#### PRESENTATION BY

## NUCLEAR ENERGY INSTITUTE FACILITY OPERATIONS COMMITTEE

#### **BEFORE**

THE U.S. NUCLEAR REGULATORY COMMISSION

June 20, 2000

Good morning Chairman Meserve, Commissioner McGaffigan, Commissioner Dicus, Commissioner Merrifield, and Commissioner Diaz. I am Marvin Fertel of the Nuclear Energy Institute and I am pleased to be here today to represent not only NEI, but all of the major material licensees that operate facilities licensed under 10 CFR Part 70. With me at the table this morning are Mr. Jack Allen of Westinghouse and Mr. Dave Dowker of Global Nuclear Fuel. I would also like to point out that there are representatives from the balance of the fuel fabricators and USEC present today.

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 rulemaking to amend 10 CFR Part 70.

As you are aware, we along with other stakeholders have been working for several years 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's health and safety without imposing unnecessary burdens on industry or the NRC. We plan to present to you today a sense of the significant progress that has been

made in finalizing the Part 70 Rule and to identify those very few, but important issues where additional Commission guidance would be helpful.

Based on our review of SECY 00-0111 we conclude that: (1) the proposed rule captures the important issues for moving further into a risk-informed, performance-based approach than the current Part 70; and (2) the rulemaking package -- particularly the draft Standard Review Plan -- is a significant improvement from the ad hoc reviews the staff has conducted in the past.

There are only three areas in the proposed rule where we would like the Commission to provide some guidance and there are two chapters of the Standard Review Plan where we are committed to continue working with the NRC Staff to clarify intent, or resolve issues, prior to finalization of the SRP.

The items in the rule include: (1) the added provision for approval of the ISA Summary; (2) the new requirement for quarterly

notices for changes to items relied on for safety; and (3) the effective date for implementation of the backfit provision. I will discuss these in detail shortly.

Great strides have also been made on the Standard Review Plan. Of the eleven chapters, there are only two that the NRC Staff and we are still working on to resolve outstanding issues. These are Chapter 3, which provides the criteria for the implementation of the ISA, and Chapter 11 which addresses the new management measures for the items relied on for safety. It is understandable that these two chapters would require more work than the balance of the chapters as they reflect the bulk of the new requirements in the rule. These two chapters address areas that have been conceptualized for a number of years; however, when the concepts are put on paper, the meanings and interpretations of the words need to be understood by all parties and be consistent with the requirements embodied in the rule. I will provide additional details on the activities in this area in a few minutes.

Turning to the proposed rule, as mentioned earlier, the first issue where we would like Commission input is the new provision requiring NRC approval of the ISA Summary (70.62(c)(3)(ii)). Throughout previous discussions with the Staff, we understand the purpose of the ISA Summary is to demonstrate that the applicant or licensee is effectively carrying out the regulatory requirement for the completion of ISA. We do not believe that approval of the ISA Summary is meaningful. The ISA integrates the safety programs for radiation protection, criticality safety, chemical safety, fire safety, emergency management, environmental protection and management measures to assure the safety of the workers as well as the public and the environment. It is the ISA that demonstrates that the performance requirements of 70.61 are met. The ISA Summary is the executive summary of the ISA. It provides the key attributes and the findings and aids the Staff in making its determination that the licensee is meeting the intent of the regulations without requiring the Staff to perform a detailed review of the ISA. Both the comprehensive

ISA, which is available at the facility and the ISA Summary, which is submitted to the NRC would support a licensee's request for a license amendment or a license renewal proceeding. Approval of the license application, amendment, or renewal request would defacto codify that the ISA has been completed within the intent of the regulations, and that the ISA Summary reflects the key attributes of the ISA. But the approval being granted or denied by the NRC applies to the license application, amendment or renewal, not to the ISA Summary. In our opinion there is no reason or benefit for a separate approval of the ISA Summary. The separate approval would not provide any additional level or margin of safety, and no benefit to the NRC or the licensee. The requirement however, places an additional burden on the licensee and the NRC Staff, as it would require additional formal licensing actions with no offsetting benefit. Finally, 70.65(b) states that the ISA Summary must be submitted with the license or renewal application but shall not be incorporated into the license. Therefore, there is no regulatory reason for NRC approval of the ISA Summary.

Accordingly, the industry recommends that the words "for NRC approval" be deleted from 70.62 (c)(3)(ii).

The second area we would like the Commission to change the proposed rule is the requirement to provide quarterly updates to the NRC for changes in the items relied on for safety (70.72 (d)(1)). This requirement appears to be an outgrowth of a previously proposed requirement to provide the NRC with 90-day updates for all changes of the facility that do not require licensing action. The Commission directed the staff in the SRM to SECY 98-185 to justify why 90-day updates were necessary. The proposed rule response is to split the requirement, such that changes that neither require licensing action nor affect items relied on for safety, be updated on an annual basis while changes that do not require licensing action, but do impact items relied on for safety, be provided to the NRC on a quarterly basis. The justification for the quarterly update requirement is that the Staff equates the items relied on for safety with the technical specifications from Part 50. First, as the Commission knows, Part 50

licensees cannot change technical specifications without NRC approval. Secondly, we believe the Part 70 items relied on for safety are more analogous to the Q list items in Part 50 as opposed to limiting conditions of operations and other characteristics embodied in Tech Specs. Part 50 licensees can change Q list items in the facility without NRC approval and the notification requirement is eighteen months to two years. We completely agree with the concept that if actions require prior NRC approval, that approval should be obtained prior to taking the action. However, if the change control process embodied in 70.72 allows the licensee to make changes without prior NRC approval, reporting of those changes to the NRC, should be done annually regardless of what the change involved. It is also not clear what the NRC will do with the information if it were reported quarterly. Other than the Technical Specification discussion, the SECY failed to justify why this information is needed on a quarterly basis. The industry recommends that 70.72 (d)(1) be removed from the rule and reliance be placed on provision 70.72(d)(3), the annual update, to gather this information.

The final rule item I would like to discuss is the "Backfit Provision" in 70.76. We are happy that the Staff has taken the wishes of the Commission and the industry into consideration and included the backfit provision. This demonstrates significant progress in making the proposed rule risk-informed and performance-based. As you are aware, the backfit provision is an aid in assuring that changes in regulation, staff positions, and/or facility modifications provide improvements in safety, rather than adding unnecessary burden or possibly even detracting from safety. Since this is the case, we question why the proposed rule has deferred the implementation for four years or more. As proposed, 70.76 does not apply to Subpart H requirements until the licensee has an NRC approved ISA Summary. The rule provides for up to four years to submit the ISA Summary, and in the meantime changes in the regulation, interpretation of regulations, NRC staff positions, or modifications to the facility are not subject to this provision. During this time period, both NRC and the industry lose the use of a valuable process to aid in evaluating these

changes with respect to risk and burden. We believe the Staff already has a sound safety basis for the facilities against which to judge the significance of a change. This basis is firmly embodied in the facility's current license, which has undergone numerous renewals in the past 20 to 30 years. In this time, NRC Staff has gained a good understanding of the basis of safety in each facility. The Staff has indicated that the ISA and ISA Summary provide a more definitive safety basis. The Staff's interpretation implies that the safety basis is the ISA. The ISA and ISA Summary are to demonstrate that the facility is carrying out the safety programs in accord with license commitments. Therefore, completion of the ISA is no reason for the delay in implementation of the backfit provision.

The Staff has also argued that if they do not have this leverage they will not be able to require licensees to make improvements that are identified through the ISA. This argument is not consistent with the proposed rule. Under the proposed rule, the facility must meet the performance requirements of 70.61 in order to receive approval of

its license, license amendment or renewal application in accordance with 70.66. If it does not meet these requirements, the facility is not meeting the regulations and will not be licensed. Therefore, it is incumbent on the facility to assure that all of its operations are in accordance with the regulation. The Staff does not need any additional leverage to require the facility to comply with the regulation. If the facility meets 70.61 criteria, there is no need for additional levels of safety and the Staff does not need to require changes or modifications in the facility. Additionally, Part 70.76 (a)(4) assures that the Staff has the authority to require changes to bring a facility into compliance with the regulation. The industry, therefore, recommends that 70.76 (a) be revised to become effective concurrent with the proposed rule.

The industry is also concerned that 70.76 does not include the qualifier that changes in safety must be "substantial" as used in Part 76.76. Without a qualifier, the use of the backfit provision becomes insignificant and has little value. There have been a number of concerns raised as to what "substantial" means, but there is a greater

concern if the changes are not qualified at all. Therefore, the industry recommends that 70.76 (a)(3) be modified to include "substantial" when discussing increases in the level of protection.

I shall now discuss the two Standard Review Plan areas where we are still working with the NRC Staff. As discussed earlier, we have not reached complete agreement on provisions contained in chapters 3 and 11. We have come a long way working with the Staff to address issues in the other nine chapters of the SRP and believe that we can resolve the issues with these remaining two chapters. The areas of discussion in both chapters deal with the level of detail to be provided.

Chapter 3 addresses the ISA program. It has three parts. The first part is a commitment in the license to perform the ISA within specific requirements. The second part is the performance of the ISA and retention of relevant information at the plant site. The third part is the completion and submittal of an ISA Summary document. The industry and the Staff are in full agreement with parts one and two.

On part three, the industry and the Staff are in full agreement with what is to be summarized in the ISA Summary. The SRP provides the Staff with criteria for what is to be provided and the level of detail for information presented in the ISA Summary. The industry and Staff have agreed that NEI will prepare an industry guidance document depicting the type of information and the level of detail that should be provided in the ISA Summary. The industry met with the Staff on June 8 and discussed the latest draft of the guidance document. As a result of the meeting we are in the process of making a number of changes suggested by the Staff. We believe we will be able to complete the guidance document in a manner that is acceptable to the Staff and the industry before the end of the summer. As such, this document would be a means of addressing the interpretation of the SRP for the ISA Summary. Therefore, we recommend when the rule is published the supporting documentation endorse the industry guidance document.

We also continue to work on achieving a congruent understanding of what is being required by the relatively prescriptive detail in Chapter 11, "Management Measures." The industry and Staff have agreement on the basic requirements for having the areas included under management measures and a fundamental understanding of the elements that make up each management measure. The industry has no concerns with committing to elements of: Configuration Management, Maintenance, Training, Procedures, Audits and Assessments, Incident Investigations, Records Management, and Other Elements of Assurance that are not captured in the above. The unresolved question is what level of detail needs to be contained as the license commitment. The Staff and industry agree that not all measures may be needed or appropriate, and that the measures can be implemented using a graded approach. However, the SRP today does not reflect this understanding. The Staff has indicated that they would be willing to provide some introductory language in the chapter to capture this intent. The SRP also establishes the expectation that the applicant will provide

In the most recent workshop, on this issue, the Staff indicated that this is not the case, and that they would consider revisions to Chapter 11 to clarify that detailed element descriptions are not required. As you can see we still have some work to complete on Chapter 11. We believe the Staff is fully committed to completing this work over the next few months. Given the importance of Chapter 11, we recommend the Commission be satisfied that the issues related to Chapter 11 are resolved before the rule becomes effective.

In conclusion, the industry believes the proposed rule would improve the regulatory process with minor modification that would: (1) eliminate the requirement for approval of the ISA Summary; (2) modify the reporting requirements for non-licensing actions for items relied on for safety to an annual frequency; and (3) make the backfit provision immediately effective including a substantial determination. When the rule is published it should include an endorsement of the industry guidance document for preparing an ISA Summary, and

revisions to SRP Chapter 11 to reflect a clear understanding of the intent of the NRC.

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 questions that you may have.

# Nuclear Energy Institute Facility Operations Committee Presentation

Part 70 Rulemaking

SECY 00-0111

June 20, 2000



# Commission Guidance Required

#### Rule

- 70.62 (c)(3)(ii) NRC Approval of ISA Summary
- 70.72(d)(1) Quarterly notices on Items Relied on For Safety changes that do not require licensing action
- 70.76 Delay in implementation of Backfit provision without "substantial" determination



## **SRP Still Being Worked**

- Standard Review Plan
  - Chapter 3 detail in ISA Summary
  - Chapter 11 detail in Management Measure elements



### 70.62(c)(3)(ii)

- NRC Approval of ISA Summary
  - ISA Summary is executive summary of ISA
  - Provides key attributes and findings of ISA
  - Supports licensing action,
  - Approval of licensing action approves ISA
  - Formal process with no offsetting regulatory benefit, no improvement in safety, additional burden
  - Recommend "NRC approval" be removed



### 70.72(d)(1)

- Quarterly updates for changes to items relied on for safety with no licensing action
  - Prior approval must be obtained for licensing action
  - IROFS equal to Q list items, not Technical specifications
  - Recommend that information be provided annually



#### 70.76

- Backfit Provision
  - Deferred implementation until ISA Summary approved
  - Does not include "substantial" determination
  - No need for delay safety basis exists
  - Loss of tool to NRC and industry
  - Recommend it is immediately effective and that a "substantial" determination be included



#### **Chapter 3**

- Level of detail in ISA Summary
  - Industry guidance to be completed by end of summer
  - Publish rule include an endorsement of guidance



#### Chapter 11

- Level of detail in elements of management measures
  - Work ongoing
  - Changes expected
  - Rule effective when revisions are complete



#### Conclusion

- 70.62(c)(3)(ii) delete NRC approval of ISA Summary
- 70.62(d)(1) revise IROFS notification to annual
- 70.76 make backfit immediately effective and add substantial determination
- Chapter 3 NRC endorsement of Industry Guidance
- Chapter 11 rule effective with revised Chapter wording



# Final Rule for Domestic Licensing of Special Nuclear Material (Part 70)



COMMISSION BRIEFING June 20, 2000

DIVISION OF FUEL CYCLE SAFETY AND SAFEGUARDS
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

#### **Briefing Overview**

- Rule Attributes
- Background
- SRM Direction
- Major Rule Issues
- Standard Review Plan
- Future Staff Actions
- Staff Recommendation

#### Rule Attributes

Like Informed and Performance Based

- Consistent with Performance Goals
  - Maintain safety
  - Increase public confidence
  - Increase effectiveness...
  - Reduce unnecessary regulatory burden

#### Background



- Operating Experience
- Staff initiatives
- Petition for rulemaking (1996)

#### **SRM Direction**

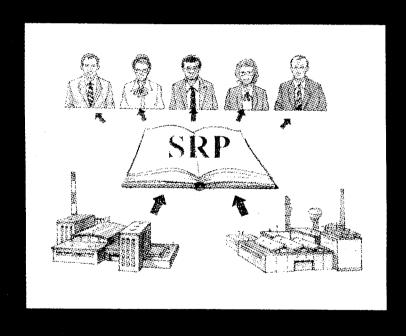
July 8, 1999 SRM

- Backfit
- Reporting in the large updates
- Definition of unlikely and promptly
- Alternative approaches to those in SRP
- Use of public workshops / web

#### Major Rule Issues

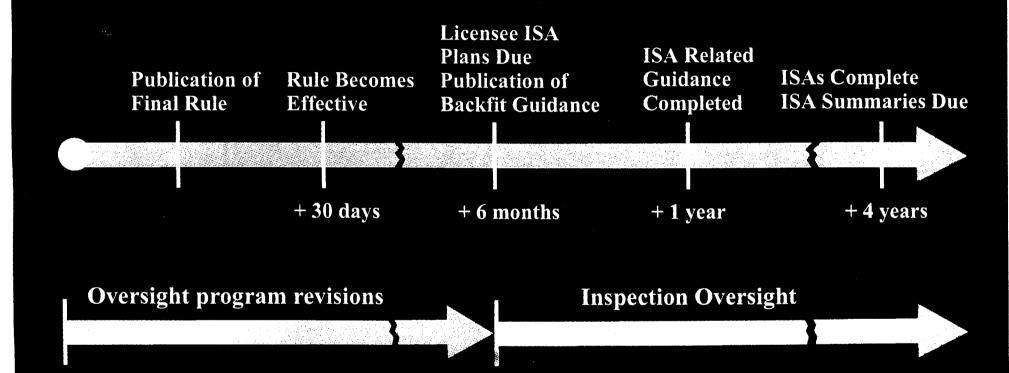
- Backfit
- Reporting frequency for ISA Summary updates
- Level of detail in ISA Summary
- Failure log for items relied on for safety
- Time period for completing ISA

#### Standard Review Plan



- General support from stakeholders participants
- Few remaining issues
  - ISA Summary detail
  - ISA methodologies
  - Management measures

#### **Future Actions**



#### **Staff Recommendation**

Commission approve final rule