

April 16, 1996

FOR: The Commissioners
 FROM: James M. Taylor /s/
 Executive Director for Operations
 SUBJECT: ALTERNATIVES FOR REGULATING FUEL CYCLE FACILITIES

- PURPOSE:
- SUMMARY:
- BACKGROUND:
- DISCUSSION:
- ISA WORKSHOP:
- NEXT STEPS:
- COORDINATION:

PURPOSE:

To solicit Commission direction regarding the alternative to be pursued in regulating the safety of fuel cycle facilities.

SUMMARY:

In the staff requirements memorandum (SRM) dated January 15, 1993, the Commission directed the staff to upgrade and more clearly define the regulatory base for major fuel cycle licensees. In March 1995 the Commission directed the staff to reconsider the plan to modify 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and to discuss with major fuel cycle licensees the draft proposed rule that was being developed. Workshops were conducted in May and November 1995 to solicit comments and information from interested parties. Based on this input, six alternatives for Commission consideration have been developed. Commission direction on how staff should proceed is requested.

BACKGROUND:

After the potential criticality incident that occurred at the General Electric (GE **EXIT**) Nuclear Fuel and Component Manufacturing facility on May 29, 1991, the U.S. Nuclear Regulatory Commission recognized possible generic weaknesses in its materials programs. A task force was formed to review how NRC regulated these licensees. The task force findings and recommendations for correcting deficiencies in the regulations and in the licensing and inspection programs are documented in NUREG-1324, "Proposed Method for Regulating Major Materials Licensees," dated February 1992. These recommendations identified a number of weaknesses in areas such as quality assurance, maintenance, training and qualification, management controls and oversight, configuration management, criticality safety, and fire protection.

The staff developed an action plan (SECY-92-337) that responded to the recommendations of NUREG-1324. Significant activities of this action plan included revising the approach for conducting safety team assessments, developing technical bases for revising quality assurance provisions, reporting the loss of criticality safety controls, requiring a hazards analysis (integrated safety analysis) as a licensing basis, updating guidance documents, and improving training for NRC license reviewers and inspectors. The regulatory base for some of these activities was not explicit. Consequently, the Commission directed the staff to first upgrade and more clearly define the regulatory base (January 15, 1993, SRM).

A short time later, management of the fuel cycle safety program was changed to focus more attention on fuel cycle safety issues. A new action plan (SECY-93-128) was developed that focused on improving the regulatory base, by revising 10 CFR Part 70, and concurrently developing a standard review plan (SRP) for reviewing fuel cycle license applications, revising the standard format and content guide (SF&CG), and developing a guidance document for licensees' use in performing integrated safety analyses (ISAs). The Commission commended the integrated approach to regulatory development and licensing for fuel facilities and reemphasized the critical importance of establishing a firm regulatory base (June 7, 1993, SRM).

After initiating revisions to Part 70, the staff noted that this approach would place another "patch" on the regulation, which had already been modified so many times since its initial issuance in the 1960s that it is difficult to administer. Therefore, in SECY-94-057A, the staff proposed to completely rewrite Part 70, and in SECY-94-288, the staff committed to submit a draft rulemaking package to the Commission by June 1995.

Following a Commission meeting on the status of completing the action plan in March 1995, the Commission directed the staff to reconsider the current plan to modify Part 70 and to discuss the proposal with major fuel cycle licensees to determine their position with respect to revising the regulation (March 28, 1995, SRM).

The preliminary draft rulemaking package was provided to industry prior to a May 1995 workshop, without the customary statement of consideration to explain the proposed changes. The package contained the draft rewrite of Part 70, with supporting draft SRP, SF&CG, and regulatory analysis, all of which were developed in parallel. Because of time constraints, these documents had not undergone a planned two-month period of refinement before the scheduled submittal to the Commission in June 1995. Discussions of these documents at this workshop identified a number of specific concerns of industry and some misunderstandings between the NRC staff and industry regarding the intent of the rulemaking.

In SECY-95-151, the staff reported on the activities of the May 1995 workshop and proposed that NRC continue the open dialogue with fuel cycle licensees and other interested parties to develop a better understanding of the need for and objectives of the proposed rulemaking and to gather applicable information. The rulemaking activity to rewrite Part 70 and to develop companion guidance documents was placed on hold pending the outcome of this further dialogue with affected parties, as directed in the SRM of June 29, 1995.

Another workshop was held with industry and other interested parties in November 1995 to discuss improving NRC's regulation of fuel cycle facilities (SECY-96-007). Some industry representatives suggested alternative approaches to upgrading the current regulatory base, rather than proceeding with a revised regulation. A "bottom-up" approach was suggested, which involves developing appropriate guidance documents first, like the ISA, SRP, and SF&CG. Then, if necessary, the current regulation would be modified to conform with the guidance documents. One licensee suggested revising one section of the current regulation to include a performance-based regulatory requirement to

perform "a reasonable scope ISA," and to implement safety and support programs to assure that important safety equipment and facilities will perform their intended function when needed. An analysis of the comments from the November 1995 workshop on improving NRC's regulation of fuel cycle facilities is presented in [Attachment 1](#).

During this time, the staff gained invaluable experience in working towards an ISA risk-based approach during the renewal of the Westinghouse Electric Corporation's license in November 1995. Westinghouse's perspective regarding the use of their license renewal process as an industry "model" is contained in [Attachment 2](#). In addition, the views of GE Nuclear Energy concerning NRC staff's proposed March 1995 rulemaking package are expressed in its March 26, 1996, letter to the Chairman ([Attachment 3](#)).

During the development of the draft proposed rule, staff coordinated with DOE [EXIT](#) representatives responsible for upgrading DOE nuclear safety requirements. The staff briefed DOE in detail concerning the proposed risk-based approach and specifically how it could be implemented at NRC facilities. This coordination and the information in the March 1995 draft proposed rule and guidance package assisted DOE in adopting the new performance-based approach, which embodies grading requirements according to risk. In addition, DOE is using this approach in responding to internal strategic planning initiatives and in responding to recommendations of internal and external oversight and review groups, such as the Defense Nuclear Safety Board.

DISCUSSION:

In general, industry is opposed to revising Part 70. Many industry participants expressed the view that a revised regulation to require an ISA is not needed. Moreover, they expressed concerns with the scope and depth of the ISA and the amount of resources involved with the ISA process. Although there is opposition to such a requirement, some participants did agree that performing a "reasonable scope" ISA is beneficial.

From the staff's perspective, a regulation based on an ISA would be risk-based in that it would (1) define the consequences of potential accidents to be protected against, (2) require licensees to systematically, and in an integrated manner, identify these potential accidents from radiological and related chemical and fire hazards, and (3) require licensees to implement protective measures commensurate with the level of consequences. NRC expectations regarding an ISA have been described in the draft "ISA Guidance Document" and are based on well known process hazard analysis techniques used in the chemical industry for over 30 years to improve the safety at chemical and petrochemical plants worldwide. (1) One of the techniques identified in the guidance document is a probabilistic risk assessment (PRA), which involves a quantitative evaluation of the probability and consequences of potential accidents. Since licensees have expressed the view that a PRA would not be cost-effective, they probably would not choose this technique.

The ISA is viewed by the staff and some industry participants as a means for identifying potential accidents resulting from radiological and related chemical and fire hazards and as a basis for identifying the items relied on for safety and for establishing appropriate measures, commensurate with risk, to assure the continual availability and reliability of these items. Other industry participants have a more limited view of the proposed ISA. Also, there is a wide divergence of views between industry and the NRC staff as to the presence of authority within the current regulations to require that an ISA be prepared and maintained current to reflect any process changes.

Industry also expressed concerns with certain features of the March 1995 proposed rulemaking package that was distributed prior to the May 1995 workshop. These features included the establishment of multiple safety programs (e.g., fire protection, chemical process safety, criticality, management controls, configuration management, quality assurance, maintenance, and training) in the draft rule and the prescriptive description of these programs in the SRP. To address industry's concerns, staff would propose that a single safety program, rather than multiple safety programs, be established to assure the continual availability and reliability of items relied on for safety. The program would consist of measures such as fire protection, chemical process safety, criticality, management controls, configuration management, quality assurance, maintenance, and training, as appropriate.

Industry also expressed a concern about dual regulation of chemical safety and the possibility of overlapping responsibility from other Federal and state governments. NRC currently has a Memorandum of Understanding, dated October 31, 1988, with the Occupational Safety and Health Administration that addresses the division of responsibility for chemical safety at fuel cycle facilities. Also, NRC will consider using, where appropriate, the standards and guidelines developed by these other agencies.

The following is a summary of six alternatives for Commission consideration. Details of these alternatives, including the pros and cons, are provided in [Attachment 4](#). These were developed to provide a range of approaches for upgrading and more clearly defining the regulatory base and with consideration of comments and information provided by industry and other interested parties on how to proceed with improvements to the current regulation.

Alternative 1: Cease NRC encouragement of licensee's voluntary commitments to perform an ISA. (No change to the current Part 70.)

The licensing staff would cease the present practice of encouraging licensees, through the renewal process, and new license applicants to voluntarily commit to measures beyond what is explicitly specified in the current Part 70 such as performing and keeping current an ISA to identify potential accidents from radiological and related chemical and fire hazards. Since an SRP for the current Part 70 does not exist, one would have to be developed; in addition, the existing SF&CG would need to be revised.

Alternative 2: Continue NRC encouragement of licensee's voluntary commitments to perform an ISA. (No change to the current Part 70.)

The licensing staff would continue the current practice of encouraging licensees, through the renewal process, and new license applicants to voluntarily commit to perform and keep current an ISA to identify potential accidents from radiological and related chemical and fire hazards. Similar to Alternative 1, a new SRP and a revised SF&CG would be developed as guidance for the application of the current Part 70.

Alternative 3: Amend the current Part 70 to include the performance of an ISA.

Part 70 would be amended to require, for both licensees and new license applicants, the performance and maintenance of an acceptable ISA. The ISA would identify potential accidents from radiological and related chemical and fire hazards and would be used as the basis for identifying the items relied on for safety and for establishing appropriate measures, commensurate with risk, to assure the continual availability and reliability of these items. The items relied on for safety are those items that are needed to reduce the likelihood of potential credible accidents (including those caused by both internal and external events) or to mitigate their consequences. Consequence limits would be developed for grading (establishing the levels of) the quality and redundancy of the items relied on for safety. The ISA would be the basis for making future changes to licensees' safety programs without NRC prior approval. A new SRP and a revised

SF&CG would be developed as guidance.

Alternative 4: Amend the current Part 70 to include the performance of an ISA and other additional requirements.

This alternative is the same as Alternative 3 regarding the performance and maintenance of an ISA, but would include additional requirements such as those described below. A new SRP and a revised SF&CG would be developed as guidance for the application of the current Part 70 and the additional requirements.

1. A new license application format would be required to assure that the safety basis is documented and formally committed to in a one-part application. This would eliminate the "snapshot in time" safety demonstration that is currently required.
2. The voluntary reporting function established by [Bulletin 91-01](#) for licensees to report the loss of criticality safety controls would be codified and broadened.
3. Licensees would be required to keep their license application up-to-date, i.e., effectively maintaining a "living license."
4. Applicants for the licensing of newly constructed facilities or of new construction at existing facilities would be required, prior to construction, to complete a preliminary ISA and submit the results to NRC for approval. The results, in essence, would provide the design bases for the facility, i.e., the safety features incorporated into the design that provide protection against credible internal and external events. After construction and prior to operation of the facility, the applicants would be required to review and update their ISAs and submit the results for approval as part of their license application.

Alternative 5: Rewrite, reorganize, and restructure the requirements in Part 70.

Current Part 70 requirements for licensees who are authorized to possess critical quantities of SNM would be rewritten, consistent with the Commission's previous direction, as the staff discussed in SECY-94-057A. These requirements would be combined with the requirements identified in Alternative 4 and placed in a new part of the *Code of Federal Regulations* (CFR). The requirements for licensing subcritical quantities of SNM would remain in Part 70. As a result, there would be no impact on comparable activities regulated by Agreement States.

Creating a new CFR part would avoid adding additional patches, i.e., multiple amendments, to the current Part 70 and would distinguish the requirements for licensees who are authorized to possess critical quantities of SNM from those who are authorized to possess subcritical quantities of SNM.

The requirements transferred to the new CFR part would be rewritten to 1) present the requirements in more performance-oriented language wherever possible, 2) eliminate redundant requirements, 3) address and correct inconsistent requirements that are now difficult to administer and are presented in a disjointed format, and 4) identify and delete any unnecessary requirements. This rewrite is consistent with the direction provided in the January 15, 1993, SRM.

The requirements would be organized and structured in accordance with the guidelines provided in the Document Drafting Handbook⁽²⁾. The text would be written and presented in a manner that is consistent with the referenced guidelines so that the regulation effectively accomplishes its intended objective, is complete, and is easy to understand, use, amend, and cite. The rewritten new part would result in a more performance-oriented, risk-informed regulation that would support the intended objective of effectively licensing new applicants as well as current SNM licensees. The current draft SRP and the SF&CG would be revised for the application of this new rewrite.

Alternative 6: Amend the current Part 70 as described in Alternatives 3, 4, or 5, with the addition of a grandfather clause in which current licensees would not be required to perform an ISA except where major process changes, new processes, or new construction is involved.

ISA WORKSHOP:

In the December 8, 1995, letter from the Nuclear Energy Institute (NEI), NEI offered to sponsor and conduct a workshop to discuss such topics as the scope and sequence of the ISA process. Such discussions can be quite beneficial for both industry and the NRC, and the staff will follow-up with NEI's offer to conduct this workshop depending on the Commission's decision on how staff should proceed.

NEXT STEPS:

[Attachment 4](#), which describes the six alternatives and their associated pros and cons, is presented to the Commission for consideration and a decision. Once direction is received from the Commission, the staff will prepare, if appropriate, an action plan and schedule for implementing the approved alternative.

COORDINATION:

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

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Attachments: 1. [Analysis of Workshop Comments](#)
2. [Westinghouse's Perspective Regarding the Use of Their License Renewal Process](#)
3. [March 26, 1996, letter from GE Nuclear Energy](#)
4. [Pros and Cons for Alternatives 1-6](#)

NOVEMBER 30 AND DECEMBER 1, 1995

- PURPOSE:
- SUMMARY:
- BACKGROUND:
- DISCUSSION:
- ISA WORKSHOP:
- NEXT STEPS:
- COORDINATION:
- 1. Does the record of operations at fuel cycle facilities show a need for regulatory change?
- 2. Does the lack of grading of requirements according to risk in the current Part 70 indicate a need for revising the rule?
- 3. Are changes to the existing Part 70 format needed to improve clarity?
- 4. Rather than modifying the current rule, could an alternative approach be used to achieve NRC objectives?
- 5. Are changes needed in licensee safety programs to provide adequate confidence of safety?
- 6. Is the identification of items relied on for safety, through the performance of an ISA (hazards analysis), a critical element in effective and efficient regulation of fuel cycle facilities?
- 7. How can the NRC obtain reasonable assurance of availability and reliability of the items relied on for safety?
- 9. Should all changes to the safety program be subject to prior NRC approval?
- 10. Should the license documentation be promptly updated when changes are made to the facility?
- 11. How should NRC implement a "performance-based" regulation?
- 12. Assuming new requirements are adopted, how long should licensees be given to implement these requirements?
- REFERENCES

The public workshop generated an exchange of diverse views concerning improvements to the process of regulating fuel cycle facilities. The transcript, as well as written comments received subsequent to the workshop, have been examined to evaluate the various alternatives for regulation of fuel cycle facilities, and for potential improvements in the March 1995 draft revision of 10 CFR Part 70.

The views expressed at the workshop are summarized below; they address the twelve issues that were presented to the participants prior to the workshop and that were the focus of workshop discussions. For each of the twelve issues, the following provides a description of (1) the initial NRC staff position on the issue (as was provided to the participants prior to the workshop), (2) a summary of the views expressed by non-NRC workshop participants, and (3) additional views of NMSS staff, including comments on the views expressed by the other participants at the workshop ("commentary").

1. Does the record of operations at fuel cycle facilities show a need for regulatory change?

NRC staff initial position:

NRC staff analysis of serious incidents at fuel cycle facilities (Reference 1) indicated that a significant fraction of those events resulted from systemic deficiencies in licensee safety programs. In addition, analysis of events reported under Bulletin 91-01 indicated that such deficiencies are not isolated, but widespread. The staff believed that the frequency and nature of events and incidents at fuel cycle facilities demonstrate deficiencies in licensees' existing safety programs that can be addressed by changes to Part 70. Such changes would help meet NRC's goal of improving safety.

Industry position:

In general, industry representatives expressed the view that the events/incidents noted by NRC are not sufficiently serious to justify a revision of Part 70. Industry representatives noted that the events reported are the result of operator errors and not the absence of or deficiency in safety programs. Industry representatives indicated that the occurrence of these operator errors is taken seriously, and that the measures taken in response have resulted in continuing improved safety performance at their facilities. In another comment, an industry representative questioned the importance that NRC attached to the precursor events, since no Information Notices or Orders were issued in response to them.

Industry representatives expressed opposition to NRC's March 1995 draft revision of Part 70. The opposition appeared to center on the requirements for broad safety programs to assure the availability and reliability of items relied on for safety. Opposition to a requirement for an integrated safety analysis (ISA) was not as strong. One licensee favored such a rule change; others suggested that NRC has authority under the present rule (70.22) to require an ISA.

Other workshop participants:

No comment on this issue.

Commentary:

NRC staff analysis of 43 criticality safety precursor incidents reported under Bulletin 91-01 indicates that 6 of those incidents were so serious that one more event, i.e. the ingress of water, would have been sufficient to cause a criticality. Although operator error was involved in many of the precursor events, further analysis indicates that there are systemic problems in the licensees' safety programs. Among the areas identified are configuration management, maintenance, quality assurance, and safety analysis. With respect to the occurrence of operator errors, the development of an effective performance-based training program, as required in the March 1995 draft revision of Part 70, would certainly help reduce the frequency of such errors.

The NRC considers the Bulletin 91-01 events to be an important indicator of licensee performance. The Operations Branch, Fuel Cycle Safety and Safeguards (FCSS)/NMSS, has developed an automated system to track the evaluations of all such events. Part of the evaluation consists of examining the event to determine whether any generic deficiencies are involved. Licensee follow-up actions are reviewed during NRC inspections. In addition, NRC has issued at least two information notices in response to these events, "Slab Hopper Bulging" (3/17/93) and "Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities" (10/4/93).

2. Does the lack of grading of requirements according to risk in the current Part 70 indicate a need for revising the rule?

Are changes needed in the regulation to help focus NRC and licensee attention on safety-significant issues? Assuming it can be accomplished without imposing burdens on Agreement States, should unnecessary or unnecessarily prescriptive requirements in the existing rule be modified or eliminated?

NRC staff initial position:

The current Part 70 does not require that licensees (1) perform a systematic hazard analysis to identify hazards and potential accidents, and through analysis of these, identify the items relied on for safety, (2) determine the quantity and quality of items needed to assure safety, commensurate with the level of consequences, and implement them, and (3) assure the availability and reliability of those items. Such requirements are considered by the staff to be important parts of a licensee's safety program, which is needed to provide adequate confidence in the margin of safety. In addition, the current rule does not adequately address areas (e.g., chemical process safety) known to contribute significant risks to the operation of many licensed processes. Instead, the current rule often contains detailed discussion of issues that are not of significant safety concern. This disproportionate attention to low-risk, mostly administrative, concerns may divert effort from more significant issues (Reference 2).

Industry position:

Many licensee representatives expressed the view that no changes in the regulation are needed to help focus NRC and licensee attention on safety-significant issues. One licensee stated (p. 142⁽³⁾) that "very significant changes...have been accomplished without any change to the regulation."

With respect to the performance of an ISA, although many participants at the public workshop agreed that hazards analyses are important and should be performed, most industry representatives oppose a requirement for such analyses in a revised rule. Instead, they expressed the view that the performance of an ISA should be addressed in guidance documents or license conditions. One dissenter from this point of view (p. 88) favored a more limited revision to the existing Part 70 to include provisions for an ISA.

Although the issue of unnecessary or unnecessarily prescriptive requirements in the existing rule was not specifically addressed, industry did not push for a change in the rule to eliminate or modify these requirements.

Others:

One participant (pp. 25-26) supports the draft regulatory package for newcomers to the business: "This set of standards is as good a set of standards as I think I've seen developed over a long period of time. They're fairly easy to use, you understand what the NRC expects, and you can adhere to what they ask for."

The Department of Energy (DOE) representative (pp. 57-58) supports the revision of Part 70 for potential new licensees.

Commentary:

A revised rule that clearly emphasizes safety-significant issues would benefit both existing licensees and potential new entrants into the industry. The current Part 70 has no specific requirements to protect against chemical and fire hazards or to implement measures (e.g., maintenance, quality assurance, configuration management), commensurate with risk, to assure the availability and reliability of items relied on for safety. It was written to apply to all who possess SNM, whether in large or small quantities, and its requirements (see § 70.23) are very general and not graded according to risk. The lack of specific requirements has resulted in a somewhat variable interpretation regarding what constitutes adequate qualifications, equipment and facilities, and procedures needed to assure safe operations at the facility. NRC would like to assure a consistent level of safety and confidence in the margin of safety at all facilities.

Some of the most prescriptive portions of current Part 70 are contained in sections not considered for modification such as emergency planning or the recently added decommissioning requirements. Since these are now major programs in their own right, consideration should be given to moving them into separate parts, subparts, or appendices of 10 CFR. The safety focus of Part 70 could be better emphasized by moving the more administrative portions of the current part to the back of the rule.

3. Are changes to the existing Part 70 format needed to improve clarity?

As a result of a patchwork of amendments since Part 70 was first issued, the current regulation contains redundant and sometimes inconsistent requirements placed in a rather illogical and disjointed format.

NRC staff initial position:

Changes are needed in the existing Part 70 format to improve clarity (Reference 3) and make it a more user-friendly regulation for new licensees.

Industry position:

Industry representatives expressed the view that the regulation should not be changed simply to improve its clarity. For example, one licensee stated (p. 330) that any proposed revision to Part 70 "should be driven not by clarification of rules, by convenience, or by the fact that there are other licensees who may need to use this in the future," but rather "by a demonstrable and cost-benefit justified improvement in health and safety."

Other workshop participants:

The DOE representative and others felt that clarification of the rule was a legitimate goal given the possibility of new licensees in the future.

Commentary:

Although improving the clarity of the rule is not the prime motivation for revising Part 70, it is important. The possibility that NRC will be given the responsibility for regulating DOE facilities in the future is added incentive for improving the clarity of Part 70.

4. Rather than modifying the current rule, could an alternative approach be used to achieve NRC objectives?

To obtain individual plant examinations (IPEs) for power reactors, the NRC invoked its authority to require additional information from licensees. This approach might be used to obtain the information produced by an ISA, including information about the items relied on for safety. Could the IPE approach also be used to ensure the

establishment of safety programs needed to guarantee the availability and reliability of those items?

Another method for achieving NRC objectives is to define needed requirements and incorporate them as conditions in the license. Is this a viable approach?

NRC staff initial position:

A rulemaking process, including the development of relevant guidance documents, is appropriate for imposing generic requirements. Although NRC has the authority to require licensees to fix any specific safety problem, it is not clear whether the Commission has the authority to impose programmatic requirements without identifying a specific safety issue that would be addressed by those requirements.

At least one licensee had voluntarily adopted, as license conditions, certain programs from the draft Part 70 revision; there is, however, no assurance that, in the future, other licensees will not challenge NRC's authority to impose such requirements.

Industry position:

Many licensee representatives expressed the view that the rulemaking process is not necessary to effect desired changes. The suggested preferred approach is for NRC to develop, with industry collaboration, guidance documents to address any changes needed in the "regulatory structure." For example, a representative from the Nuclear Energy Institute (NEI) proposes (p. 84-85) a "bottom up" approach in which, NRC, without changing Part 70, includes what is needed in the SRP, evaluates the functioning of the regulatory process under that arrangement, and then determines whether any changes to Part 70 are needed.

Some representatives suggested that NRC has the authority under the old rule (70.22) to require anything it feels is necessary. For example, the representative from one licensee expressed the view that an ISA can be required under the existing §70.22 because NRC "has the ability to ask for what they want to ask for"(pp. 347, 380). In addition, licensee representatives pointed to voluntary agreements between licensees and NRC as evidence that the rule is not needed.

Other workshop participants:

One participant (p. 126) proposed the idea of "grandfathering" the existing operating facilities, and revising the rule for new applicants only. Necessary regulatory changes for existing facilities could be addressed using the "bottom up" approach suggested by a representative from NEI.

The DOE representative (pp. 135-136) stated that rather than grandfather any facilities, DOE requires the development of an "implementation plan" to describe how the requirements in its rules will be met. The rules are consistently applied to all facilities, but current variances can be incorporated in the implementation plans. Thus, a facility not in compliance with the rules must have a plan for coming into compliance.

Commentary:

In general, it is the staff's understanding that generic requirements should be imposed through a rulemaking. Notwithstanding the statement of one licensee, it is not clear whether NRC has current authority under 70.22 to require the performance of an ISA. Furthermore, even if it were possible to require an ISA through the generic authority provided in 70.22, a clear, explicit requirement for an ISA would appear to be preferable.

The IPE approach received little comment from industry and other interested parties. The staff's position is that although such an approach might be used to, in effect, require licensees to perform an ISA, it might not be suitable for assuring the establishment of an effective safety program or determining appropriate safety goals. In other words, a sound regulatory structure for fuel cycle facilities requires not only an ISA, but other important elements as well. The whole package is more appropriately addressed in a rulemaking process.

With respect to grandfathering existing facilities, there are some disadvantages. First, such an approach would establish a different set of requirements for new facilities than for existing facilities. This could result in an unjustified competitive disadvantage for the new facilities. Second, the implementation of the grandfathering approach would have awkward implications for the construction of a new process at an existing facility. Such a process could be covered under the new regulation while the existing processes would be covered under the old regulation.

5. Are changes needed in licensee safety programs to provide adequate confidence of safety?

Are improvements needed in all these areas? Are there other areas where improvements are needed?

NRC staff initial position:

NRC staff analyses indicated that improvements in the following areas would help correct the following systemic deficiencies:

- performance of an ISA
- increased attention to chemical process safety hazards
- increased attention to fire protection
- increased attention to criticality safety hazards
- effective configuration management
- performance-based safety training
- effective maintenance of safety features
- effective management control system
- effective quality assurance for safety features

Industry position:

Many licensee representatives appeared to agree that an ISA should be performed and that any improvements needed in the facility's safety programs should be justified by the results of the ISA. Licensee representatives did not agree that, a priori, it needs to commit to the establishment of programs in the areas recommended by the NRC.

Commentary:

According to the SRM of January 15, 1993, "The highest priority should be to sharpen and upgrade the regulatory basis for determining the adequacy of licensee performance" [emphasis added]. This does not mean that licensee performance is inadequate. Rather, the goal is to upgrade the basis for determining adequacy. In the March 1995 draft proposed rulemaking package, the staff recommended that this be achieved by

(1) performing an ISA to identify hazards and potential accidents, and (through analysis of these) identify the items relied on for safety,

(2) establishing licensee safety programs that assure the availability and reliability of these items, and (3) providing clear licensee commitments that are inspectable and enforceable. An important benefit of this process was that the safety-significant information generated, both initially and as significant process changes are made, would be available to NRC staff. This would give the staff an opportunity to better evaluate, on a continuing basis, the adequacy of licensee performance and thus obtain greater confidence in the continued safety of operations at licensed facilities.

6. Is the identification of items relied on for safety, through the performance of an ISA (hazards analysis), a critical element in effective and efficient regulation of fuel cycle facilities?

Should there be a requirement for NRC licensees to perform an ISA? Could any other approaches be used to meet NRC objectives?

NRC staff initial position:

To meet its goals for (1) effective and efficient expenditure of its licensing, inspection, and enforcement resources, and (2) reduction of unnecessary burden on fuel cycle licensees, NRC would like to focus on those aspects of facility operations relied on for assuring the safety of licensed processes. Corresponding increased licensee attention to these safety-related items will have a positive impact on NRC's goal of assuring safe operations. To identify the items relied on for safety, the staff proposes that each fuel cycle licensee perform a comprehensive analysis (ISA) that identifies hazards and potential accidents, and through analysis of these, identifies the items relied on for safety.

Industry position:

In general, the majority of industry representatives did not appear reluctant to conduct an ISA. In fact, several fuel cycle licensees are in the process of performing ISAs. However, many industry representatives did not believe that the performance of an ISA should be required by regulation. Industry also expressed a desire for further discussion on what constitutes an acceptable ISA.

Other workshop participants:

There was general agreement that the performance of an ISA or hazards analysis is needed. The scope of the ISA, however, needs to be made clear.

Commentary:

The performance of an ISA is central to establishing a risk-based regulatory approach and to improving NRC's confidence in the margin of safety. The ISA will be the basis for identifying items relied on for safety and for establishing measures, commensurate with risk, to assure the continual availability and reliability of those items. With this information, and the associated commitment to adhere to these measures, licensees will be able to demonstrate, with improved confidence, their ability to operate their facilities safely.

With respect to the scope of the ISA, the language in the rule needs to provide as much clarity as possible in performance oriented terms. In addition, a meeting to further discuss the ISA approach with industry and other interested parties would be helpful.

7. How can the NRC obtain reasonable assurance of availability and reliability of the items relied on for safety?

Is the approach taken by NRC reasonable? Should any other approaches be considered?

NRC staff initial position:

The March 1995 draft revision of Part 70 would require licensees to assure the availability and reliability of all items identified by the ISA that are relied on for safety. This would be achieved through the establishment of certain programs, e.g., quality assurance, maintenance, training, and configuration management. These programs, which are described in more detail in the draft SRP, are intended to provide the requisite assurance in a manner commensurate with the level of risk present at each facility. Thus, facilities with low overall risk (i.e., facilities whose safety features are needed to protect against accidents of low consequence) might expect to implement simple and relatively less burdensome programs, while higher risk facilities might need to implement more rigorous programs. This approach is consistent with NRC's goals to (1) concentrate on items relied on for safety and (2) grade regulatory requirements so as to reduce the regulatory burden on licensees to the extent practicable.

Industry position:

Most industry representatives appeared to agree that the ISA should drive what is needed to assure the availability and reliability of items relied on for safety. Industry representatives did not agree that all elements of all such programs identified by NRC are necessarily needed at all facilities. Furthermore, industry representatives expressed the view that they did not want to be compelled by regulation to commit to such programs. It appears that the implementation of broad safety programs, as detailed in Section 70.70 of the March 1995 draft revised rule, is the source of primary industry opposition to revising Part 70. Industry representatives expressed opposition to the use of the term "program," asserting that the word implies the imposition of several burdensome administrative features such as program managers and extensive documentation to describe the program.

Commentary:

The intent of NRC staff is to ensure that licensees establish appropriate measures, commensurate with risk, to maintain the continual availability and reliability of items relied on for safety. In using the word "program," the staff did not intend to broaden the scope of such safety measures to cover items that are not of safety significance. The staff also agrees

with industry that the safety program needs to be tailored to risk. Specifically limiting the scope of the safety program to items relied on for safety, as noted above, is one way to achieve this goal. In addition, the programs themselves may be graded according to the magnitude of risks identified in the ISA. That is, if a particular safety feature is needed to protect against an accident of minor consequence, the level of reliability needed will not be as great as if that safety feature is needed to protect against an accident of major consequence.

In addition, although the language in the rule describing these programs is, for the most part, performance oriented, there are some areas (such as performance-based training) that are somewhat prescriptive. These areas could be simplified, and the prescriptive elements could be placed in the SRP as examples of acceptable approaches. In response to licensee comments, the staff would modify the March 1995 draft revised rule to require that a single safety program be developed, which would include various measures (previously called programs), applied in an appropriately graded manner to ensure that the items relied on for safety are continually available and reliable.

8. Is the concept of using defined levels of risk for the graded application of controls reasonable?

Should alternative concepts be considered?

NRC staff initial position:

The March 1995 draft revision of Part 70 specified limits (e.g. exposure to 5 rem) that the licensee must provide "reasonable assurance" will not be exceeded for any individual off site, under accident conditions identified by the ISA. The SRP contains specific criteria for judging whether the quantity and quality of the licensee's safety controls provide such "reasonable assurance."

Industry position:

Although there was not much discussion of this issue at the workshop, industry representatives did mention, on several occasions, that they needed to know when NRC believed "enough is enough." That is, industry representatives appeared to recognize the need for setting a safety goal. One industry participant mentioned a "matrix" approach for characterizing risk. The determination of acceptable risk (i.e., the safety goal), however, was not addressed in this context.

Other workshop participants:

The DOE representative questioned (p. 202) the choice of limits for radiation exposure: "I'm curious to know why five rem was chosen and not 25 rem."

He also noted (pp. 263-264) that there is not as much information on the health risks of exposure to hazardous chemicals as there is for exposure to radiation or intake of radioactive materials. As a result, this lack of information on the effects of the chemicals makes it difficult to rank the risks of chemical exposure against the risks of radiation exposure.

Commentary:

Staff may need to provide clarification on how these consequence limits will be used to bound the ISA analysis and determine the quantity and quality of protective measures that need to be implemented.

With respect to the choice of 5 rem and the other consequence limits, NRC staff will review the limits to determine whether they are appropriate and develop a clear explanation for their selection.

NRC's concern about potential releases of hazardous chemicals is limited to those hazardous chemicals that could adversely affect radiological safety or could be released from the processing of licensed radioactive material. This is consistent with the Memorandum of Understanding dated October 31, 1988, between NRC and the Occupational Safety and Health Administration. In developing an approach for addressing such chemical hazards, NRC will consider exposure limits and guidelines established by other agencies with expertise in this area.

9. Should all changes to the safety program be subject to prior NRC approval?

NRC staff initial position:

As in the case for fuel cycle facility Fundamental Nuclear Material Control, and Physical Security Plans, the March 1995 draft revision of Part 70 proposes that prior approval for certain changes would not be required if those changes did not reduce the effectiveness of the safety program. Through the performance of an ISA, it would have to be demonstrated that such changes would not increase risk or introduce any unreviewed safety issues.

Industry position:

Although industry representatives did not dispute the benefit of making certain changes without NRC approval, the NEI representative stated that industry had this right until recently. That is, with the two-part structure of the license application, the licensee could make changes to Part II of the license application without prior NRC approval. According to this view, the proposed change to the rule would simply reestablish what had been previously accepted practice.

In a letter to NRC, a licensee stated that it is necessary to distinguish between "safety programs" and "facilities and systems, structures, and components relied upon for safety (SSCSs)." According to the licensee, current licensing practices require NRC approval for changes to safety programs but not to facilities and SSCSs. If NRC revises its approach to require prior approval for changes to facilities and SSCSs, the licensee believes that "a change process similar to 10 CFR 50.59...is essential."

Commentary:

Although it may be true that licensees have great flexibility under the current regulatory structure, that could be considered a weakness with the current regulations. That is, the ability to make changes to a licensee's process or safety programs, or both, without prior NRC approval should be contingent on whether those changes would result in increased risk or introduce any unreviewed safety issues. If it could be demonstrated (through an ISA) that there were no previously unreviewed safety issues and no increased risk, then the change would be allowed with subsequent notification to the NRC.

10. Should the license documentation be promptly updated when changes are made to the facility?

Is the proposed approach reasonable? Should NRC consider any alternatives?

NRC staff initial position:

The draft proposed rule included a requirement for prompt (within 60 days) updating of the license documentation and notification to NRC when changes are made to facility operations that have an effect on the safety program. Documentation of all other changes would be made in annual updates. The prompt reporting of all changes to the safety basis provides NRC with reasonably up-to-date knowledge of activities at the facility and, thus, an increased level of confidence in the licensee's ability to operate the facility safely. This helps satisfy one of NRC's primary goals. In addition, by essentially maintaining a "living license," the need for a license renewal process may be obviated. This could mean considerable cost savings for the fuel cycle industry.

Industry position:

There was not much discussion of this issue. The main concern of industry was that it be allowed flexibility in making changes. Reporting of such changes did not seem to be a major issue. In a subsequent letter to NRC, one licensee suggested a time frame of "as soon as practical but no longer than 120 days after implementation of the change."

Commentary:

The staff will consider extending the time for reporting changes.

11. How should NRC implement a "performance-based" regulation?

Should NRC consider alternative approaches?

NRC staff initial position:

The staff position favored the development and implementation of "performance-based" regulations, where possible. This approach generally involves (1) the establishment of general performance objectives in the regulation and (2) the description of acceptable approaches for meeting those objectives in the SRP or other guidance.

Industry position:

Although industry appears to have a preference for performance-based regulations, its approach differs significantly from that of NRC staff. A representative from NEI, for example, supported performance-based regulations (p. 170) but, instead of focusing on the establishment of performance goals, he focused on measuring licensee performance. In his view, a facility should be able to adjust its safety programs on the basis of its performance. If expectations are not being met, the program would have to be strengthened. If expectations are being exceeded, a relaxation of the program requirements would be allowed.

Industry representatives initially perceived the March 1995 draft revision to Part 70 as being "prescriptive." However, this perception may have changed after staff and industry reviewed some of the actual language in the rule for new requirements.

Other workshop participants:

One participant's view (p. 152) of performance-based regulation was somewhat similar to that of the NEI representative. He felt that a standard ISA, once performed, could be used to allow a facility to move to a more performance-based set of rules. Under his performance-based rules, if a licensee were to perform well, it would be given a little more freedom. A new licensee would be subject to a period during which it would be regulated under some higher standard until it could establish a good track record. This would, in essence, provide a method of grading the various facilities and could give the general public a greater sense of confidence in the good performers, and a greater sense of confidence in NRC for identifying and more closely regulating the below-average performers.

An alternate view of performance-based regulation was offered by another participant (p. 161). He expressed the opinion that a performance-based system works very well in financial matters, but it is more of a reactive than proactive system that is too dangerous for application to the safety concerns of the nuclear industry.

Commentary:

NRC staff defines "performance-based" regulations, in contrast to "prescriptive" regulations, as regulations that define what is to be achieved (i.e., performance objectives), but not how to achieve them. As noted in NRC's initial position, a performance-based rule needs to be supplemented by an SRP which provides detailed guidance to NRC staff about what constitutes an acceptable approach (or approaches) for complying with the regulation. These acceptable approaches are not intended to be exclusive; that is, a licensee may propose an alternative approach that the staff must evaluate to determine whether it is acceptable.

With respect to the specific approach presented in the March 1995 draft revision to Part 70, the staff believes that the approach was clearly performance oriented. The approach calls for (1) the performance of an ISA to identify those systems, structures, equipment, components and human actions relied on for safety and (2) the implementation of measures, commensurate with risk, to assure the availability and reliability of those items. Thus, it is not NRC, but the licensee, who primarily identifies, through the ISA, items that are relied on for safety. In addition, the measures taken to assure availability and reliability are focused solely on safety-significant items, i.e., those that are responsible for performing safety functions.

Discussion at the workshop (see above) indicated a differing view of what constitutes "performance-based" regulation. The view focused on evaluating actual performance at a facility (either a specific program or an overall assessment) and, depending on the results of that evaluation, adjusting safety programs or even the requirements in the rule accordingly. Although the adjustment of specific programs (e.g., maintenance) would seem to be allowed under the March 1995 draft revision to Part 70, the tailoring of regulatory requirements themselves would be difficult since there are no generally agreed-upon overall performance measures. The inspection program for fuel cycle facilities will be modified under the new license performance review program to reflect quality of performance.

12. Assuming new requirements are adopted, how long should licensees be given to implement these requirements?

NRC staff initial position:

The March 1995 draft revision to Part 70 proposes to allow 12 months for implementing all new requirements.

Industry position:

Industry representatives were reluctant to discuss this issue because discussing it would lend credence to the argument that the rule was necessary (p.329). Nevertheless, it was clear that licensees think that it will take several years to complete an ISA.

Commentary:

NRC staff has considered the time frame in light of the information provided, and would consider a requirement where a plan would be provided in a relatively short time which describes the licensee program for conducting an ISA and to allow up a number of years for its completion.

REFERENCES

1. "Regulatory Concerns From Precursor Events at Fuel Cycle Facilities", SECY-96-007, Attachment 2, Enclosure 3.
2. "Current Part 70 Requirements and the Risks They Address", SECY-96-007, Attachment 2, Enclosure 1.
3. "Difficulties with Interpreting Current Part 70", SECY-96-007, Attachment 2, Enclosure 2.

ATTACHMENT 2

COMMENTS FROM WESTINGHOUSE ELECTRIC CORPORATION

The following are comments received from Westinghouse Electric Corporation in their March 8, 1996, letter to the NRC regarding their experience in addressing some of the current regulatory licensing issues in preparing their recent license renewal application.

"From the Westinghouse perspective, there is no compelling justification for expending resources to rewrite the existing Part 70 regulation. For its 1995 SNM-1107 License Renewal Application, Westinghouse took a responsible, yet common sense look at the existing Regulatory Guidance (RG-3.52) that supports the current Part 70 regulation; and, rearranged and upgraded the application to address what is believed to be a consensus on what constitutes all current regulatory licensing issues. A major part of this belief in consensus is based upon the remarkable agreement between the approach endorsed and submitted by Westinghouse, the OSHA Process Safety Management Regulation (29CFR1910.119), and the soon-to-be EPA Risk Management Program Regulation (40CFR69). Thus, Westinghouse has offered its approved license application as a "model" for demonstrating how the regulatory guidance that supports the existing Part 70 regulation could be formally rearranged and upgraded."

"If, on the other hand, there is in fact strong justification for expending resources to revise the existing Part 70 regulation (that are outside the range of the current Westinghouse perspective), Westinghouse similarly offers its approved license application as a "model" for format, content and risk oriented, performance based structure of the revised Part 70 Regulation and its regulatory guidance."

"Westinghouse extends these offers both in the interest of proper allocation of scarce resources, due in large part to the global, competitive nature of the nuclear fuel cycle business; and, in the interest of avoiding costly duplicative regulation. To Westinghouse, this appears to be the only responsible course."

ATTACHMENT 4

PROS AND CONS FOR ALTERNATIVES 1-6

Alternative 1: Cease NRC encouragement of licensee's voluntary commitments to perform an integrated safety analysis (ISA). (No change to the current Part 70.)

The licensing staff would cease the current practice of encouraging licensees, through the renewal process, and new license applicants to voluntarily commit to measures beyond what is explicitly specified in the current Part 70 such as performing and keeping current an ISA to identify potential accidents from radiological and related chemical and fire hazards. Since an SRP for the current Part 70 does not exist, one would have to be developed; in addition, the existing SF&CG would need to be revised.

Pros:

1. NRC staff resources that are expended to encourage new applicants and current licensees to voluntarily commit to perform and keep current an ISA would be saved.
2. The regulatory framework for licensing would be more firmly supported by basing licensing on what is explicitly required by Part 70. The staff is viewed by industry as engaging in "backfitting" because NRC staff encourages licensees to commit to measures beyond those explicitly required in the current regulation. Since voluntary license commitments would no longer be encouraged, there would be less of a variation in the implemented safety programs for similar facilities.

Cons:

1. The Commission directive in the staff requirements memorandum (SRM) dated January 15, 1993, to upgrade and more clearly define the regulatory base for major fuel cycle licensees would not be met. Accordingly, the deficiencies in the fuel cycle regulations identified in NUREG-1324 would not be corrected. Thus, NRC would have no increased confidence

in the margin of safety since there would be no increased knowledge that potential accidents were systematically identified through the conduct of an ISA and that appropriate safety measures were implemented.

2. The current regulation does not explicitly address such significant issues as criticality prevention, protection against credible external events (for other than plutonium processing and fuel fabrication facilities), or the conduct of a systematic analysis as the basis for identifying items relied on for safety and for establishing appropriate measures to assure their continual availability and reliability. Thus, the licensing of new, unique facilities using special nuclear material (SNM) would probably require creating new parts in 10 CFR or licensing by order, as in the case of Louisiana Energy Services.
3. In the long term, unless an ISA is performed, there will likely be more incidents of regulatory significance, which could have been anticipated and protected against, that will result in expending additional NRC and licensee resources for subsequent investigations, along with additional licensee costs if facility operations were suspended.

Alternative 2: Continue NRC encouragement of licensee's voluntary commitments to perform an ISA. (No change to the current Part 70.)

The licensing staff would continue the current practice of encouraging licensees, through the renewal process, and new license applicants to voluntarily commit to perform and keep current an ISA to identify potential accidents from radiological and related chemical and fire hazards. Similar to Alternative 1, a new SRP and a revised SF&CG would be developed as guidance for the application of the current Part 70.

Pros:

1. Because this alternative represents the status quo, additional resources, beyond what is currently being expended by new applicants, current licensees, or NRC staff, would not be needed.
2. Some benefits of a risk-based regulatory approach could be effected if licensees voluntarily commit to perform an ISA. The ISA would identify potential accidents from radiological and related chemical and fire hazards that could be used as a basis for identifying items relied on for safety and for establishing appropriate measures to assure the continual availability and reliability of these items.
3. In the short term, licensees' voluntary commitments to perform an ISA could provide some improvements to their safety programs; thus, NRC could have some increased confidence in the margin of safety. For the long term, NRC would have some increased confidence in the margin of safety for licensees who commit to keep their ISA up-to-date to reflect facility changes.
4. Because both the performance of an ISA and licensee commitments to keep it up-to-date are voluntary, it can be presumed that the licensee will do so to the extent that it views this as no net cost or perhaps a net benefit.
5. From the industry perspective, since the consequences of potential accidents to be protected against would not be clearly defined by NRC, licensees would continue to have significant flexibility in deciding which accidents to protect against, which items would be relied on for safety, and which measures would assure their continual availability and reliability.

Cons:

1. The Commission directive in the staff requirements memorandum (SRM) dated January 15, 1993, to upgrade and more clearly define the regulatory base for major fuel cycle licensees would not be met. Accordingly, the deficiencies in the fuel cycle regulations identified in NUREG-1324 would not be corrected.
2. NRC would have limited confidence in the margin of safety.
 - a. The thoroughness of the ISAs conducted and measures implemented could vary because no ISA acceptance criteria would be established. While there could be a substantial increase in the confidence in the margin of safety at some facilities, there could be little increase in this confidence at other facilities.
 - b. Consideration of certain potential accidents involving chemicals and fire⁽⁴⁾ would be at the applicant's or licensee's discretion or at least be a point of difficult negotiations between NRC and applicants or licensees.
 - c. Licensees may not commit to assessing the impact of proposed operational changes on the basis of an ISA or may not commit to keeping the ISA up-to-date. Thus, NRC confidence in the margin of safety would decrease over time.
 - d. The timing in which licensees complete their ISAs, forward the results to the NRC, and complete their facility corrections for vulnerabilities identified would vary among those licensees who volunteer to perform an ISA, with no date certain for completing the implementation of the appropriate measures.
 - e. To the extent that licensees make only general or limited commitments for specific safety measures, NRC would not have a firm basis for safety inspection and enforcement actions at fuel cycle facilities.
 - f. For licensees not volunteering to perform an ISA, NRC would not have a regulatory basis to require an ISA until an incident occurred.
3. This approach fails to provide a firm regulatory framework for essentially similar facilities by allowing wide variations in the depth and scope of licensee commitments. Relying on voluntary commitments not specified in the regulation is neither an effective method of regulating safety nor an efficient use of NRC staff resources.

Alternative 3: Amend the current Part 70 to include the performance of an ISA.

Part 70 would be amended to require, for both licensees and new license applicants, the performance and maintenance of an acceptable ISA. A new SRP and a revised SF&CG would be developed as guidance.

The following are the significant features of this alternative.

1. Both licensees and new license applicants would be required to perform an ISA. The ISA would include (1) identifying all hazards (radiological, chemical and fire) at the facility, (2) analyzing these hazards to determine potential accidents (including those caused by both internal and external events), and (3) identifying items (e.g., site, structures, systems, equipment, components, and activities of personnel) needed to prevent the occurrence or mitigate the consequences of the identified accidents. Licensees would be required to establish a safety program, which includes appropriate measures, such as fire protection, chemical process safety, criticality, management controls, configuration management, quality assurance, maintenance, and training, to assure the continual availability and reliability of these items.

2. Consequence limits would be developed for grading (establishing the levels of) the quality and redundancy of the items relied on for safety. These limits would take into consideration the existing Occupational Safety and Health Administration and Environmental Protection Agency requirements.
3. NRC guidance documents would specify an acceptable scope and depth for the ISA and the information on the ISA to be submitted to NRC.
4. Time limits would be specified for licensees to complete their ISAs, for forwarding the results to the NRC, and for completing facility corrections for vulnerabilities identified in the ISA.
5. Licensees would be required to keep their documented safety basis up-to-date by submitting revisions to their license and ISA documentation when changes are made to facility processes.
6. Licensees would not be required to have prior NRC approval for making certain changes to a licensee's process and/or safety programs. Such changes would be allowed, with subsequent notification to the NRC, if it could be demonstrated through an ISA that there are no previously unreviewed safety issues and no increased risks.

Pros:

1. To some degree, the Commission's directive in the staff requirements memorandum (SRM) dated January 15, 1993, to upgrade and more clearly define the regulatory base for major fuel cycle licensees would be met. Some of the deficiencies in the fuel cycle regulations identified in NUREG-1324 would be corrected.
2. The revised regulation would establish a firm regulatory framework for a "risk-based" regulation in that it **would** (1) define the consequences of potential accidents to be protected against, (2) require licensees to systematically identify these potential accidents, and (3) require licensees to implement protective measures commensurate with the level of consequences.
3. NRC would have some increased confidence in the margin of safety.
 - a. Since all licensees would be required to perform an ISA, NRC would have an increased confidence in the margin of safety. Licensees would be required to systematically consider the potential radiological risks and chemical risks from accidents involving licensed materials. The increased confidence in the margin of safety would be particularly important for new types of facilities or new processes at existing facilities since these may involve greater risk and may have a higher degree of uncertainty associated with their operation.
 - b. The identification of consequence limits together with NRC guidance documents would provide specification of an acceptable scope and depth for the ISA and the information on the ISA to be submitted to NRC. This would provide criteria for uniform thoroughness of the analyses at all facilities.
 - c. Licensees would be required to complete their ISAs within a certain time frame to ensure that 1) sufficient time is allotted for a quality analysis and 2) the ISA is completed expeditiously, including implementing additional measures, as appropriate, to provide confidence in the margin of safety.
 - d. Licensees would be prevented from making changes to plant equipment, operations, or procedures until evaluating the safety implications on the basis of the ISA, and licensees would be required to keep NRC informed of such changes. Thus, NRC would have assurance that the margin of safety would not diminish by such changes.
4. Licensees would have considerable latitude in making changes to plant equipment, operations, or procedures provided those changes do not adversely affect the safety basis for the license.
5. Both the inspection and enforcement process should become more efficient in that those systems, components, and procedures relied on for safety would be identified through the ISA process and committed to in the license.
6. By licensees keeping their ISA documentation and application up-to-date, i.e., by effectively maintaining a "living license," they would be able to take advantage of a shorter and more efficient license renewal process.

Cons:

1. Licensees would need to expend resources to perform an ISA. In addition, it can be expected that licensees may need to make changes to their site, equipment, operations, or procedures to address potential accidents identified through the ISA and to establish appropriate measures to assure the continual availability and reliability of these items. The costs would vary depending upon the extent to which licensees have previously voluntarily performed an ISA and have taken appropriate measures based on the results of the ISA.
2. NRC staff resources would be needed to develop a rulemaking package to amend Part 70.
3. Applicants for the licensing of newly constructed facilities or of new construction at existing facilities would not be required to have NRC approval of their design bases prior to construction. As a result, NRC could not begin to establish confidence in the design and construction of items relied on for safety at a sufficiently early stage to minimize the need for safety dictated construction modifications.

Alternative 4: Amend the current Part 70 to include the performance of an ISA and additional requirements.

This alternative is the same as Alternative 3 regarding the performance and maintenance of an ISA, but would include additional requirements such as those described below. A new SRP and a revised SF&CG would be developed as guidance for the application of the current Part 70 and the additional requirements.

1. A new license application format would be required to assure that the safety basis is documented and formally committed to in a one-part application. This would eliminate the "snapshot in time" safety demonstration that is currently required.
2. The voluntary reporting function established by Bulletin 91-01 for licensees to report the loss of criticality safety controls would be codified and broadened.
3. Licensees would be required to keep their license application up-to-date, i.e., effectively maintaining a "living license."
4. Applicants for the licensing of newly constructed facilities or of new construction at existing facilities would be required, prior to construction, to complete a preliminary ISA and submit the results to NRC for approval. The results, in essence, would provide the design bases for the facility, i.e., the safety features incorporated into the design that provide protection against credible internal and external events. After construction and prior to operation of the facility, the applicants would be required to review and update their ISAs and submit the results for approval as part of their license application.

Pros:

The pros for this alternative are the same as Alternative 3, with the addition of the following:

1. For the most part, the Commission's directive in the staff requirements memorandum (SRM) dated January 15, 1993, to upgrade and more clearly define the regulatory base for major fuel cycle licensees would be met. All of the deficiencies in the fuel cycle Part 70 regulation identified in NUREG-1324 would be addressed.
1. Applicants for the licensing of newly constructed facilities or of new construction at existing facilities would require NRC approval of their design bases prior to construction. As a result, NRC could begin to establish confidence in the design and construction of items relied on for safety at a sufficiently early stage to minimize the need for safety dictated construction modifications.
2. Establishing a requirement to report the events identified in Bulletin 91-01 would assure that the information regarding the loss of criticality controls would continue to be reported to the NRC. In addition, other safety-related events may be identified for reporting to the NRC.
3. Requiring license applicants for new facilities to review and update their ISAs (assuming these ISAs were performed prior to construction of the facility) before initiating operations would assure that the ISAs fully reflect any differences between the facility as designed and the facility as constructed. The updated ISA would be more likely to identify potential accidents and provide the basis for protecting against their occurrence.

Cons:

In addition to the following, the cons in Alternative 3, except for #3, also apply to this alternative.

1. Licensees would be required to expend resources to address the additional requirements in this alternative.

Alternative 5: Rewrite, reorganize, and restructure the requirements in Part 70.

Current Part 70 requirements for licensees who are authorized to possess critical quantities of SNM would be rewritten, consistent with the Commission's previous direction, as the staff discussed in SECY-94-057A. These requirements would be combined with the requirements identified in Alternative 4 and placed in a new part of the *Code of Federal Regulations* (CFR). The requirements for licensing subcritical quantities of SNM would remain in Part 70. As a result, there would be no impact on comparable activities regulated by Agreement States.

Creating a new CFR part would avoid adding additional patches (multiple amendments) to the current Part 70 and would distinguish the requirements for licensees who are authorized to possess critical quantities of SNM from those who are authorized to possess subcritical quantities of SNM.

The requirements transferred to the new CFR part would be rewritten to 1) present the requirements in more performance-oriented language wherever possible, 2) eliminate redundant requirements, 3) address and correct inconsistent requirements that are now difficult to administer and are presented in a disjointed format, and 4) identify and delete any unnecessary requirements. This rewrite is consistent with the direction provided in the January 15, 1993, SRM.

The requirements would be organized and structured in accordance with the guidelines provided in the Document Drafting Handbook⁽⁵⁾. The text would be written and presented in a manner that is consistent with the referenced guidelines so that the regulation effectively accomplishes its intended objective, is complete, and is easy to understand, use, amend, and cite. The rewritten new part would result in a more performance-oriented, risk-informed regulation that would support the intended objective of effectively licensing new applicants as well as current SNM licensees. The current draft SRP and the SF&CG would be revised for the application of this new rewrite.

Pros:

In addition to the following, the pros in Alternative 4, except for #1, also apply to this alternative.

1. The Commission directive in the staff requirements memorandum (SRM) dated January 15, 1993, to upgrade and more clearly define the regulatory base for major fuel cycle licensees would be completely met.
2. To the extent possible, the regulation would contain more performance-oriented language.
3. The learning process for the applicable requirements for new license applicants could be more efficient, since the requirements would be organized and structured in a more systematic and logical manner, and would be more "user-friendly."
4. Misinterpretation of the requirements for all new licensee applicants would be minimized since this alternative would clearly distinguish the requirements pertaining to licensees who are authorized to possess critical quantities of SNM from those who are authorized to possess subcritical quantities of SNM.
5. The licensing, inspection, and enforcement process would become more efficient since the requirements would be written with more clarity and presented in a more organized manner in the new CFR part.

Cons:

The cons of this alternative are the same as Alternative 4, with the addition of the following:

1. Additional resources would be expended by NRC to rewrite the rule and by current licensees to become familiar with the new rule.
2. Previous experience with revising 10 CFR Part 20 suggests that a completely rewritten rule can introduce some unforeseen difficulties.

Alternative 6: Amend the current Part 70 as described in Alternatives 3, 4, or 5, with the addition of a grandfather clause in which current licensees would not be required to perform an ISA except where major process changes, new processes, or new construction is involved.

For current licensees, the pros and cons are (1) those associated with the non-ISA requirements in Alternatives 4 or 5, and (2) those associated with Alternatives 1 or 2. For new license applicants and current licensees making major process changes or employing new processes or new construction, the pertinent pros and cons of Alternatives 3, 4, or 5 apply. In addition, the following pro and cons apply.

Pro:

For new licensees performing an ISA, Alternative 5 would provide the more efficient approach since the requirements would be organized and structured in a more systematic and logical manner and would be more "user-friendly." Misinterpretation of the requirements would be minimized since Alternative 5 would clearly distinguish the requirements pertaining to licensees who are authorized to possess critical quantities of SNM from those who are authorized to possess subcritical quantities of SNM.

Cons:

1. The requirements to perform an ISA would be based on whether the applicant is a current NRC licensee, a new license applicant, or a current NRC licensee employing new or major process changes or new construction. This would be an inconsistent regulatory approach since it would be based on operational classifications that are not related to inherent risks.
2. An NRC licensee could potentially be subject to two sets of regulatory requirements, one applying to current processes and one applying to major process changes or new construction.
3. Those licensees performing an ISA may be at a competitive disadvantage due to the ISA's associated resource and staff impacts.

1. Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples, Center for Chemical Process Safety, AIChE, New York, 1992.

2. "Document Drafting Handbook," published by the Office of the Federal Register, National Archives and Records Administration, 1991 Edition.

3. All page numbers, unless otherwise noted, refer to the Official Transcript of Proceedings, Workshop on the Regulation of Fuel Cycle Facilities, November 30 - December 1, 1995.

4. Only chemical and fire hazards that could affect radiological safety or chemical hazards resulting from the processing of licensed nuclear material are within NRC's responsibility.

5. "Document Drafting Handbook," published by the Office of the Federal Register, National Archives and Records Administration, 1991 Edition.