December 31, 1997 SECY-97-303

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: "THE ROLE OF INDUSTRY (DSI-13)" AND USE OF INDUSTRY INITIATIVES

PURPOSE

This Commission paper responds to three staff requirements memoranda (SRM). The first SRM, COMSECY-96-062, "The Role of Industry (DSI-13)" (Enclosure 1), directed the staff to (1) develop guidance to describe the process and general decision criteria NRC would use to evaluate industry activities that would be substitutes for regulatory actions and (2) develop an implementation plan that addressed a number of issues related to NRC utilization of codes and standards. The second SRM, "Briefing on NRC Inspection Activities" (Enclosure 2), contained WITS Item No. 9600086, "Monitoring the Effectiveness of Voluntary Programs." This item indicated the Commission's concern regarding the NRC's monitoring of voluntary programs or activities initiated by industry in lieu of the imposition of regulatory requirements and directed the staff to develop and activate a procedure to verify that such voluntary industry programs are, in fact, being carried out. The staff was also asked to inform the Commission of possible methods for determining the effectiveness of these programs. The third SRM, "Briefing on Codes and Standards" (Enclosure 3), contained three part WITS Item No. 9700028. The last part of this WITS item asked the staff to address the impact of the backfit rule on the staff's updating of 10 CFR 50.55a to endorse newer editions and addenda of the ASME Code. The staff's response to this SRM, dated July 23, 1997, noted that this subject would be addressed in the staff's paper on DSI-13.

SUMMARY:

This paper describes a conceptual process and items that would be addressed when developing general decision criteria related to industry initiatives. Once developed, this process and criteria could be utilized for a range of different types of initiatives such as risk-informed or performance-

CONTACT:
Joel Page, RES
(301) 415-6784

based initiatives. The paper also describes potential changes and the resource implications related to NRC endorsement of codes and standards.

The staff proposes to conduct meetings with stakeholders to discuss issues and obtain additional views and insights with regard to (1) industry initiatives that would be substitutes for regulatory action, including the related process and general decision criteria, and (2) potential improvements to the NRC process for endorsement of codes and standards. After these meetings, staff recommendations, including revised resource estimates, will be provided to the Commission. Following Commission approval, NRC Management Directives and office letters, as appropriate, will be issued to implement the revised processes and criteria.

The staff's response to the questions contained in the SRMs is divided into two areas: industry initiatives that would be substitutes for regulatory action, and codes, standards, and guides.

DISCUSSION:

An NRC Task Force was formed to review and respond to the issues contained in the DSI-13 SRM. Other issues not included in this SRM but related to NRC reliance on voluntary industry initiatives were later added to the scope to ensure a more integrated treatment of the policy questions related to the use of and reliance upon industry initiatives as a substitute for NRC regulatory action. The Task Force was composed of a Steering Committee and a Team with representatives from RES, NRR, NMSS, OGC, and AEOD on both the Steering Committee and the Team.

INDUSTRY INITIATIVES:

Industry initiatives that would be substitutes for regulatory action could include a variety of different activities. For example, industry initiatives could involve risk-informed methods, less prescriptive methods, or industry guidance documents as substitutes for regulatory actions. A more detailed discussion of these issues and a conceptual process is contained in Enclosure 4.

Meetings with Other Agencies:

As directed by the SRM for DSI-13, the staff had discussions with other public agencies to explore whether they had models or informative experiences regarding their reliance on the regulated industry's initiatives that are substitutes for regulatory actions. The staff had discussions with representatives of the Food and Drug Administration (FDA) and the Federal Aviation Administration (FAA), neither of which could identify any examples of their agency's reliance on industry initiatives as substitutes for regulatory action. The staff asked whether these agencies had established criteria or procedures that would be used if such a proposal were received. The representatives of both agencies responded that such criteria or procedures had not been developed, and that they did not anticipate the need to develop them.

Past and Current Initiatives:

Two items of policy and staff practice were noted during the review of past and current initiatives. The first involves the type or purpose of the initiative. The majority of industry initiatives have involved operating reactors. This type of initiative typically includes regulatory action, such as issuance of a regulatory guide to endorse an industry document as a method for complying with an existing regulation. NUMARC's 93-01, "Industry Guideline for Monitoring the Effectiveness of

Maintenance at Nuclear Power Plants," which is endorsed in Regulatory Guide 1.160, is an example of this type of initiative.
The second involves the policy guidance contained in Revision 2 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." This guidance states that the NRC encourages voluntary actions that enhance safety; absent an evident safety problem, great weight and due consideration should be given to these initiatives before imposing requirements to codify them in the regulations. However, for purposes of regulatory analyses, no credit should be given for the voluntary actions taken by licensees since they could be reduced or eliminated, and the safety improvements could not be assumed into the future because they would not be codified and not subject to enforcement. The result is that NRC reliance upon voluntary industry initiatives is typically limited to cases in which the initiative provides a method to meet an existing requirement.

There are various policy and legal issues related to NRC reliance on industry initiatives as substitutes for regulatory actions. The issues include enforcement aspects, the relationship of the initiative to the licensing basis, the safety significance of the issue to be addressed by the initiative, current policy concerning credit for voluntary initiatives, fee recovery, NRC monitoring of licensee implementation of the initiative, public access to information related to the initiative, consistency with the Atomic Energy Act, and compliance with the Federal Advisory Committee Act (FACA).

Staff Guidance for a Process and Decision Criteria:

The SRM states that "Staff guidance should be developed to describe the process and general decision criteria NRC would use for evaluating proposals." The staff developed a conceptual process that has three phases as shown in Figure 1. They are (1) NRC's acceptance review (i.e., to determine whether the proposed initiative should be accepted by the staff), (2) detailed NRC staff technical review, and (3) NRC's follow-up activities such as monitoring of initiative implementation, as appropriate. The staff also identified items needed to develop decision criteria which, along with the process, will be discussed with stakeholders to determine final staff recommendations regarding the process and decision criteria for industry initiatives.

Monitoring of Industry Initiatives:

Following a Commission briefing on May 31, 1996, on NRC's inspection activities, the Commission indicated its concern regarding the NRC's monitoring of voluntary programs or activities initiated by the industry that are in lieu of the imposition of regulatory requirements. Included in WITS Item No. 9600086 were instructions to the staff to (1) develop and activate a procedure to verify that such voluntary industry programs are, in fact, being carried out and (2) inform the Commission of possible methods for determining the effectiveness of these programs. One of the items the staff intends to discuss with stakeholders is the NRC's follow-up or monitoring of initiatives. As stated above, following discussions with stakeholders, the staff will determine its final recommendations regarding process and decision criteria, including that associated with follow-up or monitoring of initiatives.

CODES, STANDARDS, AND GUIDES:

A more detailed discussion of codes, standards and guides is included in Enclosure 5. The March 7, 1997, SRM directed that an implementation plan address the following seven areas.

Streamlining NRC's Codes and Standards Endorsement Process: The team reviewed the overall process for developing and endorsing new or revised standards. The first part of the process includes staff participation in a consensus standards development organization (SDO) and in the internal SDO process that results in a new or revised standard being issued. The discussion of options for improvements focused on this part of the process. The second part of the process includes the steps that the staff follows to endorse standards. The current NRC process for endorsing new or revised standards is based upon the requirements of the Administrative Procedures Act (APA) (5 USC 553). The time required to endorse a new or revised standard is lengthy and resource-intensive as a result of the requirements for public notification and comment in the APA rulemaking process.

The options for improving and streamlining the process include (1) developing an NRC Management Directive that would define responsibilities and requirements associated with staff participation in SDOs and (2) earlier staff review of emerging standards (e.g., staff review of standards before they are issued in final form but after they have been submitted to the appropriate ASME Board). Other options for streamlining and simplifying the process may be identified during discussions with stakeholders.

A number of factors are related to NRC endorsement of new or revised standards. One factor is related to the need for new or revised standards. During the period when nuclear plants were being constructed and licensed, codes and standards provided a method to identify and resolve technical issues, and to incorporate changes in technology. However, in recent years many standards, or revisions to standards, are initiated to lower operating and maintenance costs as evidenced by the increasing number of proposed "cost reduction/relaxation" revisions to the ASME Code. These types of revisions usually have limited safety significance and, when new requirements are added, may not meet the criteria contained in 10 CFR 50.109. [Note: an exception to voluntary implementation of revised standards that do not meet 10 CFR 50.109 are the standards (primarily the ASME Code) referenced in 10 CFR 50.55a that are required to be implemented by licensees.]

An additional factor related to endorsement of standards involves their technical acceptability. There are recent examples of revisions to standards by consensus committees that did not have an adequate technical basis or did not comply with existing regulations. For example, in 1995 revisions were made to the ASME Section III piping design criteria. Early in the revision process the staff identified that these revisions did not have adequate technical bases and, as a result, could not be endorsed by the NRC. Despite staff concerns and objections, as reflected in negative ballots, the Code committees approved these revisions. NRC wrote to the ASME and stated that the revisions could not be used by NRC licensees. These revisions and the related technical bases are now being reviewed by an ASME special task group to determine what actions or revisions should be initiated.

NRC Internal Performance Indicators: Existing internal performance indicators and tracking systems for rules and regulatory guides were reviewed to determine whether they were adequate to ensure the timely update of regulations and regulatory guides. As a result of the Strategic Assessment and Rebaselining Initiative and the development of the NRC Strategic Plan, tracking systems that monitor revisions of rules and regulatory guides are under development. Subsidiary plans, such as the NRC Performance Plan, the Rulemaking Action Plan, and individual office operating plans, routinely identify and track revisions of rules and regulatory guides. The staff

believes that these tracking systems provide adequate performance indicators to ensure timely update of rules and regulations.

Impediment by the Backfit Rule: A review was conducted to determine the degree to which the current backfit rule implementation unnecessarily impedes the adoption of updated codes and standards. Based upon this review, the staff concluded that the backfit rule does not unnecessarily impede adoption of updated codes and standards. In some cases, new standards, such as those that relate to risk analysis, may not pass 10 CFR 50.109 backfit criteria and would, therefore, be implemented by licensees on a voluntary basis. When the staff proposes an action that would require reactor licensees to meet the criteria contained in a revised code or standard, the provisions of 10 CFR 50.109 apply.

With the exception of routine updating of endorsements to certain sections of the ASME Code in 10 CFR 50.55a, staff proposals to require licensee use of a particular code or standard must be justified in accordance with 10 CFR 50.109. This is because 10 CFR 50.55a requires licensees to update on 120-month intervals to newer editions and addenda of the ASME Code for inservice inspection and testing; therefore, these routine "regulation required" updates are not subject to backfit analysis. Also, codes and standards are often endorsed in regulatory guides as an acceptable method to meet an existing regulation and, since utilization of these guides is voluntary, the provisions of the backfit rule are not applicable.

Greater Use of Codes & Standards: The review examined the scope or range of standards used by the NRC to determine whether greater use should be made of all available codes and standards (not just ASME and IEEE standards) in our regulations and regulatory guides. NRC documents contain over 4000 citations to standards developed by more than 30 different organizations. Staff activities related to utilization of codes and standards are based on the requirements contained in Public Law 104-113 (P.L. 104-113) and the supporting Circular A-119 (A-119) issued by the Office of Management and Budget. While the staff did not identify any specific needs for increased use of standards at this time, staff activities associated with A-119 will result in increased NRC consideration and use of codes and standards. For example, as part of the implementation of A-119, the staff proposes to revise the Federal Register notice for all future proposed rules and regulatory guides to specifically request commenters to identify any standards that the staff should consider as substitutes, in whole or in part, for the proposed action.

Public Law 104-113: The staff conducted a review of P.L. 104-113 and A-119 to determine whether the intent of this law is being fully addressed in all of our regulatory requirements and guides. P.L. 104-113 contains three provisions related to Federal agencies' utilization of consensus technical standards. Briefly, these provisions are that Federal agencies shall (1) when practical use technical standards that are developed by voluntary consensus standards bodies, (2) consult with voluntary consensus standards bodies and participate with such bodies when such participation is in the public interest and is compatible with the agency mission, authority, priorities, and budget resources, and (3) report to the Office of Management and Budget when the agency elects to use a technical standard that was not developed by a voluntary consensus standards body. Based on this review, the staff concluded that the intent of

the law is being addressed. Nevertheless, additional actions are planned to improve NRC's compliance with this law. One example is establishing NRC procedures to report to OMB when NRC uses a technical standard not developed or adopted by a consensus standards developing organization.

Identification of Needs for New Codes, Standards, and Guides: The staff met with representatives of ASME in June 1997 to discuss the need for new standards in probabilistic risk assessment (PRA). As a result of these discussions, a preliminary process has been developed that will guide the staff in identifying the need for new standards and for the initial interaction with standards organizations. In October 1997, the ASME Board on Nuclear Codes and Standards voted to propose to the ASME Council on Codes and Standards development of a standard on risk management that would define the level of quality needed using PRA techniques in various nuclear applications. ASME codes and standards are being developed that apply risk-informed techniques to inservice inspection and inservice testing. The staff has participated in the development of these standards. The ongoing and planned PRA standards are a part of the PRA Implementation Plan, which is included in DSI-12 activities.

Assessment of Required NRC Resources: The SRM for DSI-13 directed the staff to provide resource estimates for the six items listed above. The activities associated with the first item, earlier development of a regulatory position on emerging standards in order to streamline the endorsement process, could require a significant increase in resources. Approximately 10 additional FTEs could be required annually for this item.

As previously discussed, a meeting with stakeholders is planned and is intended to (1) help the staff define a process to identify the new or revised standards that the staff should review, and (2) help define improvements to the efficiency and effectiveness of staff reviews of these standards, including a better estimate of resource requirements. Following this meeting, the staff will recommend to the Commission any items that could result in a significant impact on programmed activities, with the potential benefits and detriments for each item.

Additional resources should not be required for internal performance indicators or backfitting. The remaining three items, increased use of codes and standards, P.L. 104-113, and needs for new standards, could each require an additional 1 to 3 FTE annually. Resources to develop new standards are dependent upon the number and nature of the new standards that the staff would request from the standards developing organizations.

The estimate of additional resources is based on past experience with new or revised standards that were consistent with existing regulations, and assumed that any significant changes to the standard were made early in the development process. This is not always the case. Standards are sometimes issued that do not meet regulatory requirements. As a result, additional NRC resources are needed to complete a detailed review of the standard and to develop the modifications or limitations necessary for the NRC to endorse that new or revised standard. A new complicating factor is an expedited process that ASME committees will use to develop new or revised standards. With this process, it is likely that the significance of individual changes will not be clear until much later in the revision process when a complete revision begins to be assembled. While there may be long-term resource savings by early development of regulatory positions on emerging standards, the magnitude of these savings cannot be determined at this time.

Additionally, resources will be required to support the actions proposed in this SECY paper. NRR support to the DSI-13 initiative was not budgeted in its Operating Plan, but is expected to be 3-6 staff months in January-April 1998 to support stakeholder meetings, determine future actions, and prepare the next Commission paper on DSI-13. NRR support for this initiative will result in NRR being unable to support the Regions on three to four inspections related to inservice testing and motor operated valves. The NRR Operating Plan will be revised to reflect this impact.

In addition to the seven areas identified above, following a Commission briefing on codes and standards on January 22, 1997, the Commission indicated its concern regarding (1) the staff's rationale for applying backfit considerations when endorsing later editions of the ASME Code, (2) how backfit analyses consider the Code consensus view if licensees are permitted to selectively determine which Code requirements are applicable to their facilities, and (3) the practicalities and implications related to the inspection and enforcement of licensees' conformance to various different Code edition requirements. These subjects are also addressed in Enclosure 5. The staff intends to include these subjects as items of discussion with stakeholders and update the guidance or information as appropriate.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Chief Information Officer has no objection to this paper.

This paper has been coordinated between offices to ensure that implementation plans developed for DSI-13 are compatible with and do not duplicate activities being planned and conducted for DSI-11, "Operating Reactor Program Oversight," and DSI-12, "Risk-Informed, Performance-Based Regulation." Additionally, DSI-13 actions that are directed toward expediting evaluation of industry initiatives and promoting more rapid adoption of consensus standards are being included in the goals and strategies for the FY 1998 NRC Excellence Plan.

RECOMMENDATIONS:

That the Commission note that, unless otherwise directed, it is my intention to:

(1) Direct the staff to meet no later than June 1998 with stakeholders to discuss issues related to (a) the process and issues that would be addressed in the acceptance criteria and review criteria for utilization of industry initiatives as substitutes for regulatory action, and (b) NRC endorsement of codes and standards, including how and whether the endorsement process can be streamlined.

(2) Direct the staff to provide two separate papers to the Commission no later than four months after meeting with stakeholders. One paper will discuss the staff's conclusions regarding how to proceed with the proposed process for receipt, review, endorsement, and monitoring of industry initiatives that would be substitutes for regulatory action. The second paper will discuss the staff's proposed recommendations regarding improvements to the endorsement process for codes and standards. In each paper, the staff will provide

a summary of relevant stakeholder comments and identify resources and impacts that would be necessary to implement the staff recommendations.

L. Joseph Callan
Executive Director
for Operations

Enclosures:
1. SRM dated March 7, 1997
2. SRM dated July 30, 1996
3. SRM dated February 12, 1997
4. Industry Initiatives
5. NRC Use of Codes and Standards

Distribution: DET r/f Central File EDO r/f

J Tappert (NRR)	L Shao (RES)	S Treby (OGC)	J Surmeier (NMSS)
G Mizuno (OGC)	B Morris (RES)	E Brown (AEOD)	F Coffman (RES)
C Jones (NMSS)	F Miraglia (NRR)	M Slosson (NRR)	B Sheron (NRR)

DOCUMENT NAME: a:\dsi13.scy

To receive a copy of this document, indicate in the box: "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy

OFFICE	RES/DET		RES/DET		RES/DET		RES/DIR		NRR	
NAME	JPage *		GMillman *		JCraig *		MKnapp *		SCollins *	
DATE	11/3 /97		11/3 /97		11/3 /97		11/13 /97		11/7 /97	

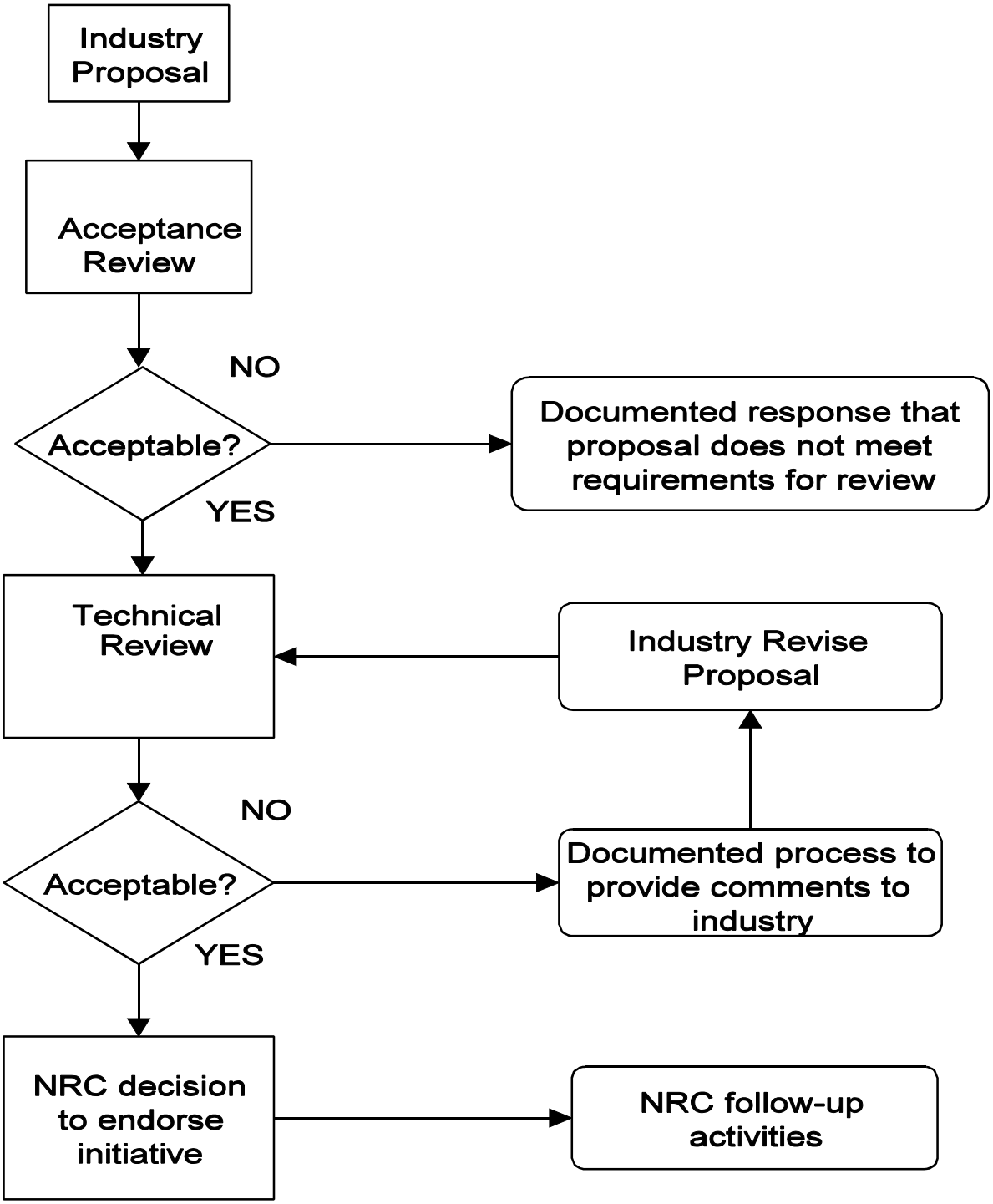
OFFICE	NMSS		AEOD		CFO		CIO		OGC	
NAME	CPaperiello *		TMartin *		JFunches *		AGalante *		KCyr *	
DATE	11/4 /97		11/7 /97		11/6 /97		11/4 /97		11/6 /97	

OFFICE	DEDE		EDO							
NAME	AThadani *		JCallan							
DATE	11/21 /97		12/ /97							

*See previous concurrences

OFFICIAL RECORD COPY

FIGURE 1 Conceptual Evaluation Process



ENCLOSURE 1

March 7, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-062 - STRATEGIC ASSESSMENT ISSUE PAPER: THE ROLE OF INDUSTRY (DSI 13)

The NRC should move as expeditiously as possible, within budget constraints, to evaluate on a case by case basis initiatives proposing further NRC reliance on industry activities as an alternative for NRC regulatory activities. Staff guidance should be developed to describe the process and the general decision criteria NRC would use for evaluating proposals. (Option 1) The staff should explore whether other public agencies provide models or informative experiences regarding this type of process and general decisional criteria. In addition, the staff's development of decisional criteria should include consideration of the effects on public access to information on safety-significant industry activities if the NRC relies on an industry activity as a substitute for NRC regulatory action. Accreditation and certification programs for licensee activities can be considered in the context of Option 1.

In addition, the NRC should increase its focus and emphasis on interacting with both industry groups and professional societies and technical institutes to develop new codes, standards, and guides needed to support efficient, effective, and consistent performance of industry activities important to safety. These codes, standards and guides would then be endorsed by the NRC. (Option 4) The staff should develop an implementation plan for pursuing Option 4 that addresses the following:

1) the need to streamline and simplify the NRC's internal process for endorsing codes and standards within a year after they are issued by a professional society. Consideration should be given to the American Society of Mechanical Engineers' recommendation to maximize concurrency in the professional society process and the NRC regulatory process.

2) internal performance indicators to ensure timely update of regulations and regulatory guides.

3) the degree to which the current backfit rule implementation unnecessarily impedes the adoption of updated codes and standards.

4) whether greater use should be made of all available codes and standards (not just ASME and IEEE standards) in our regulations and regulatory guides.

5) whether the intent of Public Law 104-113 is being fully addressed in all of our regulatory requirements and guides.

6) where there are needs for new codes, standards, and guides and recommendations for areas of emphasis. The NRC's initial activities in pursuing option 4 should include standards development in Probabilistic Risk Assessment (PRA) as discussed in the PRA Framework Document (SECY-95-280).

7) an assessment of the required NRC resources and anticipated periods for commitment of such resources.

(EDO) (SECY Suspense: 8/29/97)

This Direction Setting Issue (DSI) is closely related to DSI-11, Operating Reactor Program Oversight, and DSI-12, Risk-Informed, Performance-Based Regulation. The staff should ensure that implementation plans developed for these issues are mutually compatible and do not create duplicate activities.

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner McGaffigan
Commissioner Diaz
K. Cyr (OGC)
D. Rathbun (OCA)
H. Bell (OIG)
A. Galante (CIO)
R. Scroggins (CFO)
E. Jordan (SARSC)
J. Silber (SARSC)

ENCLOSURE 2

IN RESPONSE, PLEASE
REFER TO: M960531

July 30, 1996 REVISED

MEMORANDUM TO: James M. Taylor
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON NRC INSPECTION ACTIVITIES, 10:00 A.M., FRIDAY, MAY 31, 1996, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the staff on NRC inspection activities including the spent fuel pool licensing basis review, the FSAR inspections and findings, and the 10 CFR 50.59 review and action plan. As part of the Lessons Learned Report resulting from these and on-going inspection activities the staff should develop recommendations for improvement to the reactor oversight program, and brief the Commission before final decisions are made. In the context of these efforts, the staff should consider whether the regulations should be amended or guidance developed to clarify, in particular, the scope of applicability for 10 CFR 50.59, the FSAR update requirements in 10 CFR 50.71(e), and whether the "current licensing basis" should be defined in 10 CFR Part 50. There must be a clear delineation of which approach is most workable for the different requirements. The staff should ensure that the Action Plan clearly defines: (1) respective responsibilities and accountability of headquarters and regional personnel, including appropriate interfaces with appropriate senior management oversight, and (2) guidance for performing licensing reviews and subsequent inspections regarding execution of those licensing actions. The staff should also ensure that effective mechanisms are in place for regional and resident inspector input in the development of these recommendations.

(EDO) (SECY Suspense: 8/30/96) 9600068

The Commission also indicated its concern regarding the NRC's monitoring of voluntary programs or activities initiated by the industry in lieu of the imposition of regulatory requirements. The staff should develop and activate a procedure to verify that such voluntary industry programs are, in fact, being carried out. The staff should also inform the Commission of possible methods for determining the effectiveness of these programs.

(EDO) (SECY Suspense: 3/31/97) 9600086

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-24

ENCLOSURE 3 IN RESPONSE, PLEASE
REFER TO: M970122A

February 12, 1997

MEMORANDUM TO: Hugh L. Thompson, Jr
Acting Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON CODES AND STANDARDS, 10:00 A.M., WEDNESDAY, JANUARY 22, 1997, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the NRC staff and representatives from the American Society of Mechanical Engineers (ASME) and the Institute of Electrical and Electronics Engineers (IEEE) on the use of consensus codes and standards.

The Commission requested that the staff identify those plants which have reactor vessels or safety-related piping systems that do not fall under the design rules of ASME Code Section III and identify the design rules or Codes that do apply, characterize the significant differences between ASME Code Section III and ANSI/ASME Codes B.31.1 and B.31.7, and describe any inspection inconsistencies that could arise from the use of these differing standards.
~~(EDO)~~(RES/NRR) (SECY Suspense: 4/25/97) 9700028

The staff should discuss the applicability of ASME Code Section III or other design/construction Codes of Record to operations, in particular, to those attributes that may not be addressed by the relevant Code requirements referenced in paragraphs (f) and (g) of 10 CFR 50.55a, and address the nature of design/construction Code requirements in the context of operations and the current licensing basis of operating plants.
(RES/NRR) 9700028

The ASME Code is a product of a consensus process. The staff should discuss its rationale for applying backfit considerations when endorsing later editions of the ASME Code that would allow licensees to selectively determine which requirements are applicable to their facilities, since the bases of many relaxations in one portion of the Code may be a result of consensus agreement for increased requirements in other portions of the Code.
~~(EDO/OGC)~~(RES/OGC) (SECY Suspense: 4/25/97) 9700028

The Commission urged the staff to improve the timeliness to complete NRC endorsement of new editions or revisions to previously endorsed codes and standards, where appropriate.

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-24

ENCLOSURE 4
Industry Initiatives

1. Introduction

Direction-Setting Issue (DSI) 13, "The Role of Industry," seeks to strike a proper balance between reliance on industry measures and NRC independent regulatory action to ensure safety and maintain the public trust. The DSI-13 Issue Paper, dated in September 1996, recognizes that the NRC does not have an explicit policy statement regarding how much credit should be given to industry activities that contribute to achieving the necessary safety objectives. In the DSI-13 Issue Paper, the staff performed an integrated review and provided a range of options for crediting industry activities.

Option 1 from the DSI-13 Issue Paper states that, "NRC would take no actions to either substantively increase the role of industry or expand the scope or pace of current NRC and industry initiatives to further rely on industry activities." Option 1 does note, however, that activities for which additional credit is involved or sought would be evaluated on a case-by-case basis if and when they are identified by industry or the staff. It also notes that, to improve the efficiency of NRC review of industry proposals involving increased reliance on industry measures, staff guidance will be issued to describe the process and the general decision criteria NRC will use for evaluating such proposals. Staff Requirements Memorandum (SRM) COMSECY-96-062 endorsed option 1 and stated, "Staff guidance should be developed to describe the process and the general decision criteria NRC would use for evaluating proposals." Further, this SRM stated, "The staff should explore whether other public agencies provide models or informative experiences regarding this type of process and general decisional criteria." This enclosure describes a conceptual process and the items that would be addressed when developing the general decision criteria for evaluating industry initiatives to determine whether they can be endorsed as an alternative to regulatory action.

The crux of this issue will be developming an objective evaluation process and general decision criteria that can be used to determine whether an industry initiative can be relied on as an adequate and effective substitute for NRC regulatory activities. In this context, NRC regulatory activities are interpreted broadly to include issuance of rules, orders, regulatory guides, bulletins, and generic letters; inspections; and other activities with a regulatory impact on licensees. An industry initiative is defined as an industry-proposed program or a plan of action that is being proposed to replace an existing or anticipated regulatory action. Other voluntary programs instituted by licensees that do not seek to substitute for regulatory activities will not be considered as industry initiatives. Additionally, codes and standards developed by consensus committees are reviewed using a separate process and therefore are not considered industry initiatives; see Enclosure 5.

The current staff practice of reviewing initiatives is informal and relies on judgments that are not explicitly acknowledged or systematically documented. There is no specific definition of an industry initiative or stipulation of criteria to use in evaluating them. There is no tracking or repository of industry initiatives, and there is no program in place to verify that licensees follow through on proposed initiatives. However, the staff is currently developing a tracking system for such commitments. The items to be addressed when developing the general decision criteria and the conceptual process are a first step to providing a structured approach to (1) determine whether a proposed initiative should be reviewed and (2) monitor its implementation if it is an acceptable substitute for a regulatory action.

This enclosure discusses a draft conceptual process and concomitant policy issues to be considered by the staff. It also discusses items to be considered in developing general decision criteria for judging the acceptability of industry initiatives that are alternatives to agency action. The general decision criteria will include monitoring, which would be used by the NRC to evaluate the effectiveness of such industry initiatives. The process is based on the current practice for NRC's review of topical reports or industry documents. These reports are typically endorsed in a safety evaluation report or regulatory guide. The topical report or industry document serves as a substitute for the detail that would otherwise be included in a regulatory action such as a regulatory guide.

The monitoring criteria for initiatives are related to an SRM dated July 30, 1996, WITS Item No. 9600086 (see Enclosure 2 of this package), which expressed concern regarding the NRC's monitoring of voluntary programs or activities initiated by the industry in lieu of the imposition of regulatory requirements. The SRM stated that, "The staff should develop and activate a procedure to verify that such voluntary programs are, in fact, being carried out. The staff should also inform the Commission of possible methods for determining the effectiveness of these programs." Because the activities related to answering the policy issues raised by DSI-13 encompass the actions of the earlier Commission direction and represent much broader policy issues related to the acceptability and use of voluntary industry initiatives, work on the earlier Commission request has been suspended until the Commission has resolved the broader policy issues and endorsed the general decision criteria that will be provided in a subsequent paper.

One aspect of the approach outlined in this enclosure is that the staff plans to meet with stakeholders to solicit comments on the conceptual process and issues to be addressed by the acceptance criteria and review the criteria for industry initiatives as substitutes for regulatory action.

This paper has been coordinated between offices to ensure that implementation plans developed for DSI-13 are compatible with and do not duplicate activities being planned and conducted for DSI-11, "Operating Reactor Program Oversight," and DSI-12, "Risk-Informed, Performance-Based Regulation." Additionally, DSI-13 actions that are directed toward expediting evaluation of industry initiatives and promoting more rapid adoption of consensus standards are being included in the goals and strategies for the FY 1998 NRC Excellence Plan.

2. Industry Initiatives--Past Practices

2.1 Materials Licensees

In the materials program, there have been relatively few industry initiatives compared with those from reactor licensees. This is primarily due to three contributing factors: 1) no broad industry-wide advocacy or technical assistance group works to represent the interests of all materials licensees, 2) industry resources devoted to supporting new codes and standards activities are limited, and 3) NRC uses several advisory committees to seek advice on technical topics in the nuclear reactor/engineering fields or medical areas but not for areas that involve the industrial application of radiation.

There are two joint NRC-industry initiatives in the materials area that have relied on the concept of an enhanced nonreactor industry role. The first initiative is the National Voluntary Laboratory Accreditation Program (NVLAP). The second initiative, the revision of 10 CFR Part 34, does not require radiographer certification until 1999, so it is too early to tell whether this program is successful. Both processes took considerable time to resolve (approximately 14 years) with various industry groups, Agreement States, licensees, and the NRC. Both initiatives relied on industry input and commitment in order to be successfully integrated into NRC regulations.

2.2 Reactor Licensees

As noted in the introduction, there is no formal NRC process to identify and review industry initiatives. The staff reviewed examples of prior and ongoing industry initiatives to characterize the types of initiatives and to identify specific positive elements to emulate and incorporate and specific elements to avoid. The staff also reviewed internal NRC processes that may provide models for evaluating industry initiatives in lieu of regulatory action. For reactor licensees, there appear to be two broad categories of industry initiatives: (1) initiatives in response to generic technical issues and (2) initiatives in response to policy, process, or programmatic issues.

The first, initiatives for generic technical issues, are typically sponsored by owners groups and address specific technical issues. Often an owners group takes the lead in assessing and resolving the technical issue, and the NRC staff closely monitors their efforts in lieu of initiating independent regulatory action. The staff obtains enough information to make a safety assessment, but many of these issues may be reactive in nature and the NRC may forego regulatory action while an industry group develops additional information. Based on the results and pace of industry action, the staff may ultimately take regulatory action.

The second broad category of industry initiatives results from policy, process, or programmatic issues. These initiatives typically would be sponsored by an industry-wide group such as NEI and are developed over a relatively long period of time. The staff met with the Nuclear Energy Institute (NEI) on August 6, 1997, to discuss past and current activities related to initiatives as discussed in DSI-13. NEI defines an initiative as a proposal that is approved by 80% of their membership. Because these initiatives do not necessarily represent an alternative to regulatory action, NEI initiatives would not necessarily meet the definition of an industry initiative as used in this paper. NEI typically determines the NRC's expectations on an issue, determines options for the industry, and then decides whether or not to officially pursue an initiative. NEI does not use documented general decision criteria regarding whether or not to pursue an initiative. They stated that each situation in the past was sufficiently different to require a unique approach, and NEI does not endorse the concept of general decision criteria to evaluate all industry initiatives because the scope and substance of industry initiatives vary significantly.

Several specific industry initiatives on policy, process, or programmatic issues were identified and reviewed. One example, NUMARC 93-01, Maintenance Rule Implementation Guidance, was developed by the industry in close coordination with the NRC over a period of two years. The NRC was able to endorse the initial industry guidance in Regulatory Guide 1.160 with essentially no exceptions. Another example is the role of the Institute of Nuclear Power Operation (INPO) in providing accreditation for training programs at nuclear power plants. When the training programs maintain their accreditation with INPO, the NRC presumes that the program meets the requirements for a systems approach to training in accordance with 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel," and 10 CFR 55.59, "Requalification." The NRC conducts routine inspections of the licensed operator requalification program but does not inspect in other training areas except "for cause."

One aspect of defining, reviewing, and endorsing industry initiatives is the time required for each step. For example, the issue of severe-accident management (SAM) and the potential reduction in risk that could result from developing procedures and training operators to manage accidents beyond the design basis was first identified in 1985. Even though managing severe accidents was beyond the plants' licensing bases, and thus would have required rulemaking to implement broadly, the industry developed generic SAM strategies in 1990 for consideration by utilities in the individual plant examination process. The staff has continued to work with industry to define the scope and content of utility SAM programs, and these efforts have culminated in industry-developed SAM guidance for utility implementation. Industry has committed to implement an accident management program at each nuclear power plant.

In late 1995, the staff met with industry representatives to discuss plans for inspecting utility implementation of the formal industry position on SAM and the major elements of a draft temporary instruction (TI). These plans included

staff visits to 2 to 4 sites to obtain an early understanding of how the various elements of the formal industry position were being implemented. While the NEI initiative called for universal implementation no later than 1998, NEI committed to nominating sites in 1996 for early information-gathering visits. However, these information-gathering visits did not take place at that time because NEI did not identify licensees that were either prepared or willing to support the visits. The visits began in 1997.

Finally, the staff reviewed internal NRC processes that may provide models for evaluating industry initiatives in lieu of regulatory action. The topical report program was identified as a process that can provide an informative model. The topical report program, which is described in NUREG-0390, "Topical Report Review Status," is triggered by the submission of a topical report from a sponsoring organization to the NRC. The report is judged against four criteria before being accepted for review: (1) the subject requires a safety assessment by the staff, such as component design, analytical models or techniques, or performance testing of components or systems, that can be evaluated independently of any specific license application, (2) the report is sponsored by a lead plant, (3) the report contains complete and detailed information, and (4) approval of the report will result in increased efficiency for the NRC. The staff requests additional information from the sponsoring organization during the review as needed. At the conclusion of the review, the NRC transmits its safety evaluation report (SER) by letter to the sponsoring organization and the topical report is available to be referenced by licensees, subject to any conditions or limitations contained in the staff's SER. Pursuant to 10 CFR Part 170, applications for topical report reviews, except those that meet the criteria in Footnote 4 to 10 CFR 170.21 and Footnote 5 to 10 CFR 170.31, are subject to fees based on the full cost of the review.

The review of past practices highlighted the fact that there is no standard, consistent process for determining which initiatives should be accepted for detailed review. The review also demonstrated that industry initiatives can be useful for the staff and the regulated industry. Industry groups may be able to quickly gather information needed for decision making or develop consensus industry positions. However, some shortcomings associated with these initiatives were also identified, such as long time periods to identify and address issues and long time periods for licensees to implement the consensus position. The lessons learned from this review have been incorporated into Section 6 of this paper that addresses developing the general decision criteria.

3. Other Federal Agencies' Activities

The staff conducted discussions with two Federal agencies, the Federal Aviation Administration (FAA) and the Food and Drug Administration (FDA), to review their actions taken to rely on industry initiatives as an alternative to regulatory activities. These agencies were selected because they regulate highly technical areas, are currently subject to rapid changes, and have highly organized public constituencies in the areas regulated. FAA and FDA experience with initiatives has primarily been limited to new product approval. Representatives of these agencies stated that they did not have an explicit process or criteria to evaluate industry initiatives proposed as substitutes for regulatory activities. Agencies utilize different approaches to interact with their regulated industries, such as the designated industry representative. However, these approaches do not address industry initiatives as an alternative to regulatory action. As a result of the meetings, the staff concluded that the agencies reviewed do not have processes that could be used as a model for the NRC's proposed process.

4. Policy and Legal Considerations

NRC reliance upon regulated entities' initiatives as a substitute for regulatory action raises several important policy and legal issues, as does the process by which the NRC interacts with representatives of the regulated entities during the regulated entities' formulation and refinement of initiatives. The policy issues include enforcement,

monitoring of initiatives, and maintaining public confidence in the NRC's independence. The legal issues include compliance and consistency with the Atomic Energy Act of 1954, as amended, the Federal Advisory Committee Act (FACA), and the Administrative Procedures Act (APA).

4.1 Policy Considerations

4.1.1 Enforcement

Enforceability is a significant consideration in the use of industry initiatives. If NRC relies on an initiative and does not include a regulatory action such as an order or license amendment, enforcement options would be limited or nonexistent when a licensee did not implement the actions associated with the initiative or eliminated them at a later time. Conversely, regulatory controls placed upon initiatives or portions of initiatives would ensure that the NRC has a basis for evaluating the adequacy of the initiative's implementation and for taking appropriate regulatory enforcement action if a licensee fails to implement all elements of the initiative or if there is inadequate implementation. Documentation of the substantive elements of an initiative would increase the efficiency of NRC inspections and audits by allowing the NRC to easily verify the specifics of the initiative. Documentation also facilitates each applicable licensees' understanding of the NRC's expectations concerning implementation of the initiative. For reactor and facility licensees, and materials licensees that have specific rather than general licenses, the elements involving actions to be undertaken by each entity in its licensed activities must be documented in the licensing basis for each regulated entity covered by the initiative. For nuclear power reactor licensees, documentation could be by license condition (i.e., an amendment of the license), a technical specification change, an addition to the Final Safety Analyses Report, or other document.

The nature of the regulatory controls could depend on the safety or risk significance of the problem being addressed. For nuclear power reactor licensees, issues of relatively high safety significance should be documented in: (i) a license condition if related to the design of the facility and if it may not be changed except by license amendment, (ii) the FSAR if the NRC determines that it is acceptable for the licensee to make a change to the initiative element pursuant to 10 CFR 50.59, or (iii) a technical specification if related to operation. Less-important issues can be documented in the FSAR, in a separate document subject to controls defined in the document, or simply in written form on the docket (in which case the NRC can only issue a "notice of deviation" for any failure to comply with the commitment).

4.1.2 Safety Significance

Important additional factors in regard to reliance on industry initiatives are the safety significance of the underlying issues and the timeliness of the initiative. For issues of high safety significance, the NRC would take timely regulatory action that is likely to preclude reliance on industry initiatives. At the other extreme, the safety significance of an issue may be low enough that immediate action is not necessary. As safety significance decreases, there could be increased reliance on an industry initiative provided the timetable of the initiative is commensurate with the safety significance. The timetable would include the time to define the initiative and conduct staff review, as well as the time to implement it. Another assessment of safety significance could include an evaluation of three separate cases: (1) no action taken (base case), (2) the industry initiative is implemented, and (3) the agency's regulatory action is implemented. Comparison of the results of these three cases would assist the NRC in determining the proper course of action.

4.1.3 Credit for Voluntary Initiatives

Another consideration is the policy guidance contained in Revision 2 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." This guidance states that the NRC encourages voluntary actions that enhance safety; absent an evident safety problem, great weight and due consideration should be given to these initiatives before imposing requirements to codify them in the regulations. However, for purposes of regulatory analysis, no credit should be given for the voluntary actions taken by licensees since they could be reduced or eliminated and the safety improvements could not be assumed in the future because they would remain uncodified and not subject to enforcement. The result is that NRC reliance upon voluntary industry initiatives is typically limited to those cases in which the initiative provides a method to meet an existing requirement.

4.1.4 Fees and Resources

Another issue to be considered is the fee structure associated with the review of industry initiatives that would be substitutes for regulatory action, specifically, whether or not the sponsoring organization should be charged for the cost of the review. Based on the level of effort that has, in the past, been necessary for staff to review and endorse industry initiatives, this is likely to be a significant issue. Currently, consistent with the fee policy for topical reports, fees will be assessed for the full cost of the reviews unless the industry initiative meets the criteria specified in Footnote 4 to 10 CFR 171.21 or Footnote 5 to 10 CFR 171.31. As provided in these footnotes, fees will not be assessed for requests or reports submitted to the NRC: (a) In response to a Generic Letter or NRC Bulletin that does not result in an amendment to the license, does not result in the review of an alternative method or reanalysis to meet the requirements of the Generic Letter, or does not involve an unreviewed safety issue; (b) In response to an NRC request (at the Associate Office Director level or above) to resolve an identified safety, safeguards, or environmental issue, or to assist NRC in developing a rule, regulatory guide, policy statement, generic letter, or bulletin; or (c) As a means of exchanging information between industry organizations and the NRC for the purpose of supporting generic regulatory improvements or efforts. The resources necessary to review or implement a proposed initiative are discussed in Section 6. The resources to be committed by the NRC, the scheduling constraints of the initiative, and the commitment of the industry also have to be considered. The proposed initiative would be rejected if the sponsor or industry does not make a firm commitment to devote the necessary resources, including any NRC fees, to support the agreed-upon schedule and milestones for the initiative.

4.1.5 Monitoring of Initiatives

The NRC has occasionally relied upon voluntary initiatives and commitments by nuclear power plant licensees. For example, voluntary actions have been credited as part of the bases during GSI resolutions. One example is GSI-91, "Main Crankshaft Failures in Transamerica Delaval Inc. Emergency Diesel Generators." In this example, an owners group publication was considered adequate to incorporate the essential elements needed to resolve outstanding concerns on the reliability and operability of emergency diesel generators. A recurring weakness in NRC reliance upon voluntary initiatives has been the absence of NRC verification that the initiatives and commitments are implemented in a timely fashion. Absent such monitoring, the NRC would not have a basis for determining whether the initiative or commitment was successful in addressing the safety concern, or whether the initiative should be discontinued because there was little positive impact on safety. Accordingly, Section 6 includes items to be considered in the development of a general decision criterion that would identify NRC follow-up actions.

4.1.6 Maintaining Public Confidence in the NRC's Independence

As discussed below in Section 4.2, NRC reliance or endorsement of an initiative by regulated entities must be consistent with the Atomic Energy Act (AEA). Even if these requirements are met, the NRC's reliance on or

endorsement of an initiative could be perceived as a capitulation to the regulated industry. The staff believes that public confidence rests in large part on the following elements: (i) openness and public participation in the agency's review of the initiative and (ii) public access to information on the bases for acceptance of the initiative and the implementation of the initiative. Each of these elements has been reflected in one or more of the items to be considered in the development of the general decision criteria (see discussion in Section 6). The policy considerations for each of these elements are discussed in greater detail below.

As discussed below in Section 4.2, Legal Considerations, the APA sets forth requirements for notice and comment with respect to agency rulemaking. NRC review and endorsement of an initiative proposed by regulated entities, however, may not involve "rulemaking" as defined in the APA, especially when the NRC action would endorse the substantive elements of the initiative in a regulatory guide (at most, a regulatory guide would be viewed as an interpretive rule, for which the notice and comment provisions of the APA are not applicable). Currently, as a matter of policy, all regulatory guides are issued first as drafts for public comment. Failure to provide an opportunity for public comment, although not required by the APA, could be viewed by some members of the public as undercutting public involvement and indicative of the "capture" of the regulator by the regulated entities. Moreover, even if the public were given an opportunity for comment at the end of a lengthy interaction between the agency and the regulated entities, in which the elements of the proposed initiative were discussed as they were developed, the public comment process may be viewed by some members of the public as pro forma.

The staff also believes that if regulated entities are to propose initiatives as substitutes for agency action, the regulated entities themselves could reach out to other stakeholders and involve them in the development of the initiative. However, absent a proposal by the regulated entities to engage other stakeholders, the Commission could consider engaging stakeholders in the process of initiative development through processes similar to negotiated rulemaking.

Questions regarding public access to information regarding initiatives proposed by regulated entities generally focus on access at two different points in the process: (i) during the NRC's review, evaluation, and endorsement of the proposed initiative and (ii) during ongoing implementation of the initiative. With respect to the former, the Commission has indicated that information relied upon by the Commission in making a regulatory decision must be scrutable to the public. Commission action to accept or endorse an initiative proposed by regulated entities in lieu of formal agency action would seem to involve the same policy considerations favoring information access as a Commission decision to proceed with agency action. Thus, items in Section 6 favor initiatives that commit the entities to public disclosure of all information submitted to the NRC, or referenced by the regulated entities, in support of an initiative.

By contrast, the Commission has not spoken to the circumstance of public access to information during initiative implementation. Extending the policies that underlie the Commission's decision to provide access to information underlying an agency's decision would seem to argue in favor of providing public access to information. On the other hand, the Commission has not expressed an opinion concerning unfettered (or even a qualified) right of the public of access to information gathered or otherwise examined as part of the agency's oversight responsibilities. Accordingly, the staff proposes that regulated entities proposing an initiative should agree that information inspected *and retained* by the NRC in the course of the NRC's audits and inspections of initiative implementation

should be placed in the NRC's Public Document Room, absent a significant privacy or proprietary interest. However, the Commission should not require entities to provide the public access to information that is reviewed and inspected by the NRC in the course of its audits and inspections of initiative implementation, but that is *not* retained by the NRC.*

4.1.7 Anti-Competitive Concerns

When regulating nuclear power plants, the NRC generally deals with a relatively homogenous set of licensees (large utilities), a single industry organization representing them (NEI), a relatively small number of vendors of the nuclear steam supply system (NSSS), and professional or industry organizations with specific, non-overlapping jurisdictions or areas of interest (e.g., ASME, EPRI, IEEE).

This is not the case in the nuclear materials area as the NRC's nuclear materials program regulates approximately 40 different activities, devices, and systems, which range in complexity from simple devices using sealed sources to large facilities. There are more than 20,000 materials licensees, including governmental entities, large commercial firms, and small "mom and pop" businesses. Some materials users have trade associations with a strong (nuclear) technical capability, while other users have no trade or professional organization. Even if trade or professional associations exist, competitive pressures largely do not allow for significant sharing of technical information. There are multiple trade or professional organizations with overlapping areas of interest (e.g., various medical organizations and professional societies). This diversity of licensees, users, and organizational representation means that the views of a single organization cannot necessarily be viewed as representing a consensus of all regulated entities of the class. Indeed, based upon anecdotal evidence in other regulated areas, it is quite possible for an organization representing a specific set of regulated entities to propose standards that provide an unfair advantage to their members at the expense of some other set of entities who are competitors. To minimize the possibility that the NRC would unwittingly adopt an initiative with a significant anti-competitive intent, the NRC should evaluate each proposed
initiative to determine (i) whether there is a justifiable radiological health and safety objective that the initiative is intended to achieve, (ii) whether the initiative has the effect of disadvantaging a competing class of regulated entities or promoting the interests of the class or regulated entities who developed the initiative, and (iii) if there are such effects, whether the effect is an unavoidable consequence of the attaining the health and safety objective.

4.2 Legal Considerations

***The staff notes that the matter of public access to information inspected or audited by the NRC, but not retained by the NRC, is the subject of a 10 CFR 2.802 petition filed by the Ohio Citizens for Responsible Energy (OCRE). See 59 FR 30308 (June 14, 1994).**

A significant legal issue is whether Commission reliance upon a regulated industry initiative, which has as one of its elements ongoing oversight of the regulated entities by a third party, is both consistent with the AEA and does not constitute an unlawful delegation of agency power to a private entity. Such concerns can be avoided if (i) the third party meets certain prerequisites with respect to its organization, (ii) the NRC continues to exert independent oversight and authority over the regulated entities (including the authority to conduct inspections of the regulated entities with respect to the subject matter of the industry initiative), (iii) the third party's findings are not binding on the NRC and the NRC has the capability to monitor the activities of the third party, and (iv) the NRC has complete access to information collected by the third party with respect to the oversight function it administers.

A second issue focuses on whether the NRC's interaction with an outside entity with respect to an initiative complies with the Federal Advisory Committee Act (FACA). FACA imposes certain restrictions on a Federal agency's use of a committee, panel, group, or organization that is not composed solely of full-time Federal employees for advice (relating primarily to chartering the advisory committee, taking full minutes, and holding open meetings). The Commission's regulations implementing FACA, 10 CFR Part 7, provide that an advisory committee includes groups that are a preferred source from which to obtain advice or recommendations on a specific issue or policy, but does not include meetings initiated by the NRC held with more than one individual for the purpose of obtaining advice of the individual attendees and not for the purpose of utilizing the group to obtain consensus advice or recommendations. FACA also would not apply if the NRC did not participate in regulated entities' deliberations on development of their initiative.

The Administrative Procedures Act (APA) requires that, when an agency engages in rulemaking, the agency must provide for public notice in the Federal Register and opportunity for public comment, except in certain circumstances that are delineated in 5 U.S.C. 553(b)(3). Although a "consensus process" for developing an initiative the Commission intends to adopt through rulemaking would, it is hoped, develop a product on which little additional comment would be expected, the consensus process may not be relied upon as a basis for avoiding notice and comment requirements of the APA.

These policy and legal considerations have been utilized in the development of the conceptual process and the items for consideration in the development of the general decision criteria.

5. Evaluating Industry Initiatives

A conceptual evaluation process is depicted in Figure 1 of this enclosure. The process is triggered when an industry initiative is submitted, that is, an industry-proposed program or plan of action is proposed to replace either a clearly identified existing regulatory action or one that is being anticipated. Petitions for rulemaking under 10 CFR 2.802 are a special case and will be excluded from this process as there are already mechanisms in place to handle these petitions.) The proposal typically is made in writing to the appropriate office director.

The first step in the process is the staff's initial acceptance review, which would be completed within 30 days. The purpose of this review is to determine whether there is a clearly demonstrated basis for accepting the proposed industry initiative for a detailed review. The general decision criteria would be utilized to make this determination. Items to be considered in developing the general decision criteria are discussed in greater detail in the following section and include issues such as technical adequacy and safety significance. The reviews would be conducted by the appropriate program office. At the conclusion of the initial review, a recommendation would be made to NRC senior management for a decision on whether to proceed with the reviewt. The sponsoring organization would be notified in writing of the results of the initial review.

If the decision is to proceed, a task action plan would be developed for the review effort with scheduled milestones appropriate for the scope of the proposal. The initiative is then more thoroughly reviewed against the general decision criteria. Requests for additional information and comments are provided to the sponsor, which can be an iterative process. The mechanics of this feedback will depend on the specifics of each initiative. Feedback on an industry initiative on a specific technical issue in lieu of a generic communication may be discussed at a public meeting and documented in the meeting minutes. An industry sponsored document proposed to be endorsed in a regulatory guide would be made publicly available and a Federal Register notice would solicit public comment.

At the conclusion of the review, a recommendation would be made to NRC senior management for a decision on whether to accept the industry initiative as an alternative to regulatory action. This acceptance could take several forms. A proposed industry initiative could be endorsed in a regulatory guide, rulemaking activities could be canceled, or a generic communication or inspection program could be revised or canceled. The sponsoring organization would be notified in writing of the results of the review.

As part of the review of the proposal, the NRC would determine what follow-up and monitoring activities are appropriate to provide confidence that the initiative remains effective. These follow-up activities would be determined on a case-by-case basis and could consist of meetings or inspection activities at selected licensees. If the follow-up activities indicate that the initiative no longer is consistent with the general decision criteria, the NRC would initiate appropriate regulatory action.

The issue of monitoring of voluntary programs or activities initiated by industry in lieu of the imposition of regulatory requirements was addressed by an SRM dated July 30, 1996, WITS Item No. 9600086 (see Enclosure 2 of this package). The SRM directed the staff to develop a procedure to verify that such voluntary industry programs are, in fact, being carried out. The SRM also stated that the staff should inform the Commission of possible methods for determining the effectiveness of these programs. Draft NRR Office Letter 506, "Procedure for Tracking Licensee Implementation of Voluntary Industry Programs," has been developed to be responsive to the SRM and is a first step in incorporating initiative monitoring into approved agency procedures. However, the final office letter must await approval of the general decision criteria.

6. General Decision Criteria

Each initiative proposed by regulated entities should be evaluated by the NRC using the same set of criteria. These general decision criteria should be defined and available to the public and industry in advance of the submission and evaluation of any initiative (i.e., the staff does not recommend development of a "revealed" standard that is developed on a case-by-case basis over time). Public disclosure of the general decision criteria will facilitate efficient development of proposals and facilitate the submittal of comprehensive and detailed descriptions of the initiative so that key technical and policy issues raised by the initiative can be quickly identified and resolved by the NRC. Public disclosure of the general decision criteria may also increase the public's perception that the agency's decision-making process is an impartial and objective one. The criteria should also reflect the Commission's determinations with respect to key policy and legal issues.

The items to be considered in the development of the general decision criteria are presented in three preliminary tables. Table 3-1 lists items to be addressed by the sponsoring organization in their submittal for the initial acceptance review. Table 3-2 lists items that will be provided by the staff during the initial acceptance review. Table 3-3 lists items to be used during the detailed technical review. While each item may not be directly applicable to every proposal, Commission approval of the criteria will allow regulated entities to prepare proposals for initiatives in a cost-effective manner. Guidance on information to be submitted, if approved by the Commission, would be formally documented. Each item is discussed in detail below.

6.1 Items For Initial Acceptance Review: To Be Described in the Submittal

6.1.1 Definition of Issues and Safety Significance

The problem or issue the initiative is addressing must be clearly identified and described by the initiative proposal. In general, initiatives are undertaken (i) to address a radiological health and safety problem or (ii) to reduce licensee and NRC resource expenditures when the reduction would not adversely affect the current level of safety or risk being afforded (i.e., resource optimization or burden reduction). Accordingly, the purposes of the initiative must be identified.

If the initiative's purpose is to address a safety or risk problem, the proposal for the initiative must clearly identify the current level of safety, as well as the improvement in safety expected from implementation of the initiative. In addition to an aggregate assessment of the current level of safety, the proposal would indicate the level of safety with respect to the targeted problem.

If the initiative's purpose is resource optimization or burden reduction, the proposal for the initiative must clearly identify the level of resources being expended by licensees and the projected incremental reduction in resource expenditures. An aggregate assessment of current expenditures and incremental reduction would be provided, as well as the highest and lowest expenditures and projected reductions for entities that are expected to experience the greatest and least benefit from the initiative. The projected decrease would be summed for the remaining license term or for the expected period that the licensed activity would be conducted, as appropriate.

6.1.2 Number of Licensees or Sites Included

The initiative proposal must (i) identify the regulated plants or licensees that may be subject to the safety problem or resource optimization issue of the initiative and (ii) identify the plants or licensees that are committed to the initiative. Depending on the safety or risk significance and the nature and level of potential resource savings to the regulated entities and to the NRC, 100% participation in the initiative by the affected population of regulated entities may be required in order to preclude NRC regulatory action.

6.1.3 Identification of Existing or Anticipated NRC Regulatory Action

The definition of an industry initiative is an industry-proposed program or plan of action that is being proposed to replace either an existing regulatory action or one that is anticipated. A key element of this definition is the existing or anticipated regulatory action. The elements of the existing or anticipated regulatory action being addressed by the initiative must be identified in the proposal.

6.1.4 Definition of Industry Resources Devoted to the Initiative

The proposal must specify the industry resources that would be committed to the initiative. The proposal should also demonstrate why the committed resources will be sufficient to implement an initiative to be used as an alternative to regulatory action.

6.1.5 Identification of Specific "Products" that Will Result from the Initiative

The initiative proposal must contain sufficient information that a reasoned engineering determination can be made concerning its technical adequacy. This determination would entail two considerations: (i) the technical adequacy and practicality of the activities and actions that form the elements of the initiative and (ii) some demonstration that the proposed elements will have a substantial impact on the safety issue or, for resource optimization or burden reduction initiatives, that the initiative will not result in any significant reduction in the level of safety currently provided. The initiative proposal must clearly state whether the issue is fully understood or whether additional research is needed. The proposal must clearly identify the specific "products" (e.g., industry guidance document) that will result from the initiative.

If the purpose of the initiative is to significantly reduce licensee or NRC resource expenditures without any significant decrease in the current level of safety or risk, the proposal would identify the estimated decrease in licensee resources that would be expected for each regulated entity and for the entire industry, as well as the predicted decreases in NRC resource expenditures for each regulated entity and for the entire industry**.**

6.1.6 Proposed Schedule, Including Milestones

The initiative must include a proposed schedule of milestones for review. This schedule is only a proposal and establishes a framework of expectations from which the NRC and industry can work to set a mutually acceptable review schedule. The schedule would identify the issues that require more immediate action and those that would be addressed on a more extended schedule.

6.1.7 Proposed Schedule of Industry Implementation of Initiative

The schedule for implementation of a proposal addressing a safety or risk problem must be commensurate with the safety significance and the immediacy of the problem. A significant "safety enhancement" for a problem that could be a candidate for relatively quick implementation, or one in which there is not time to establish, submit, review, endorse, and implement an initiative, may not be appropriate for an industry initiative. A schedule for implementation of resource optimization or burden reduction initiatives must be consistent with the total resources projected to be saved over the remaining term of operation or the expected period that the licensed activity will be conducted.

6.2 Items For Initial Acceptance Review: To Be Provided by the Staff upon Receipt of the Submittal

6.2.1 NRC Resources Needed To Review and Endorse the Initiative

The NRC should make an assessment of NRC resource requirements for the industry initiative. This assessment should take into consideration the initial acceptance review, the detailed technical review, and subsequent monitoring activities. The resource assessment should also address schedular constraints. The assessment of resources to be committed by the NRC also must consider the commitment of the industry.

6.2.2 NRC Resource Savings Resulting from the Initiative

The NRC should make an assessment of NRC resource requirements if the agency pursued independent regulatory action. These resources should be compared to those that would be expended if the NRC accepted the industry initiative to determine whether there is any net savings.

6.2.3 Public Access to Details of Initiative and Comparison with Commensurate Public Access Associated with the Avoided NRC Regulatory Activity

Initiatives should be developed by regulated entities through an open process that includes an opportunity for participation by all potential stakeholders before the initiative is submitted to the NRC. Any interactions between the NRC and regulated entities and their representatives with respect to developing an acceptable initiative should be open to public participation. Initiatives that entail continuing interactions with the NRC concerning the development of the elements and detailed implementation guidance of the initiative must be carefully assessed for compliance with FACA.

In all cases, notice will be published in the Federal Register announcing the receipt of a proposed initiative and its acceptance. If the proposed initiative was developed with the opportunity for participation of all potential stakeholders and a consensus was achieved, and if the proposed initiative is acceptable, the Commission will, unless the adoption of the proposal is in the form of rulemaking, publish notice that the Commission has determined to adopt the proposal without any public comment period. For all other proposed initiatives, the Commission will publish in the Federal Register a notice

of its intention to accept or reject the proposed initiative for public comment, as well as its final decision to accept or reject the proposed initiative.

The NRC should disclose all information supplied by or obtained from industry (subject to relevant FOIA/Privacy Act exceptions) in support of the industry initiative as an alternative to regulatory action. The NRC should also disclose all information supplied by or obtained from industry (subject to relevant FOIA/Privacy Act exceptions) that it uses to assess (i) the quality of implementation by licensees and (ii) the effectiveness of the industry initiative in resolving the underlying issues. This disclosure typically will be through the public docketing process.

6.2.4 Fees Associated with the Review

Based on the resources estimated for the review of the industry initiative, the staff will develop estimates of any 10 CFR Part 170 fees to be assessed to the sponsoring organization to recover the full costs of the review.

6.2.5 NRC Follow-up and Monitoring Activities

Initiative proposals should specify the measures and schedule for monitoring the initial and continuing implementation of all substantive elements of the initiative. The proposal should also provide for notification to the NRC that full initial implementation has been achieved, with the basis for this notification.

Initiative proposals addressing safety problems should specify the measures for assessing the effectiveness of the initiative in resolving the safety or risk issues that underlie the

industry initiative. The bases for selecting the measures should also be described. Initiative proposals addressing resource optimization or burden reduction should specify the measures for ascertaining the reduction in resource expenditures attributable to the initiative. In both cases, quantitative measures are preferred. The frequency of measurement and the bases for selecting the measurement frequency should be specified in the initiative proposals.

6.2.6 Enforcement Policy

Initiative proposals must document all substantive elements of the initiative to ensure that the NRC has appropriate regulatory control over the implementation of an initiative. Regulatory controls may be necessary to ensure that the NRC has a basis for evaluating the adequacy of the initiative's implementation and for taking appropriate regulatory or enforcement action if a licensee fails to implement all elements of the initiative, or whether there is inadequate implementation. Documentation of the substantive elements increases the efficiency of NRC inspections and audits by allowing the NRC official to easily verify the specifics of the initiative. Documentation also facilitates the licensees' implementation of the initiative. For reactor and facility licensees, and materials licensees that have specific rather than general licenses, elements involving actions to be undertaken

by each entity in its licensed activities should be documented in the licensing basis for each regulated entity covered by the initiative. For nuclear power reactor licensees, documentation would be by license condition (i.e., an amendment of the license), a technical specification change, an addition to the FSAR, or other document.

The nature of the regulatory controls deemed necessary by the NRC would depend on the safety or risk significance of the problem being addressed. For nuclear power reactor licensees, issues of relatively high safety significance should be documented (i) in a license condition if an issue is related to the design of the facility and may not be changed except by license amendment, (ii) in the FSAR if the NRC determines that it is acceptable for the licensee to make a change to the initiative element pursuant to 10 CFR 50.59, or (iii) in a technical specification if related to operation. Less-important issues can be documented in the FSAR or in a separate document subject to controls defined in the document, or simply documented in written form on the docket (in which case the NRC can issue a "notice of deviation" for any failure to comply with the commitment).

6.3 Items For Detailed Technical Review of Initiative

6.3.1 Applicable Rules, Regulatory Guides, Standard Review Plan

The staff's detailed technical review of the proposed initiative will be conducted to ensure that the desired level of safety is maintained. Deviation or exemptions from existing regulations will be identified as part of the review. The adequacy of NRC follow-up activities will be included in this review.

No initiative that limits the NRC's authority to conduct inspections of the regulated entities or the auditing organization with respect to the subject matter of the industry initiative will be accepted. No initiative that limits the authority of the NRC to have access to information collected by the third party with respect to the oversight function the NRC administers will be accepted.

An initiative must not be anti-competitive, constitute an unfair trade practice, or otherwise constitute unlawful discrimination. NRC would review the initiative to ensure that the initiative does not unfairly burden competing entities that are not covered by the initiative or does not provide an unfair competitive advantage to entities covered by the initiative.

The review would include a discussion of whether there is any significant adverse environmental impact from the proposed initiative, together with the bases for the discussion. This discussion must address whether the initiative will have a disproportionate adverse impact on minorities, consistent with Executive Order 12898 (February 11, 1994) on environmental justice. Additionally, if the initiative involves rulemaking, an environmental assessment must be performed that includes information and discussion regarding disproportionate impact unless excluded categorically by 10 CFR 51.22. However, if the initiative does not involve rulemaking and only involves issues of guidance, no environmental assessment is necessary pursuant to 10 CFR 51.22(c)(16).

The initiative must not preclude the NRC from complying with requirements imposed by law on the agency or otherwise waive licensee compliance with any applicable statutes.

6.3.2 Consistency with Commission Policies

The initiative proposal should be reviewed to ensure it is consist with all applicable Commission policies.

TABLE 3-1

ITEMS FOR INITIAL ACCEPTANCE REVIEW TO BE DESCRIBED IN THE SUBMITTAL

- Definition of Issue and Safety Significance
- Number of Licensees and Sites Included
- Identification of Existing or Anticipated NRC Regulatory Action
- Definition of Industry Resources Devoted to the Initiative
- Identification of Specific “Products” that Will Result from the Initiative
- Proposed Schedule, Including Milestones
- Proposed Schedule of Industry Implementation of Initiative

TABLE 3-2

ITEMS FOR INITIAL ACCEPTANCE REVIEW TO BE PROVIDED BY THE STAFF UPON RECEIPT OF THE SUBMITTAL

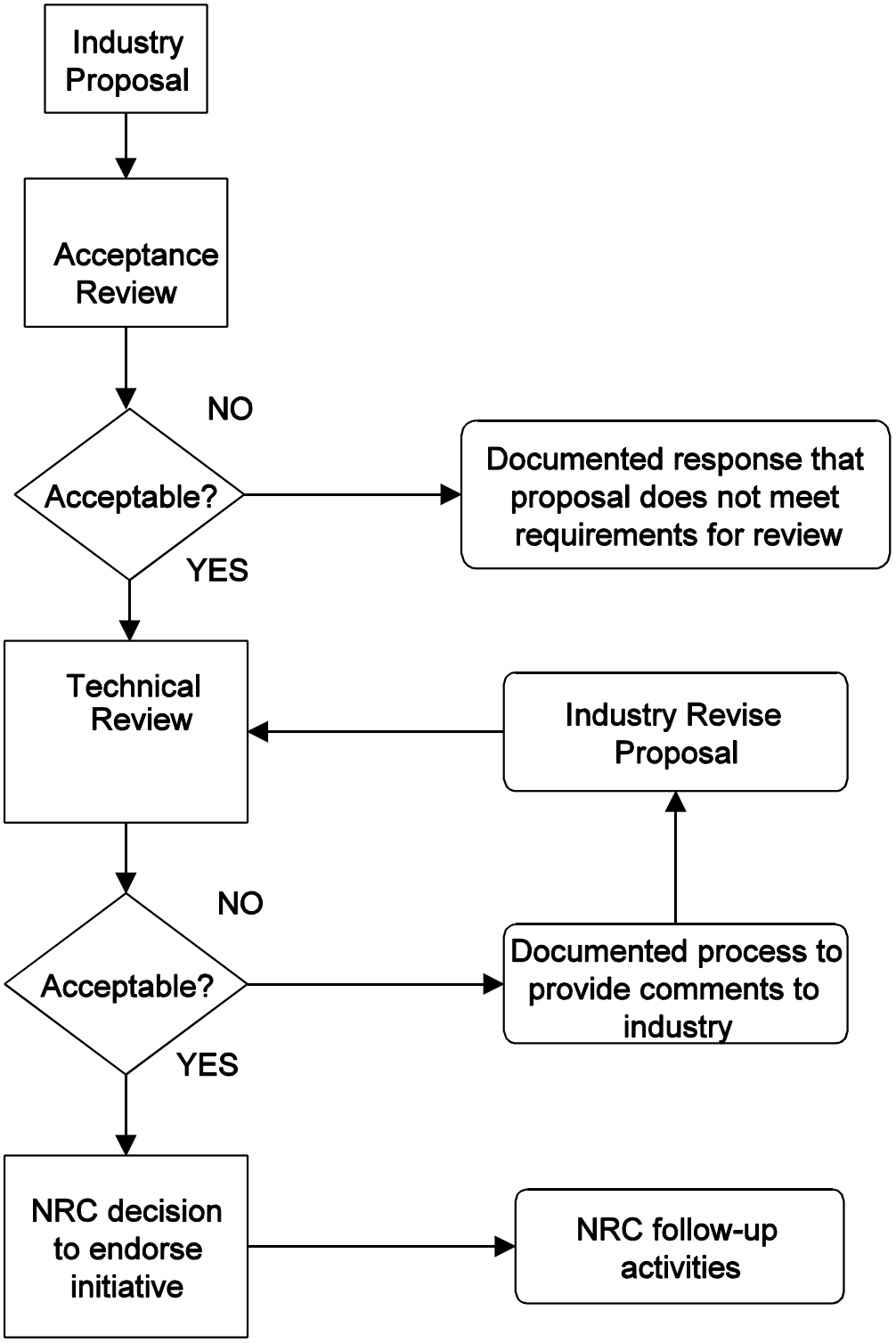
- NRC Resources Needed To Review and Endorse the Initiative
- NRC Resource Savings Resulting from the Initiative
- Public Access to Details of Initiative and Comparison with Commensurate Public Access Associated with the Avoided NRC Regulatory Action
- Fees Associated with the Review
- NRC Follow-Up and Monitoring Activities
- Enforcement Policy

TABLE 3-3

ITEMS FOR DETAILED TECHNICAL REVIEW OF INITIATIVE

- Applicable Rules, Regulatory Guides, Standard Review Plan
- Consistency With Commission Policies
- Other Information Sources, Including But Not Limited To:
  - Probabilistic Risk Assessments
  - Research Results
  - Operating Experience

FIGURE 1 Conceptual Evaluation Process



ENCLOSURE 5
NRC Use of Codes and Standards

1. INTRODUCTION

DSI-13, "The Role of Industry," is directed toward assessing the consideration the NRC should give to industry activities in performing its regulatory responsibilities. Five options were considered by the Commission: (1) continue the current program, (2) expand the role of industry, (3) increase accreditation and certification of licensee activities, (4) increase interaction with industry and professional groups, and (5) use a "Designated Industry Representative." In its final decision on DSI-13, as detailed in Staff Requirements Memorandum (SRM) COMSECY-96-096, the Commission directed the staff to implement Options 1 and 4.

Option 4, as addressed in this enclosure, focuses on consensus codes, standards, and guides (hereafter referred to as standards) developed by standards developing organizations (SDOs). NRC would work with SDOs to develop and endorse new and revised standards needed to support efficient, effective, and consistent performance of industry activities important to safety. It is expected that this would encourage industry to further increase its involvement in the development of standards that could be endorsed by NRC and used by licensees.

As part of the DSI-13 activities, the Task Force reviewed the current NRC process for endorsing codes and standards. Standards have been, for almost three decades, an integral part of the NRC regulatory process. The standards that are well established and referenced by NRC incorporate many years of accepted, good engineering practice. NRC regulatory guides are the primary mechanism for endorsing standards. In a few cases, standards are incorporated by reference directly into the NRC regulations. Without consensus standards, NRC would have to develop the engineering bases for many more of its rules and regulations. NRC participates in the development of and uses standards developed by organizations from a broad range of disciplines. In general, the staff determines which standards should be reviewed or endorsed based upon knowledge gained by participation in SDOs, discussion with licensees, or license amendment requests from licensees. The staff believes that this process is adequate to identify standards that have the highest priority for staff action.

About 150 members of the NRC staff participate in SDOs on standards writing, consensus, and board-level committees. These organizations include the American Society of Mechanical Engineers (ASME), Institute of Electrical and Electronics Engineers (IEEE), American Society for Testing and Materials (ASTM), American Society of Civil Engineers (ASCE), American Concrete Institute (ACI), Health Physics Society (HPS), American Nuclear Society (ANS), and American National Standards Institute (ANSI). The standards developed by these organizations have general industry agreement and thus are more readily accepted for use by licensees.

NRC staff practices for participating in the development and use of standards have been, to some extent, undocumented.** Implementation of Option 4, in conjunction with issues identified

in the SRM [see Section 2 for a discussion of these issues], will require a significant change in staff thinking and action. The staff, while active in the development of standards, is and has been for some time in a reactive mode. Although there are exceptions, the staff essentially reacts to revisions brought forth by other participants in the standards development process and does not often identify new actions or new standards to be developed by SDOs. Further, there is no defined mechanism or process to determine which new standards are needed, which existing standards should be endorsed, and when the endorsement process should be initiated. Also, staff activities in the standards development process are often not sufficiently integrated with the endorsement process to ensure consistent staff positions between development and endorsement, or to ensure timely endorsement actions.

Option 4, which is intended to increase the effective use of standards within the regulatory process, could be accomplished by establishing the option as specific Commission policy, defined in a Management Directive that outlines a structured process for implementing that policy. Effective implementation would require NRC management and other staff to recognize the implementation of Option 4 as an ongoing priority activity. The Management Directive would also integrate support for implementation of Public Law 104-113, "National Technology Transfer and Advancement Act of 1995" (March 7, 1996) (P.L. 104-113), and the supporting Office of Management and Budget (OMB) Circular A-119, "Federal Agency Participation in the Development and Use of Voluntary Standards" (October 20, 1993) (A-119).

P.L. 104-113 requires that Federal agencies use and participate in the development of consensus standards. It also provides for an agency's use of technical standards not developed by consensus bodies. In such a circumstance, the head of the agency is to transmit to OMB an explanation of the reason for using such a technical standard. For example, if NRC were to endorse, in lieu of a consensus standard, a document prepared by the Nuclear Energy Institute (NEI), a report to OMB explaining the reason for the action would be required. Circular A-119 provides guidance for implementing P.L. 104-113. A-119 emphasizes that it is the policy of the Federal government in its procurement and regulatory activities to rely, when feasible, on (consensus) standards; to participate on (consensus) standards bodies; and to coordinate agency participation to ensure that agency resources are used effectively and that views expressed by agency representatives are in the public interest and, as a minimum, do not conflict with the interests and established views of the agency.

** Direction regarding conflict of interest issues pertinent to staff participation in professional organizations is provided in Management Directive 7.3, "Participation in Professional Organizations." Direction on the levels of concurrence and signature for codes and standards correspondence regarding routine and policy matters is provided in the Office of Nuclear Regulatory Research Office Letter No. 11, "Administrative Procedures."

The staff has developed a preliminary implementation plan, which is outlined in Section 3. The plan is structured in two phases: (1) development of a Management Directive and (2) implementation of that directive. It is proposed that upon approval of this plan by the Commission, the staff would, consistent with the Phase I description, develop the Management Directive. Phase II, implementation of the directive, would commence upon approval of the Management Directive.

Three additional subjects, (1) the staff's rationale for applying backfit considerations when endorsing later editions of the ASME Code, (2) how backfit analyses consider the Code consensus view if licensees are permitted to selectively determine which Code requirements are applicable to their facilities, and (3) the practicalities and implications related to the inspection and enforcement of licensees' conformance to various different Code edition requirements, were among the items transmitted to the staff by an SRM dated February 21, 1997, "Briefing on Codes and Standards" (WITS 9700028). The staff responded to this SRM by a Commission Paper dated July 23, 1997, stating that the subjects of this WITS "will be addressed in the implementation of DSI-13, which will also involve interactions with industry groups, professional societies, technical institutes, and other stakeholders." The staff's preliminary findings on these issues are presented in Issue 3 of Section 2, below.

The initial step in Phase 1 is a meeting with stakeholders. Development of the Management Directive would commence after the stakeholder meeting. Issues to be discussed at the meeting would include (1) the standards development process, including the importance of the SDO identifying the safety significance of new standards and revisions, the impact of proposed standards on licensees and the regulatory process, and the NRC process for developing regulatory positions; (2) the NRC endorsement process, including the impact of the Administrative Procedures Act (APA) (5 USC 553); (3) P.L. 104-113 and A-119, as these government-wide provisions affect NRC participation in the development and use of consensus standards and the development of ballot positions by the NRC staff, and (4) 10 CFR 50.55a, "Codes and Standards," with regard to its 120-month update provision and the above described concerns identified in WITS 9700028.

This paper has been coordinated between offices to ensure that implementation plans developed for DSI-13 are compatible with and do not duplicate activities being planned and conducted for DSI-11, "Operating Reactor Program Oversight," and DSI-12, "Risk-Informed, Performance-Based Regulation." Additionally, DSI-13 actions that are directed to expediting the evaluation of industry initiatives and promoting more rapid adoption of consensus standards are being included in the goals and strategies for the FY 1998 NRC Excellence Plan.

2. COMMISSION IDENTIFIED ISSUES

In its decision on DSI-13, the Commission directed the staff to develop an implementation plan for pursuing Option 4. In that decision, the Commission identified seven issues that the staff should consider in developing the plan. These issues, along with a discussion of each issue and a related proposed action, are provided below. The implementation plan to address these issues is in Section 3.

Issue 1 **The need to streamline and simplify the NRC's internal process for endorsing codes and standards within a year after they are issued by a professional society. Consideration should be given to the American Society of Mechanical Engineers' recommendation to maximize concurrency in the professional society process and the NRC regulatory process.**

Discussion

The process and timeframe for preparing a regulation to endorse a standard is largely defined by the need to comply with the APA. Appendix I depicts the time typically spent in developing a regulation and in its review and approval; the process for a regulatory guide is similar. The schedule for issuing a proposed and final rule is about 18 months; the time for a draft and final regulatory guide is similar. This time is composed of about 5 months for development of a regulatory position based upon a technical review of the standard, 3 months for public comment, and 10 months for internal review and approval. The responsibilities for developing and issuing a regulation are defined in NRC Management Directive 6.3, "The Rulemaking Process," which is intended, among other things, to ensure compliance with the APA.

During its review, the team divided the overall process to develop and endorse new or revised standards into two phases. The first phase includes staff participation in an SDO and the internal SDO process that results in the new or revised standard being issued. The discussion of improvements to streamline the process focused on the first phase. While the activities in this phase have evolved from U.S. Atomic Energy Commission (AEC) practices, clear procedures that guide staff participation in SDO activities have not been developed. The second phase includes the steps that the staff follows to endorse these standards. The current NRC process for the second phase of endorsing new or revised standards is based upon the requirements of the APA. Endorsing a new or revised standard can be a lengthy and resource-intensive process as a result of the requirements for public notification and comment in the APA rulemaking process.

In practice, the internal process begins when a determination is made that a member of the staff should be nominated to a specific standards writing committee. The Director of the Office of Nuclear Regulatory Research nominates staff to serve on SDOs. An important aspect of staff participation on a standards writing committee involves coordination of staff views on ballot actions at all levels of the standards development process. While this has been done in the past, coordination is sometimes too limited in some areas to ensure that issues, that could affect NRC endorsement are adequately identified by cognizant staff and presented consistently by the staff representatives at the various standards writing and consensus committee levels. P.L. 104-113 and A-119 place increased emphasis on criteria the staff must meet concerning coordination of agency views on ballot actions as part of staff participation on SDOs.

The process described above results in delays in the review and endorsement of standards. Most significant are (1) delaying development of a regulatory position to accept or reject the proposed standard until after final publication of the standard and (2) developing the draft rulemaking or regulatory

guide at the same time as developing the standard. These issues must be addressed to achieve the goal of endorsing standards within one year after issuance by an SDO.

One method of streamlining the process is to focus resources only on standards the NRC would consider for endorsement in the regulatory process. To accomplish this standards endorsement efforts must be prioritized. The determination of which standards the staff will consider for endorsement involves several factors. One factor would be requests from licensees for NRC endorsement of a new or revised standard. Another factor would be whether the new or revised standards are safety significant or constitute relaxations for reactor licensees. These changes may not satisfy the criteria of the backfit rule, 10 CFR 50.109, and their use would be voluntary. Another factor is that A-119 encourages endorsement of consensus standards.

Changing the NRC's review and endorsement process to facilitate earlier development of a regulatory position will not be practical in all cases and may become increasingly difficult. Early development of a regulatory position on a standard that undergoes frequent revision as it moves up through various committees levels during the development process would require far more staff effort than would be required if the staff were to wait to review the revised final standard. An additional factor is the changes that are now being made to the ASME standards development process. In an attempt to shorten the time to develop a standard, ASME committees are increasing their use of computer technology. As this process is implemented, the development time will be compressed and the opportunity to formulate regulatory positions before the ASME issues the standard will be reduced. The ASME is using this new process to develop a standard on risk management; both the ASME and the NRC staff will see whether the time to develop a standard can be shortened.

An additional factor is the acceptability of standards. There are recent examples of revisions to standards that did not have an adequate technical basis or comply with existing regulations. These revisions were approved over the negative ballots of the NRC representatives on the writing and consensus committees. For example, in 1995 revisions were made to the ASME piping design criteria. These revisions did not have an adequate technical basis and, as a result, could not be endorsed by the NRC. The revisions and technical basis are being reviewed by an ASME special task group with NRC staff involvement. Another recent example involves changes made to the ASME standard for quality assurance programs at nuclear facilities. Several revisions to this standard are inconsistent with the provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR 50. In both examples, the consensus standards were inadequate and have not been endorsed by the NRC.

Finally, there is the potential problem that, if NRC develops a regulatory position on a standard still under development by an SDO, the SDO organization may perceive it as trying to unfairly influence the independent consensus process of the SDO by indicating the acceptability or unacceptability of the proposed standard during the consensus process.

Proposed Action

In order to streamline the endorsement process, the present process needs to be more efficient and its scope carefully defined. It is not intended that steps be eliminated from the process, but rather that the steps be started earlier. Efficiencies can be gained in the existing steps of the rule and regulatory guide development process, but to achieve the major reduction in time desired, the existing process must be started earlier and closer adherence to schedules must be achieved. Potential improvements to the existing process are:

- Develop a process and criteria for identifying and prioritizing standards that should be considered for endorsement in the regulatory process.

- Initiate the staff development of technical bases for regulatory positions and draft rulemakings and regulatory guides before the standard has been issued in final form by the SDO. The staff review process would begin when the standard has been defined sufficiently to enable development of the technical basis for a regulatory position. It is recognized that final development actions may alter the standard, which could affect the technical basis for the regulatory position. Nevertheless, early initiation of staff review could save as many as 4 months in the development process by having the latter phase of development and the initial phase of endorsement run in parallel.

- Establish an interoffice, interdisciplinary working group to develop regulatory positions on emerging standards. This group would be composed of staff who are cognizant of the subject and who are able to infuse the thoughts of their office into the regulatory position. Implementation of this concept would require ongoing assignments of staff participating in the group and could reduce the number of comments during the internal NRC division reviews and, thereby, shorten that portion of the review cycle.

- Reduce the overlapping requirements for analysis. The staff's current practice of documenting its analyses in multiple documents results in unnecessary expenditures of time and resources. In particular, the staff develops a regulatory analysis, that attempts to identify the regulatory costs and benefits of a proposed action, a submittal to the Committee to Review Generic Requirements (CRGR) on backfitting, and a clearance package submitted to OMB to address the Paperwork Reduction Act. In substance, each of these documents attempts to address the backfit rule (i.e., is the cost of a proposed regulatory requirement justified in light of the increment and value of the safety improvement to be achieved). The problem of multiple documentation was identified and discussed in a 1990 report for the NRC.[***]

- Ensure adherence to the approved schedule for each rulemaking or regulatory guide.

These actions are addressed in the plan, Table I, Elements I-3 through I-6.

[***] "Needs and Options for Improving Guidance for Regulatory Analysis in Support of Safety Resolution," MITRE Corp., 1990.

Issue 2 **Internal performance indicators to ensure timely update of regulations and regulatory guides**

Discussion

As a result of the Strategic Assessment and Rebaselining Initiative and the development of the NRC Strategic Plan, internal performance indicators and tracking systems that monitor revisions of rules and regulatory guides are being implemented. Revisions of selected rules and regulatory guides are identified in the NRC Performance Plan for FY 1999, dated September 1997, as output measures. Revisions of rules and regulatory guides are also contained in office Operating Plans. Additionally, rulemaking activities are contained in the Rulemaking Action Plan, and regulatory guide activities are contained in office tracking systems. The staff believes that these performance indicators are adequate to ensure timely update of rules and regulations once the need for such updates has been identified.

The Office of Nuclear Material Safety and Safeguards (NMSS) has initiated an effort to have each of its divisions (1) identify the regulatory guides it uses, (2) identify whether there is an existing standard associated with the regulatory guide, and (3) if there is none, determine whether a standard exists or should be developed to replace the internal technical standard. Each regulatory guide is then prioritized relative to its importance in carrying out the division's functions. Appendix II provides the format that is being used to document this evaluation. Once each division completes its inventory, its progress in completing revisions or deletions to key guidance is tracked in the Operating Plan.

Proposed Action

No additional action. Consistent with the discussion of Issue 5, a plan would be developed to review existing rules and regulatory guides that reference consensus standards to determine whether there is a need to update or revise the reference.

Issue 3 **The degree to which the current backfit rule implementation unnecessarily impedes the adoption of updated codes and standards**

Discussion

The staff does not believe that implementation of the backfit rule unnecessarily impedes NRC's endorsement of new, revised, or updated standards for nuclear power reactors.[****] If the premises are accepted that the backfit rule was imposed to ensure that substantive regulatory requirements are well-founded in protection of public health and safety, and that the costs imposed on regulated entities are commensurate with the benefits accrued,[*****] then compliance with the backfit rule is consistent with good regulatory practice. The staff agrees that regulatory action should be imposed only where there is a defined safety benefit whose costs are justified; therefore the staff concludes that the backfit rule is

---

[****]The Backfit Rule, 10 CFR 50.109, sets forth the backfitting standards applicable to nuclear power plants. Sections 72.62 and 76.76 set forth backfitting standards applicable to independet fuel storage facilities and gaseous diffusion plants. Sections 72.62 and 76.76 have rarely been invoked by the NRC or by licensees or applicants. Thus, the impact of backfitting on the adoption of standards occurs primarily with respect to nuclear power plant licensees. However, in a Commission SRM (June 29, 1995) that approved the staff's recommendation in SECY 95-061 (March 14, 1995) that a backfit rule applicable to nuclear materials licensees should not be developed, the Commission directed the staff to consider, as part of the materials licensing reevaluation program, the applicability of a backfit provision to particular classes of licensees (e.g., uranium mills). In an SRM (August 21, 1996) regarding COMSECY-96-028, the Commission directed that the CRGR scope be expanded to include NMSS activities, and on March 23, 1996, the Commission approved an amendment to the CRGR Charter permitting it to review, at its discretion, proposed regulatory actions that are directed at nuclear materials licensees. Backfitting may therefore become a *de facto* consideration for the adoption of standards that affect certain nuclear materials licensees. However, there is insufficient experience in the application of backfit criteria to materials licensees, independent spent fuel storage licensees, and gaseous diffusion plant licensees for the staff to determine whether application of backfit criteria in these areas will have a substantial adverse impact on the staff.

[*****]Appendix III describes the historical evolution of the backfit rule in 10 CFR 50 and recent (1993) Commission consideration of staff-identified issues involving its implementation.

properly screening out proposed regulatory actions that are not well founded or are not cost-justified.[******] New standards that the staff would want licensees to consider using, such as those related to risk-analysis, may not pass 10 CFR 50.109 backfit criteria and, therefore, would only be implemented by licensees on a voluntary basis.

In a February 21, 1997, SRM, the Commission raised a number of issues with respect to the ASME Boiler and Pressure Vessel Code (ASME Code) and the impact of the backfit rule on the staff's updating of 10 CFR 50.55a to endorse newer editions and addenda of the ASME Code. In SECY 97-159, the staff responded to some of the Commission's questions, but noted that the staff's response to the questions involving how the backfit analysis considers the consensus process, and the enforcement and inspection practicalities involved if a licensee were to have an option to selectively determine among acceptable ASME Code editions and addenda, would be addressed in the staff's paper on implementation of DSI-13. In this regard, the staff's view is that the Backfit rule has *not* been a significant impediment to adoption of newer ASME Code editions and addenda. However, the difficulty of preparing the backfit analysis would substantially increase if the staff were required to analyze each revision or group of related revisions of the ASME Code. The difficulty of preparing the backfit analysis would not be lessened by acknowledging that the ASME Code is the product of a "consensus process," since the backfit analysis must address the criteria in the backfit rule and the ASME does not prepare any documentation that could function in lieu of the staff-prepared backfit statement. In addition, it is OGC's view that the ASME's process for Code development would not serve as an acceptable legal basis for avoiding the notice and comment requirements for rulemaking in the APA.

The staff does not believe there would be any fundamentally new challenge to the inspection or enforcement of licensees' ASME Code programs if licensees were permitted to selectively determine which ASME Code requirements, among those previously endorsed by the NRC, were applicable to their facilities would pose. As a general matter, each licensee already exhibits considerable diversity with respect to the licensing basis relevant to the ASME Code. First, licensees have taken advantage of the provisions in 10 CFR 50.55a to diverge from the Code editions, addenda, and individual requirements mandated in 10 CFR 50.55a. These provisions include approval of alternatives under 10 CFR 50.55a(a)(3), the use of "portions" of editions or addenda under 10 CFR 50.55a(f)(4)(iv) and (g)(4)(iv), and approval of relief under 10 CFR 50.55a(f)(6) and (g)(6). Second, the ASME's issuance of "Code Cases," which provide alternatives to the Code that are endorsed, as appropriate, by regulatory guides, provide another potential avenue for licensee diversity in implementing the Code. Because of this existing diversity, the staff does not believe that the difference between the current regulatory regime and one that would allow licensees to selectively determine which requirements are applicable to their facility poses a fundamental shift in inspection and enforcement.

[******]Although the staff believes that the backfit rule does not pose an unwarranted substantive impediment to the NRC's endorsement of new and revised standards, the staff believes that improvements can be made in reducing the overlapping documentation requirements for analysis. This is discussed in Issue 1.

Proposed Action

No new action is proposed to address the issue of backfitting.

Issue 4 **Whether greater use should be made of all available codes and standards (not just ASME and IEEE standards) in our regulations and regulatory guides**

Discussion

NRC has a long history of using consensus standards. In a review[*******] of its regulatory documents, NRR identified over 4000 citations to standards (some individual standards had multiple references to specify different portions of the same standard) developed by more than 30 separate standards developing organizations. Similarly, NMSS regulatory documents reference numerous standards from a variety of standards developing organizations. P.L. 104-113 and implementing A-119 both emphasize the need for agencies to integrate the use of consensus standards as part of their procurement and regulatory functions.

Proposed Action

One action that could be implemented that would focus on increased utilization of codes and standards would be the addition of specific questions in each proposed rule or regulatory guide published for public comment. The questions could be added to the Federal Register notice for the proposed action and specifically request commenters to identify codes or standards that could be substitutes, in whole or in part, for the proposed rule or regulatory guide.

The final rulemaking or regulatory guide issuance would restate the statement, acknowledge and summarize any comments received, and respond to the comments.

This action is addressed in the plan in Table 1, Element I-6.

Issue 5 **Whether the intent of Public Law 104-113 is being fully addressed in all of our regulatory requirements and guides**

Discussion

[*******] J.R. Nickolaus and K.L. Bohlander, "Codes and Standards and Other Guidance Cited in Regulatory Documents," NUREG/CR-5973, Revision 2, August 1995.

Based upon the NRC's longstanding and continuing practice of utilizing consensus standards and participating on the Interagency Committee on Standards Policy (ICSP),[********] the staff believes that the intent of P.L. 104-113 is being fully addressed. There are, however, several caveats. The first is that since present practice is not documented, staff participation in the development and use of standards across the agency is not consistent. Second, a process has not been developed to identify technical standards used by NRC that are not developed by voluntary consensus bodies and, accordingly, no action has been taken to advise OMB as to the reason for using such standards. Third, one item contained in A-119 involves a review of agency technical standards (e.g., regulations, regulatory guides, Standard Review Plan sections) to identify the provisions that could be replaced by reference to consensus standards. A-119 currently states that each agency should conduct this review on a 5-year cycle. However, a revision to A-119 is being prepared that would replace the 5-year requirement with a provision to establish a process for ongoing review of the agency's use of standards for the purpose of appropriate updating. The staff has not initiated the review based upon several factors: the long-standing NRC practice of utilizing consensus standards, the resources required, and the evolving nature of the guidance contained in A-119.

P.L. 104-113 promotes the use of standards to reduce the cost to Government of developing its own standards and to further the policy of reliance upon the private sector to supply the Government's needs for goods and services. The law specifies that Federal agencies should use and participate in the development of consensus standards, but it also contains provisions that permit agencies to use technical standards not developed by consensus bodies. P.L. 104-113 specifies that:

> . . . a Federal agency may elect to use standards that are not developed or adopted by voluntary consensus standards if the head of the agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards.

A-119 provides detailed guidance for implementing P.L. 104-113. A-119 emphasizes that:

> It is the policy of the Federal Government in its procurement and regulatory activities to rely, when feasible, on voluntary standards; to participate on voluntary standards bodies; and to coordinate agency participation to ensure that agency resources are used effectively and that views expressed by agency representatives are in the public interest and, as a minimum, do not conflict with the interests and established views if the agency.

[********]The ICSP is administered by the Department of Commerce through the National Institute of Standards and Technology. The ICSP is comprised of representatives from various Federal agencies, including the NRC. The committee provides an interface between Federal agencies and the OMB regarding the implementation of P.L. 104-113 and A-119. Part of this effort includes discussions with OMB staff to clarify and revise A-119.

A-119 emphasizes that an agency is not committed to use a voluntary standard that is, in its opinion, inadequate, does not meet statutory criteria, or is otherwise inappropriate. A-119 requires that each agency establish an agency Standards Executive who is responsible for, among other things, (1) ensuring coordination of agency views among its representatives and among other Federal agencies on the same standards developing body, (2) developing and implementing an agency-wide directory that identifies agency employees participating on standards developing bodies, and (3) submitting an annual report on the status of agency interactions with standards developing organizations.

Proposed Action

The plan provides for a documented process to define staff participation in SDOs, identification of non-consensus documents that are endorsed in rules or regulatory guides, and a plan to address the review of existing rules and regulatory guides.

This action is addressed in the plan inTable I, Element I-2.

Issue 6 **Whether there are needs for new codes, standards, and guides and recommendations for areas of emphasis. The NRC's initial activities in pursuing Option 4 should include standards development in Probabilistic Risk Assessment (PRA) as discussed in the PRA Framework Document (SECY-95-280).**

Discussion

As part of activities related to DSI-13, the staff met with representatives of ASME in June 1997 to discuss the need for new standards, including standards in probabilistic risk assessment (PRA). As a result of these discussions, a preliminary process has been developed that will guide the staff in identifying the need for new standards and for the initial interaction with standards organizations. In October 1997, the ASME Board on Nuclear Codes and Standards voted to propose to the ASME Council on Codes and Standards to undertake development of a standard on risk management that would define the level of quality needed for the use of PRA techniques in various nuclear applications. The Council approved the proposal to develop this standard in November 1997. Development is continuing on ASME codes and standards that apply risk-informed techniques to inservice inspection and inservice testing. The staff has been heavily involved in the development of these standards. Both the ongoing and planned PRA standards are a part of the PRA Implementation Plan as part of DSI-12 activities, consistent with the structure given in SECY-95-280.

The staff has in the past, on an ad hoc basis, requested SDOs to develop new or to revise existing standards to address specific issues. This included developing new rules for thermal annealing a reactor pressure vessel and revising existing rules to expand reactor vessel examinations.

Proposed Action

The plan provides for developing of guidance for determining when an issue, identified through existing processes, should be referred to an SDO for resolution. The guidance will include defining NRC's process to identify the need for new standards, internal review process, and initial interaction with SDOs. The staff will review the ASME standards on PRA with the intent of endorsing them, as appropriate, in regulatory guides and the Standard Review Plan.

This potential action would be addressed in the plan in Table 1, Elements I-4, I-5, and I-6.

Issue 7 An assessment of the required NRC resources and anticipated periods for commitment of such resources

Discussion

The proposed Management Directive would address both new and ongoing activities related to staff participation in SDOs and the use of codes and standards in regulations and regulatory guides. One aspect of implementing the proposed actions is the identification of staff time expended on specific codes and standards activities, which would slightly modify the current system of tracking time spent on various tasks. The purpose of this change would be to provide a more accurate accounting of resources devoted to this activity for future decisions related to the benefits of participation in specific standards organizations.

Estimates of the resources required to implement the actions associated with each of the previously discussed issues follow. No cost benefit is implied by the resource estimate. The resources were estimated in compliance with the SRM directive. The additional resources generally represent increased effort by the staff already involved in the process. Significant additional travel is not anticipated as the additional work will typically consist of additional inhouse reviews and coordination.

Issue 1 (Streamlining): The activities to shorten the endorsement process by earlier development of a regulatory position on emerging standards could require a significant increase in resources. Approximately 10 additional FTEs annually could be required for this item. As discussed below, there are drawbacks to this approach. The meeting with stakeholders is intended to (1) help the staff determine a process that would identify those new or revised standards that the staff should review, and (2) help determine improvements that could be made to improve the efficiency and effectiveness of staff reviews of these standards. Following this meeting, the staff intends to provide a more clearly defined process and resource estimate in a subsequent paper to the Commission. Since this item could have a significant impact on programmed activities, and may not appreciably shorten the time needed to endorse a standard, potential benefits and detriments for each item, as well as resource impacts, will be discussed in that paper. The paper will discuss the potential time reductions in the context of the total time required to endorse a standard.

Issue 2 (Internal performance indicators): Actions to ensure tracking of regulations and regulatory guides will require no additional resources.

Issue 3 (Backfitting): No additional resources are required to implement the ongoing backfit process for endorsing standards.

Issue 4 (Greater use of all available codes and standards): Each proposed regulation or regulatory guide could contain a statement that requests public input regarding whether there is a consensus standard that could be used to replace or supplement the details of a regulatory action. This would require new resources. Based upon the number of noticed regulatory actions, it is estimated that an additional 1 to 3 FTEs annually would be required to review and resolve public comments regarding the availability and applicability of standards that could be used in the context of the proposed actions.

Issue 5 (P.L. 104-113): The action to fully implement P.L. 104-113 and supporting A-119 will require additional resources. Currently resources are expended to comply with the OMB request for an annual report regarding NRC's use of codes and standards. It is estimated that an additional 1 to 3 FTEs annually would be required to implement, among other things, the ongoing review of regulatory documents required by A-119 to determine which provisions could be replaced with a reference to a consensus standard.

Issue 6 (Need for new standards): This action would implement a new process and would require additional resources. It is estimated that an additional 1 to 3 FTEs annually would be required to identify specific needs for standards that should be referred to an SDO for resolution, prepare a brief cost/benefit analysis to support the recommendation, and process the action through NRC office-level management for action by the NRC Standards Executive to interact with the appropriate SDOs.

The estimate of additional resources is based upon past experiences when the standard being developed or revised was consistent with existing regulations and any significant changes made to the standard were made early in the development process. This is not always the case. Standards are sometimes issued that do not meet applicable regulatory requirements. As a result, additional NRC resources are needed to complete a detailed review of the standard and to develop the modifications or exceptions necessary to clearly identify the extent to which NRC endorses that new or revised standard. A new complicating factor is the expedited process ASME committees will use to develop new or revised standards. As this process is implemented, it is likely that the significance of individual changes will not be clear until much later in the revision process when a more complete revision begins to be assembled. While there may be long-term savings of resources by early development of regulatory positions on emerging standards, the magnitude of these savings cannot be determined at this time.

3. THE IMPLEMENTATION PLAN

3.1 Guiding Principles

The preliminary plan was developed based on the following principles:

- The plan should define agency policy and objectives and staff responsibilities for the development and use of standards needed to support the efficient, effective, and consistent performance of industry activities important to safety.

  - The plan should include activities and responsibilities to fully implement P.L. 104-113 and A-119.

  - The plan should provide for monitoring and evaluating program effectiveness.

3.2 The Plan

The preliminary plan is structured into two phases. Phase I, Development of Management Directive, provides for development and documentation of a structured process that addresses the major aspects of staff participation in the development and use of consensus standards. This Management Directive would define, among other things, policy, objectives, authorities and responsibilities. There would be a Handbook that provides procedures for implementation of the directive. Phase II, Implementation, would provide for phased implementation of the documented activities. Phases I and II are delineated, respectively, in Tables 1 and 2, below.

Development of the Management Directive is scheduled to be completed within 4 months of initiation. Phase II is scheduled to be initiated upon approval of the Management Directive. Implementation will be phased in and will continue as an ongoing process that will be monitored periodically to ensure program effectiveness.

TABLE 1

PRELIMINARY
IMPLEMENTATION PLAN

PHASE I -- Development of Proposed Management Directive

"Staff Participation in the Development and Use of Consensus Standards"

Element #	Recommended Element for Management Directive
I-1	Meet with Stakeholders
I-2	P.L. 104-113 and OMB Circular A-119
I-3	Staff participation on standards developing organizations to include: • selection of committees and authorized staff representatives (criteria for committee selection and staff participation) • performance elements and standards of authorized staff representatives • agency directory of staff membership • agency policy regarding participation in professional organizations
I-4	Internal coordination to include: • agency-wide responsibilities of Standards Executive • early development of regulatory positions during standards development process • preparation of trip reports and other communications • database of staff actions • office determination of the need for new standards or revisions of existing standards

Element #	Recommended Element for Management Directive
I-5	External coordination to include: • appropriate SDO informed of standards needed by staff • staff participation in SDOs
I-6	Endorsement to include: • timeliness (performance indicators) • implementation of interoffice, interdisciplinary team • integration of staff input from standards development with endorsement process • backfitting • Federal Register notice with request for information on applicable standards
I-7	Orientation to include: • initial familiarization with Management Directive, P.L. 104-113, and A-119 • periodic review of changes in governing procedures
I-8	Monitoring and assessment to include: • all phases of implementation • parameters to be monitored • criteria for acceptance

TABLE 2

IMPLEMENTATION PLAN

PHASE II -- Implementation

Element #	Element	Milestone	Schedule (months)
II-1	NRC Management Directive	Issue to all staff	1*
II-2	Staff participation	Complete review of NRC participation, revise format, as necessary, of existing agency directory, and update staff SDO committee information	4
II-3	Training	Hold initial indoctrination session on Management Directive for all staff participants identified in II-2, above, and their cognizant management.	5

*Schedule measured from date of approval of Management Directive.

Element #	Element	Milestone	Schedule (months)
II-4	Internal coordination	• Initiate agency-wide coordination by Standards Executive (A-119) • Initiate initial phase of review (A-119) • Identify standards presently endorsed by NRR and NMSS • Identify needs for new and updated standards and prioritize them in each program office -- include in Performance Plan	1 1 2 3
II-5	External coordination	• Identify and establish high-level liaison with SDOs • Present documented needs to standards writing committees	4 4
II-6	Monitoring of program	• complete baseline review • validate compliance with law and circular	4 6

APPENDIX I
EXISTING STANDARDS ENDORSEMENT PROCESS
BY RULEMAKING

DEVELOPMENT	CUMULATIVE TIME (months)	APPROVAL AND ISSUANCE
Task initiation	-5	
Rulemaking Plan developed	-4	
	-3	Rulemaking Plan approved by OGC, OSP, and Program Office
	-1	Public comment period for Agreement States (if applicable)
	0	Rulemaking Plan approved by EDO
Proposed Rule completed	4	
	5	Division
	6	Office
	6	CRGR
	6	ACRS/ACNW/ACMUI
	7	EDO
	7	OMB
	8	Commission Review
	9	Issue proposed rule
	12	Public comment period ends
Public comments resolved	14	
Final rule completed	15	
	16	CRGR and ACRS/ACNW
	16	OGC
	16	OSP, OE (if applicable)
	16	Program Office
	17	Division--RES
	18	EDO or Commission Approval
	18	Final rule issued

Note: Regulatory Guide process is similar.

APPENDIX II

FORMAT FOR EVALUATING NEED TO UPDATE REGULATORY REFERENCES TO STANDARDS

Is There an

		Yes	**Yes**	**No**					

APPENDIX III

BACKFITTING

. Historical Background

The Commission originally adopted a backfit rule in 1970 (35 FR 5317, March 31, 1970),[1] which provided that:

> The Commission may, in accordance with the procedures specified in this chapter, require the backfitting of a facility if it finds that such action will provide substantial, additional protection which is required for the public health and safety or the common defense and security. As used in this section, "backfitting" of a production or utilization facility means the addition, elimination or modification of structures, systems, or components of a facility after the construction permit has been issued.

In 1983, in response to nuclear power plant licensees' complaints about the NRC's lack of compliance with the 1970 backfit rule, the Commission published an Advanced Notice of Proposed Rulemaking (ANPR) on backfitting (48 FR 44217, Sept. 28, 1983), as well as an "Interim Policy Statement on Revision of Backfitting Process for Power Reactors" (48 FR 44173, September 28, 1983). Thereafter, the Commission published a proposed rule (49 FR 47034, November 30, 1984) and a final rule (50 FR 38097, September 20, 1985) on backfitting. The 1985 backfit rule was vacated by the U.S. Court of Appeals for the D.C. Circuit in 1987. Union of Concerned Scientists v. NRC, 824 F.2d 103 (D.C.Cir. 1987). The Court held that economic costs may not be considered in ensuring or redefining adequate protection of the public health and safety or common defense and security, but that the language of the 1985 backfit rule was unclear whether economic costs could be considered in ensuring or redefining adequate protection. The Court remanded the rule for further consideration and action by the agency. In 1988, a revised backfit rule (53 FR 20603, June 6, 1988)[2] was published to clearly state that economic costs cannot be considered when the backfit is necessary for ensuring or redefining adequate protection. The current backfit rule states:

> (a)(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the

---

[1]The proposed rule was published at 34 FR 6540 (April 16, 1969). The 1970 final rule did not differ from the proposed rule.

[2]The proposed rule was published at 52 FR 34223 (September 10, 1987).

analysis described in paragraph (c) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(a)(4) The provisions of paragraph. . . (a)(3) . . . are inapplicable...where the commission or staff . . . finds and declares, with appropriate documented evaluation for its finding, either:

> (I) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or
>
> (ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or
>
> (iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

II. Recent Commission Consideration of Implementation Issues

In 1993, the Staff prepared SECY-93-086, “Backfit Considerations” (April 1993), which requested Commission guidance on whether the backfit rule should be revised to address difficulties encountered in situations in which a seemingly worthwhile change to the regulations could not be adopted because of difficulties in demonstrating that the change represents a “substantial increase in the overall protection of the public health and safety or the common defense and security.” The SECY paper identified several areas in which rulemakings thought to be worthwhile have been difficult to justify as involving a substantial increase in safety.

- Rulemakings to achieve consistency with national and international standards, or consistency with state-of-the-art technology, or advanced risk assessment methodology were sometimes recommended to ensure that licensee programs reflect current knowledge and are not based upon obsolete regulatory requirements.

- Codification of industry practices in order to ensure that all licensees, and not just a high percentage, achieve expected performance results and that backsliding does not occur.

SECY 93-086 identified revisions to (1) Part 20 to "[achieve] conformance with...national and international standards . . . ;" and (2) Part 26, "Fitness for Duty Programs," to achieve conformance with revised industry and governmental drug testing standards, as rulemakings for which it was difficult to demonstrate the "substantial increase" criterion of the backfit rule.

In a June 30, 1993, SRM, the Commission declined to initiate rulemaking to amend the backfit rule. Instead, the Commission noted that the "substantial increase criterion was flexible enough to permit qualitative arguments on increased safety, as well as to allow for arguments that "consistency with national and international standards, or the incorporation of widespread industry practices, contributes either directly or indirectly to a substantial increase in safety." The Commission also indicated that when a proposed rule does not meet the "cost-justified substantial increase" standard but, nonetheless, should be adopted for non-safety reasons, it would be willing to consider promulgating such rules as exceptions to the backfit rule on a case-by-case basis if the proposal, not to apply the backfit rule, were made the subject of notice and comment.

Since issuance of the June 30, 1993, SRM, the staff has had an additional 4 years of experience in backfit rule compliance and has developed and relied upon the following qualitative arguments in attempting to demonstrate a substantial increase in safety:

- Ensuring a minimally acceptable level of regulatory performance for all licensees (i.e., raise the performance of poorly performing outliers to a minimum level of safety).

- Ensuring consistency of performance by all licensees.

- Preventing "backsliding" (e.g., assuring the continuation of voluntary actions for which there is no regulatory requirement).

- Ensuring the proper legal basis for enforcement action, including issuance of a notice of violation, a penalty, and issuance of an order to comply with the minimum level of acceptable performance.

To date, the Commission has not approved any rulemaking that relied upon these qualitative arguments.

III. Endorsement of the ASME Code and Backfitting

Current Backfitting Practice

SECY 97-159 discusses the staff's current practice with respect to backfitting of the ASME Boiler and Pressure Vessel Code (ASME Code). In brief, the staff's position is that backfit

analyses are not required for the NRC's endorsement in 10 CFR 50.55a of newer versions of Section III of the ASME Code, which deals with design. The reason is that these provisions are applicable only to future construction permits, to repair and replacements, and to other voluntary changes in the design of existing nuclear power plants that are initiated by the licensee. Backfit analyses are also not required of the 120-month updates to licensees' ISI and IST programs, the reasoning being that the concept of the 120-month update was understood to be part of the regulatory regime that the licensee accepted when it received its operating license. However, backfit analyses are required for new ASME Code requirements that expand the scope of 10 CFR 50.55a or constitute a fundamental change in the nature of the requirements.[3] In light of the staff's position that backfit analyses are not required for routine NRC endorsement of updated editions and addenda of the Code, the staff's current practice of applying the backfit rule only to those proposals that constitute an expansion of the scope of the Code does not result in unacceptable burdens or inordinate delays. If the staff were required to analyze each provision or group of related provisions of the ASME Code, there would be a significant impact on the staff in terms of the complexity of preparing the backfit analysis.

Consideration of the Consensus Process

The ASME Code is described as the product of a "consensus process," which is often taken to mean that all affected parties in the industry are represented in the code development process.[4] Consideration of the consensus process would neither (1) reduce the scope or depth of consideration of either the analysis showing that the proposed requirement meets the "cost-justified substantial increase in safety" criteria of the backfit rule, nor (2) limit the scope of the inquiry regarding whether a proposed backfit is necessary for adequate protection under 10 CFR 50.109(a)(4)(ii) or (iii), or for compliance under 10 CFR 50.109(a)(4)(I). The ASME committees and subcommittees do not make or document their findings on the costs and benefits of individual code or group of related provisions to the same level of detail and rigor performed by the staff under the Regulatory Analysis Guidelines in Revision 1 of NUREG/BR-0058. In addition, the ASME committees and subcommittees do not make or document their findings with respect to whether individual code provisions are necessary for adequate protection, and they have no authority to determine whether a provision is necessary for compliance with the Commission's regulations. Thus, it is the staff's view that ASME does not

---

[3]OGC approved the staff's position in a March 15, 1989, Memorandum from Stuart A. Treby, Assistant General Counsel for Rulemaking and Fuel Cycle, OGC, to Eric S. Beckjord.

[4]The National Technology Transfer and Advancement Act of 1995, P.L. 104-113, refers to "voluntary consensus standards bodies," but does not provide a definition for this term, and does not use the term, "consensus process." OMB Circular A-119 (October 20, 1993) also does not refer to "consensus process," nor does it use or define "voluntary consensus standards bodies." However, the circular does use the term "voluntary standards," and defines these as being "established generally by private sector bodies . . . . The term includes what are commonly referred to as "industry standards" as well as "consensus standards . . . . " The circular also defines "voluntary standards bodies" as "private sector or international organizations -- such as nonprofit organizations, industry associations, professional and technical societies, institutes, or groups, and recognized test laboratories -- that plan, develop, establish, or coordinate voluntary standards."

generate documentation of its decisions that could be utilized by the staff to reduce the scope or depth of its backfit analyses on the basis that the documentation was the result of a "consensus process."

It could be argued that the consensus process may provide the basis for finding that NRC endorsement of updated editions and addenda would not constitute the "imposition" of the updated editions and addenda on nuclear power plant licensees. The problem with this line of reasoning is that not every utility participates in the process, and even if they did, the decisions of the ASME do not require unanimous approval for adoption. Hence, there may be individual licensees for which a given Code provision would represent an "imposition" because of those licensees' disagreement with that provision.

OGC does not regard the consensus process as an acceptable substitute for the notice and comment requirements for rulemaking in the Administrative Procedure Act. OGC's views on this SECY paper are set forth in a separate memorandum to the Commission.

In sum, consideration of the consensus process would be unlikely to lead to any significant reduction in or narrowing of the backfitting analyses for updated editions and addenda of the ASME Code.