whatever is needed from the ISA that is in here, call it quote-unquote, docketed, but not part of the license?

MS. EYCK: I think maybe that might be a better question for OGC.

MS. CYR: I don't think you have to have that as part of your license in order to be develop enforceable license conditions. I think there are other ways that you could get at -- it is a matter of approach -- at what seems to be most straightforward or usable between the staff and

the licensee, in terms of how you want to go about having a basis to make sure that those elements of the activities at the site, that you have a way to make sure that they maintain those. I mean and that is -- you may be able to do that through a license condition or it may be without

necessarily having it as a piece --
COMMISSIONER DIAZ: As part of the license.
MS. CYR: As part of the license.
MS. EYCK: We have the answers to come in to our response to questions. They are documented, they are not necessarily a part of the license, but they might be included in the safety analysis report that is written for the licensing activity.
COMMISSIONER DIAZ: Because there is an issue here whether it is part of the license or not, and there is another issue is having the information that is required available. And it might be that we can have whatever information is available and not having it part of the license.
CHAIRMAN JACKSON: What is -- I guess I am trying to understand what the significance is, if you are talking in terms of a summary, of having it as part of the license versus having it docketed. What is the difference?
MS. EYCK: We think, from our perspective, I think one of the reasons is we think that have it a part of the

license is a formal commitment to, particularly, on the identification of items relied on for safety. We have had situations where we have had events and we have gone to the facility and we have said, okay, what are the items that are you are relying on for safety? And they weren't initially able to provide us with the details of what are those items that are relied on for safety.
And then there's other situations where we are trying to develop a risk-informed inspection program. And if we knew and had a commitment to what were the items relied on for safety, then we can focus our inspections on those high risk areas to make sure that the measures are being maintained and the controls are available and reliable. So there's just more of a formal identification and commitment when it is contained in the license.
COMMISSIONER McGAFFIGAN: It just strikes me that what you just said could be achieved through the alternative of having a commitment to having a living ISA but without having it in the license. You will then -- they will have. If they don't have it, like they said, you enforce them for not having it. And if they --
CHAIRMAN JACKSON: I think, though, there is a question of what the NRC needs to have in its hands.
MS. EYCK: Yeah, it is a question also -- I'm sorry -- of the documentation of what is the basis of our

determination of the license -- in the license that we say that they are safe to operate. And that, by incorporating it in the license is their documented safety basis.
CHAIRMAN JACKSON: What about -- is there a way to do it as a docketed -- see, I guess that is a legal issue for me.
MS. CYR: I mean again, NMSS staff has

traditionally written licenses where they incorporate by reference large segments of the applications as part of the license conditions or the license impositions.

NRR doesn't do it that way. I mean they write up SERs, which in a sense is their safety basis for the decision. And then you have a license which consists of technical specifications and a set of very specific license conditions, which take these, for instance, these items that you are relying on for safety and you impose those as tech specs or something that you have to maintain with respect to the license. I mean it has been a difference of an approach. So it is certainly possible to document the basis for your decision and sort of what you have relied and what -- to determining that there is an adequate protection of safety here, without necessarily incorporating all that information into the license itself.

CHAIRMAN JACKSON: You were going to say something?

COMMISSIONER DIAZ: And I will bring Part 65 back. I mean we had a lot of requirements under Part 65, and they do all of this configuration management and process controls, you know, and all of these things. But they are actually, you know, not part of, quote, of the licensing document. They do all of the activities, but they remain part of the licensing activities.

We have the right of inspecting them, but they remain.

CHAIRMAN JACKSON: Can you, if you go to your slide 11, can you -- this is the one you are on, I think.

MS. EYCK: Right.

CHAIRMAN JACKSON: Can you have all of these requirements in the rule? Have the information that you need documented and docketed in some other way, but still be able to get at these three elements without having them in?

MR. CALLAN: Chairman, I think that the -- whether or not we have the information available is separate from the question of whether it is in the license.

CHAIRMAN JACKSON: What form it is in.

MR. CALLAN: Yes.

CHAIRMAN JACKSON: That's right.

MR. CALLAN: We can definitely have it docketed without having it in the license.

CHAIRMAN JACKSON: Right. Okay. Go ahead, Carl.

DR. PAPERIELLO: I don't think we are all that far from the industry on this issue. I mean I think this is one of these things that, within a relatively short time, we can work out something.

CHAIRMAN JACKSON: Well, it sounds to me like what may have happened goes back to what we talked about earlier in terms of to what extent you felt you were free to share everything. But you need to kind of get this one worked out and so it strikes me that, you know, there is a success path

that ought to be possible, but it ought -- you know, without losing these essential elements.

MR. CALLAN: Chairman, there is one point I think Marv made regarding this issue that I'll try to paraphrase. And that is if the ISA is in the license, then it is difficult to keep it a living document, because every change becomes --

CHAIRMAN JACKSON: Becomes a license amendment.

MR. CALLAN: Becomes a license amendment. It is a much more ponderous process.

CHAIRMAN JACKSON: Right.

MR. CALLAN: And I think that is --

CHAIRMAN JACKSON: Well, that's why I asked the question. I mean it seems to me that, you know, another big piece would have to do with changes and how easily one could make those changes.

MR. CALLAN: Right.

CHAIRMAN JACKSON: But I think --

COMMISSIONER McGAFFIGAN: Next viewgraph.

CHAIRMAN JACKSON: Right. All right. Well, no, and the issue is if you treat it -- shudder, shudder, like an FSAR --

[Laughter.]

COMMISSIONER McGAFFIGAN: That's what they are worried about.

CHAIRMAN JACKSON: Well, no, because the FSARs are not -- so, go ahead.

COMMISSIONER McGAFFIGAN: A lazier way of dealing with it.

CHAIRMAN JACKSON: Right.

MS. EYCK: Okay. The ISA by itself will not ensure adequate safety. An effective management system is also needed to ensure that when the items are called on to perform, that they indeed will be able to accomplish their particular role. And this is the issue, one of the issues that the industry had concerns on. We listed some items that would be considered as potential candidates for a management system and activities like maintenance must be provided to ensure that when hardware is used as an engineering control, or an engineered control, that it is available and reliable to perform its function.

Training should be established to ensure that an individual, when they are asked to perform a function as an administrative control, and this happens quite often at our fuel facilities, are appropriately trained and understand the function that they are supposed to -- the safety function that they are supposed to perform. So that is why we have included these items in the ISA -- I mean in the SRP, it is to give guidance to the licensee -- to the reviewer and the licensee on things that could be included, whether it is a human factors issue that maybe an individual could take an action that could complicate a accident or

make it worse from a risk perspective. There could be maintenance configuration management control, there's a long list of them. But they are certainly requirements that we are putting on all of their programs.

It is only on these controls and they will be graded based on the fact, whether they are providing protection against a right risk accident or an intermediate accident. So that is how -- that was our proposal and how we propose to use the information that is in the standard review plan.

COMMISSIONER McGAFFIGAN: The other thing that comes to mind from the previous discussion, the systematic approach to training requirement that's in the SRP for high-risk, again, you heard industry differ with that, but

that is the de facto approach that's in the SRP at the moment.

I'm partly afraid, in all honesty, as I see this, that you all are taking stuff from reactor space where we have, you know, systematic approaches to training and all that, and these facilities may not need just as much because the risks are so much lower than for the reactors.

But there's an awful lot of verbiage that is familiar as you look at this, and it's coming over from reactor space into material space, and we need to think about whether we need it all in the SRP, I think.

MS. EYCK: Okay. Well, we, as I say, just provided it there to -- basically what's there is to address the high-risk items with the thought that it would be graded for lesser risk, and to -- if there was a single human administrative control that's going to protect against some high-risk item, we wanted to make sure that we had guidance on what would be an acceptable training for that individual to ensure that they properly performed their safety function.

CHAIRMAN JACKSON: It seems that the nub is in what the gradation is. I mean, that's how you really address the issue as to whether the requirements are as onerous as they might be in a reactor situation or not, and if they're not, but it's graded appropriately, then that in

principle should address the issue.

MS. EYCK: Okay. Next slide, and this deals with the issue of changes that can be made without NRC prior approval --

CHAIRMAN JACKSON: Has minimal been defined?

[Laughter.]

MS. EYCK: Well, we know that it's greater than negligible but less than significant.

COMMISSIONER DIAZ: There you go. There you go. You've been doing your homework.

CHAIRMAN JACKSON: Or at least you're turning into a politician.

[Laughter.]

MS. EYCK: And also, we feel that it's important that the change not create a possibility for an accident different than those previously evaluated in the ISA, and that is another important criteria for us.

Okay. Next slide.

The proposed rule also includes a risk-informed graded approach for licensee reporting of events. Now, reporting deviations from the safe operating conditions involving nuclear criticality was covered by bulletin 91-01, and that has been incorporated in the rule.

But the proposed rule also requires the reporting when all items relied on for safety are no longer

operational or are degraded so that they cannot perform their intended function. And the time frame for reporting of such events are based on consideration of consequences of concern. So it's a graded reporting of events and also the timeliness for reporting of such events.

Next slide, please.

The proposed rule also contains two provisions specifically addressing new facilities and new processes. This was also discussed earlier. And based on staff experience providing support to DOE in their development of a remediation system to process the waste from the Hanford tanks, the staff has realized that it's very important to have new baseline design criteria to be considered initially at the beginning of the design, and it's also for new facilities or for a totally new process at an existing facility.

These baseline design criteria ensure that certain design principles are followed in the initial design, and applicants or licensees would use these criteria, and -- unless the preliminary ISA submitted to NRC prior to construction demonstrates that a given item is not needed or to be relied on for safety.

Now, we get into the preliminary ISA, and basically what this is is that it's no different than what's done in the chemical industry. They use their hazards

analysis through the entire process, through design and implementation. We felt that it's prudent management practice for the design of a -- for a new design for them to think through the risks that would be associated with that activity rather than getting to the point where they're ready to construct or they come in or a license and then it's a question of having to go back and incorporate the considerations of risks and the hazards from nuclear criticality and chemical and fire into their design.

That's why we felt that it was appropriate to have an initial preliminary ISA done, and then as they go through and finish their design, build their facilities and everything, then they will be finalized --

CHAIRMAN JACKSON: Would licensees be able to begin construction of a new facility at their risk before

the --
MS. EYCK: Oh, sure. We're not --
CHAIRMAN JACKSON: -- preliminary ISA --
MS. EYCK: All we're saying is that if they gave us their preliminary ISA, we could re-review it and we can see that if we feel that they've addressed all the potential risks, based on our experience --
CHAIRMAN JACKSON: But they can begin the construction, and if later --
MS. EYCK: No problem. We don't approve it.

We're just going to review it.
CHAIRMAN JACKSON: Okay.
MS. EYCK: Okay. Next slide, please.
Okay. Well, basically in summary, the staff feels that our draft proposed rulemaking is responsive to Commission direction. We have added a couple things that we feel are important as we have developed the rule based on our experience from other activities. It is risk-informed and its implementation will provide increased confidence in the margin of safety at operating facilities.
Since 1995, as was mentioned earlier, staff has been working closely with industry during the development of this rulemaking process, and although staff and industry have not agreed on every facet of the proposed rulemaking, we feel that our views have been converging, and I think that it's important to make the distinction here between the rule and the standard review plan. I don't think that we have heard any specific differences with what's included in the specific rule; it's questions with the SRP and the guidance to the reviewer.
But basically, as Carl mentioned, we hadn't been able to share our documents with him because of the fact that we were operating under a little different rulemaking process than was used in Part 35.
In closing, I would just like to remind the

Commission that we have been working on this rulemaking process for a long time, and that we would encourage the Commission to support our publishing the proposed rulemaking package for public comment.
Thank you.
CHAIRMAN JACKSON: Thank you.
Commissioner Diaz?
COMMISSIONER DIAZ: Yes. Just one comment or one question that we asked before. In the issue of a license renewal for this facility's licensed continuation, how will an ISA that is docketed play into solving the issues that you presently have?
MS. EYCK: I think that if we have a docketed ISA that represents the program --
COMMISSIONER DIAZ: Docketed doesn't mean the license, now.
MS. EYCK: Right. Oh, I understand that. But at

least NRC has something that represents the safety basis that represents the current operation. What we're in a situation now is that we get at the time of licensing a discussion of the safety program. The licensees are free to make changes to that program, and so what happens when it comes to the time of renewal, just as it was mentioned, we almost have -- we have to reconstruct the safety basis because it has changed so much over time.

So I think that if we did have the process where they did keep it up to date and it was docketed or whatever mechanism that's worked out so that we did have something to have a current basis, that the licensing renewal would be a pro forma activity because we wouldn't have to spend the enormous amount of time, both our time and the industry's time now, on trying to reconstruct this safety basis.

COMMISSIONER DIAZ: Okay. Thank you.

CHAIRMAN JACKSON: Commissioner?

COMMISSIONER McGAFFIGAN: I think you may be a little more optimistic than warranted about the lack of difference on rule language. You know, a lot of the things that they are raising issues about, the chemical concentration level, et cetera, are in rule language, the requirement that the license -- that the ISA be in the license et cetera. So I think there are very significant differences still remaining between you and the industry on rule language as well as obviously the SRP.

CHAIRMAN JACKSON: Well, I want to thank each presenter for providing us with very useful information in terms of the Commission's decisionmaking. I want to remind everybody that what's being proposed is for the rule to go out for public comment, which means it's not final, and so the Commission has to make a decision about that, presumably together with having the SRP also be available and have

there be some continued work on it.

So unless there is any further comment, we're adjourned.

[Whereupon, at 12:14 p.m., the public meeting was concluded.]