March 2, 1999

FOR: The Commissioners

FROM: William D. Travers /s/ Executive Director for Operations

SUBJECT: THE USE BY INDUSTRY OF VOLUNTARY INITIATIVES IN THE REGULATORY PROCESS

PURPOSE:

This Commission paper responds to the voluntary industry initiatives portion of the staff requirements memorandum (SRM) issued on April 16, 1998, related to SECY-97-303, "The Role of Industry (DSI-13)" and Use of Industry Initiatives. It provides the Commission with the requested analysis that includes a review of stakeholder comments, discussion of the resource implications of implementing industry voluntary initiatives, conclusions from the analysis, and recommendations. The Codes and Standards portion of the April 16, 1998, SRM is addressed in a separate Commission paper, SECY-99-029, "NRC Participation in the Development and Use of Consensus Standards" dated January 28, 1999.

SUMMARY:

This paper presents the findings of a staff assessment, including consideration of stakeholder contributions, concerning how voluntary industry initiatives can be used in lieu of, or to complement, regulatory actions. The paper proposes definitions of different categories of voluntary actions that parallel the criteria for regulatory action given in 10 CFR 50.109. The staff has concluded that the current regulatory framework does not preclude implementation of voluntary industry initiatives and that such initiatives, except in cases in which adequate protection is concerned, can be accepted in lieu of, or complementary to, regulatory actions.

The staff concludes that the current regulatory analysis policy will not impede the implementa- tion of voluntary initiatives because such initiatives, if successfully implemented, will preclude the need for regulatory action that would involve backfit considerations. The only case where backfitting considerations could be expected would be a case where a regulatory action was necessary because a voluntary industry initiative was not put in place or the industry had not completed an initiative to which they had previously committed. In such a case the staff recommends that the current regulatory analysis methodology be continued.

The staff has been advocating the use of voluntary industry initiatives in lieu of regulatory actions for the past several years and the industry has responded favorably by forming specialized working groups to address technical issues of interest. As such, methods for interaction between the staff and industry working groups have developed and have generally been quite successful. However, if these interactions are to become an integral part of the regulatory process, more formal guidelines on the process for identifying and implementing initiatives should be developed and issued. If a change in policy relative to credit in the regulatory analysis occurs, it would be incorporated into the process for industry voluntary initiatives. It is proposed that such guidelines be developed with contributions from affected stakeholders. It is intended that the guidelines would promote a consistent and predictable process that makes for efficient use of resources and enhances public confidence. The staff has concluded that utilization of industry initiatives can provide effective resolution of issues while optimizing resource expenditures. Effective resource utilization will require coordination with the industry to assure appropriate development of budgeting and operating plans. The staff notes, for example, that it will be important for the industry to identify which issues it prefers to address through voluntary initiatives rather than through consensus codes and standards activities.

A major comment received from the industry during the stakeholder discussions concerned the desire to make all regulatory activities, including voluntary industry initiatives, more risk-informed and performance-based. The staff sees no limitations to utilizing risk-informed, performance-based approaches in voluntary initiatives, other than those that might be imposed by the current regulations. This is a broader issue related to the overall regulatory process and is the subject of a separate Commission paper, SECY 98-300, on risk-informing 10 CFR Part 50. However, it is the staff's intention that the proposed guidelines for voluntary industry initiatives allow for risk-informed, performance-based approaches to the maximum extent possible.

The April 16, 1998, SRM also requested that ongoing work in this area be coordinated with staff review of the policy guidance in Revision 2 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." Staff review of the current regulatory analysis methodology requested by SECY 97-168, dated December 11, 1997, will be the subject of a separate Commission paper.

BACKGROUND

SECY-97-303, dated December 30, 1997, was sent to the Commission in response to three SRMs: COMSECY-96-062, "The Role of Industry (DSI-13)"; WITS item No. 9600086, "Briefing on NRC Inspection Activities"; and WITS Item No. 9700028, "Briefing on Codes and Standards." SECY-97-303 described a conceptual process and items that would be addressed when developing general decision criteria related to industry initiatives. The paper also described potential changes and the resource implications related to NRC endorsement of codes and standards. The staff proposed to meet with stakeholders to discuss issues and obtain additional views and insights with regard to (1) industry initiatives that would substitute for regulatory action, including the related process and general decision criteria, and (2) potential improvements to the NRC process for endorsement of consensus codes and standards.

The Commission advised the staff in an SRM dated April 16, 1998, that it did not object to the stakeholder meetings. This paper presents the requested analysis that includes a review of stakeholder comments, a discussion of the resource implications of implementing voluntary industry initiatives, and recommendations. As a part of the analysis, we have included such issues as the use of a voluntary industry initiative in lieu of, or complementing,

regulatory actions, as well as using industry initiatives instead of consensus codes and standards. Potential improvements to the NRC process for endorsement of consensus codes and standards are discussed in SECY-99-029, "NRC Participation in the Development and Use of Consensus Standards" dated January 28, 1999. A public meeting that discussed consensus codes and standards development, endorsement and use, and voluntary industry initiatives as substitutes for regulatory actions and reporting requirements for nuclear power plants was held with stakeholders in Chicago, Illinois, on September 1, 1998. The following is a summary of the portion of the meeting dealing with industry initiatives. An analysis (as discussed above), conclusions, and recommendations follow.

DISCUSSION

Meeting With Stakeholders

The public meeting with stakeholders consisted of (1) an opening plenary session that briefly introduced the topics for the three breakout sessions, (2) the breakout sessions, and (3) a closing plenary session. The objective for the breakout session on industry initiatives was to obtain answers from the stakeholders on the following questions:

- Can industry initiatives be relied upon as adequate and effective substitutes for NRC regulatory activities?
- Can industry initiatives be relied upon to complement NRC regulatory activities?

The format of the session was a panel discussion with audience participation. The panel addressed the following questions and topics:

(1) How do licensees intend to assure compliance with voluntary initiatives.

(2) Commitment: What happens to an initiative if licensees start to back out?

(3) Must voluntary initiatives be documented in the FSAR?

(4) If a regulatory action becomes necessary to ensure adequate protection, would an industry initiative be an adequate substitute for such action?

(5) To what extent are NRC and licensee resources saved through the use of industry initiatives instead of regulatory actions, such as generic letters, regulations, etc.?

(6) Process and general decision criteria to evaluate industry activities that would substitute for regulatory actions.

(7) Are there similar processes that have been developed by other agencies or governments from which the NRC could learn?

(8) Risk-informed, performance-based initiatives.

(9) Discussion of future industry initiatives.

A comprehensive summary of the meeting is in the attachment and a complete transcript may be found on the Internet.

Types of Industry Initiatives

Voluntary industry initiatives can generally be put into one of the following four categories, three of which parallel the types of regulatory actions presented in 10 CFR 50.109: (1) those intended to ensure adequate protection or redefine what level of protection should be regarded as adequate, (2) those put in place in lieu of or to complement a regulatory action to ensure that existing requirements are met, (3) those used in lieu of or to complement a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and (4) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern. The items of regulatory concern from Category 4 would generally be of lower safety significance than Category (2) or (3) above. Each of these categories is discussed below.

A comment from a majority of participants at the September 1, 1998, stakeholders' meeting, including people with interests in industry and the environment, was that issues related to adequate protection of public health and safety are the responsibility of the NRC and should not be addressed through voluntary industry initiatives. The staff agrees that relying on voluntary industry initiatives in lieu of NRC actions to ensure adequate protection would be inappropriate since they would be based on commitments rather than requirements.

The most likely voluntary industry initiative is the second type described above: one that is undertaken by the industry in lieu of a regulatory action to ensure that compliance continues to be maintained or corrective actions will be taken to achieve compliance. The Boiling Water Reactor Vessel Internals Project (BWRVIP) is an example of such a program. This proactive program was instituted to address the potential for intergranular stress corrosion cracking of austenitic stainless steel and Alloy 600 safety-related components. The staff and industry agreed that a voluntary program in lieu of a regulatory action would be advantageous for addressing long-term aging concerns. All BWR licensees participate in the BWRVIP. The program entails developing generic industry guidelines for inspection scope and frequency, flaw evaluation, and repair of BWR internal components. The schedule for completing the program addressed the most important components from a safety perspective first. The program was implemented by commitments from all BWR owners to adhere to the program or inform the staff of any plant-specific deviations.

Further, the BWRVIP representatives have agreed that since the components were safety-related, actions taken to inspect, evaluate, and repair these components are within the scope of, and covered by, the licensee's Appendix B quality assurance (QA) program. The consensus of participants at the stakeholder meeting was that this type of an approach was appropriate and cost effective. Further, participants agreed that this type of voluntary initiative should be implemented with an associated licensee commitment.

The third type of voluntary industry initiative is one in lieu of a regulatory action in which overall protection could be substantially increased with costs of implementation justifying the increased protection or in which a voluntary industry initiative is used to provide an approach to complement such a regulatory action. In this type of initiative, similar to the second type discussed above, it appears that some type of commitment would be appropriate from licensees since the industry initiative may be in lieu of a regulatory action. An example of this type of initiative is the NEI guidelines that were developed to complement the performance-based maintenance rule. The NEI guidelines were referenced in a regulatory guide as a satisfactory way of meeting the rule.

The fourth type of voluntary initiative might address an issue dealing with productivity, balance of plant system performance, or cost management. An example that was discussed by the stakeholders related to site access authorization. There was neither a regulatory requirement nor a safety concern related to the issue. The initiative was simply a case in which the industry thought a common approach would be beneficial. In this case the participants agreed that a commitment to the NRC regarding the initiative was unnecessary.

Risk-Informed and Performance-Based Issues

A theme that ran through the stakeholder discussions was that regulatory actions should be both risk-informed and performance-based. The view was held that an industry program could be implemented to complement the regulatory action by providing criteria for performing the activity and measuring performance, i.e., such things as scope and extent of component inspections, evaluation, and repair details.

A stakeholder at the September 1, 1998, meeting stated that one of the biggest problems facing the industry and the NRC is making the regulations and the regulatory process more risk-informed. The staff does not see any limitation to using a risk-informed, performance-based approach for voluntary initiatives other than limitations that might be imposed by the current regulations. This issue is related to the overall regulatory process in general and is the subject of another Commission paper, SECY 98-300, on possible options for making 10 CFR Part 50 risk-informed. The staff believes that a risk-informed, performance-based approach to voluntary initiatives should be used to the extent possible.

Process

On the basis of the stakeholders' comments and the staff's assessment of voluntary initiatives as part of the regulatory process, the staff has concluded that the existing regulatory framework can support voluntary industry initiatives as described in Categories 2-4, above. However, the staff has also concluded that clear guidelines addressing the process for initiating and implementing voluntary industry initiatives are essential to ensure that such initiatives are effectively and uniformly integrated into the regulatory process. In this regard, it is important that such guidelines promote a consistent and predictable process that makes for efficient utilization of resources and enhances public confidence. The staff intends on formalizing the process, with stakeholder contributions, within one year from the date of this paper.

The staff has concluded that the process needs to contain the following key elements:

1) **Initiation of Voluntary Industry Initiatives**

   The staff has concluded, as previously discussed, that the criteria for backfitting in 10 CFR 50.109 are acceptable for defining regulatory issues that are amenable to resolution through voluntary industry initiatives.

2) **Definition of the Voluntary Industry Initiative Approach**

   The appropriate approach for implementing the voluntary industry initiative would need to be defined. Several options could be made available. These include licensee commitment to implement topical reports following NRC review, e.g., BWRVIP topical reports; licensee commitment to implement industry guidelines documents, e.g., NEI guidelines for the maintenance rule; FSAR change; and Appendix B plant procedures.

3) **Fees**

   Appropriate guidance for assessment of NRC fees for voluntary industry initiatives that involve NRC review of documentation, e.g., topical reports on industry guidelines.

4) **Identification of Staff Role**

   The staff's role in developing the voluntary industry initiatives would need to be defined. Staff participation could range from review and approval of topical reports or review for comment of industry guideline documents to no reviews and only inspection follow-up.

5) **Planning**

   A mechanism for developing industry and NRC plans and schedules would need to be established to support NRC and industry budgeting and resource assessments.

6) **Public Participation**

The process must provide appropriate forums for public participation and access to information from voluntary industry initiatives that are being utilized to complement a regulatory action or substitute for it. Care must be taken to ensure that sufficient information is available from voluntary initiatives to keep the public informed and to support appropriate opportunities for public participation. Issues such as the proprietary nature of material would need to be addressed. The staff intends to solicit stakeholder input to help with the process development and make the guidelines publicly available.

7) **Tracking**

Guidelines would need to be developed for tracking licensee commitments and other aspects of the implementation of voluntary industry initiatives. Current NRC information and workload management systems, off-the-shelf commercial software, and future systems such as the Agency-wide Documents Access and Management System (ADAMS) provide an adequate means to track the implementation of voluntary industry initiatives. As discussed in SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments Made by Power Reactor Licensees to the NRC," regulatory commitments made by licensees would be included in commitment management systems and would be subject to licensees' administrative controls. The staff is currently working with NEI on a revision to the industry guidance document on the control of regulatory commitments made to the NRC. The staff is also preparing additional internal guidance pertaining to the identification and verification of regulatory commitments made by licensees during interactions with the NRC. These efforts would support the proposed approaches to handling voluntary industry initiatives.
The appropriate estimate of resources for the issue would be included in the budgetary process and included in the operating plan. Resources expended could be tracked through NRR's resource tracking systems.

8) **Inspection**

Inspection guidelines would need to be developed to ensure that inspection criteria are implemented consistent with NRC and industry understanding of the initiative.

9) **Enforcement**

Failures to meet commitments may be addressed under the provisions of 10 CFR Part 50, Appendix B, 10 CFR 50.9, and through process controls such as Section 182 of the Atomic Energy Act. The staff will assess enforceability of commitments in the development of the process.

The staff believes that guidelines addressing these process elements should be developed, making use of existing regulatory processes and NRC and industry procedures. It is recognized that many processes that could be utilized in the implementation of voluntary industry initiatives are currently being reassessed and may undergo revision, e.g., 10 CFR 50.59. Most of these changes will create a more risk-informed and performance-based regulatory program. It is the staff's intent that the guidelines to be developed for voluntary industry initiatives would reflect these changes and the overall goal of the risk-informed, performance-based process. To the extent possible, the staff will rely on existing programs and processes, so that as these programs and processes are modified, the changes will be implicitly reflected in the voluntary industry initiatives.

RESOURCE IMPLICATIONS

General Considerations

The use of voluntary industry initiatives in lieu of regulatory actions is an area that is relatively new and insufficient information is available to support a quantitative analysis of resource impacts at this time. However, based on limited experience, it is expected that addressing issues through a voluntary industry initiative process will save resources for both the NRC and the industry. These savings would be realized through the elimination of the resource expenditures associated with issuance of a number of generic communications (e.g., generic letters, regulatory guides). For example, this includes the staff resources necessary to develop the generic letter, industry resources required to comment on and respond to the generic letter, and NRC resources to review and document the responses to the generic letter. Further, since industry and other members of the public would be involved at an earlier stage in addressing an issue, we expect better communication and more timely identification of appropriate actions to address the issue. This would save resources and could improve timeliness of actions, thereby enhancing safety. It is expected that most voluntary industry initiatives would address issues generically, rather than on a plant-specific basis, and staff experience is that the generic approach saves resources. Thus, the overall expectation is that NRC reliance upon voluntary industry initiatives will save resources.

However, it should be noted that significant resources may still be required for voluntary industry initiatives to effectively address issues. The industry would still have the responsibility to develop generic guidelines, topical reports, or other appropriate documents, and licensees would maintain the responsibility for implementing the initiatives that could involve such activities as program and procedure changes and training. NRC staff would remain responsible for reviewing industry guidelines, topical reports, etc., as appropriate, and may also have to expend inspection resources in order to verify effective implementation of voluntary industry initiatives. NRC action to address a licensee's failure to effectively implement a voluntary initiative could also involve greater resource expenditures, inasmuch as the burden of showing the safety impact of the licensee's inaction (or ineffective implementation) would rest with the NRC.

Another aspect regarding resources is the connection between resources expended on the development and implementation of consensus codes and standards and resources expended on voluntary initiatives to address an issue. In many cases, an option will exist to address issues either through the voluntary industry initiatives or the consensus codes and standards approach. The approach considered most viable from a resource perspective will be driven by industry preference. In our view, the industry decision will most likely be dependent on the nature of the issue in terms of generic applicability,

the time frame available to address the issue, and the regulatory factors related to implementation. Usually the same technical expertise on the part of both the industry and the NRC are needed to generically address an issue through either the consensus codes and standards or voluntary industry initiatives approach. The staff's expectation is that the process for voluntary industry initiatives would include discussion with the industry to identify resource commitments. Information from the industry regarding industry's preference on whether to address issues through voluntary industry initiatives or the consensus codes and standards process would be used in developing the agency's operating plan; thereby assuring a proper distribution of agency resources.

In one case it may be necessary (e.g., in order to modify an existing requirement) or preferred by the industry to address an issue through the consensus codes and standards process and have the NRC endorse the code action. In this case, the need for individual plant licensing actions would be minimized and both the industry and the NRC would save resources. In the case of the ASME Code, to implement this, timely endorsement of the code and code cases would be needed. This matter is addressed in a separate Commission paper on the consensus codes and standards aspect of DSI-13.

In another case, the industry might choose a voluntary industry initiative. The voluntary industry initiatives approach will most likely be applied in areas that are not currently covered by consensus codes and standards activities and for which the industry has concluded that the voluntary industry initiatives process may be more expeditious.

Specific Resource Needs

In order to formalize and supplement current guidance for the process, the staff estimates that one-quarter of an FTE would be needed to prepare a guideline for the process and modify it as necessary to accommodate stakeholder comments. The work would be split between two NRR divisions and can be accommodated with existing resources. The staff will rely on experience gained from current voluntary initiatives as well as existing guidance, methods and tracking systems, where available. This action, including solicitation and resolution of stakeholders' comments, would be completed within a year of the date of this Commission paper. Resources for FY 2000 and FY 2001 for addressing voluntary industry initiatives will be addressed in the upcoming FY 2001 budget process and as part of the FY 2002 budget process.

Coordination With Staff Review of Regulatory Analysis Methodology

In the SRM of December 11, 1997, the staff was asked to "...review current regulatory analysis methodology in light of the SRM on DSI-13 and submit, for Commission review, options that would address possible revisions to the methodology, particularly with regard to recognition of existing initiatives and voluntary actions in the cost-benefit analysis." In the subsequent SRM of April 16, 1998, the staff was asked to coordinate this regulatory analysis review in its response to this SRM.

The staff is preparing a separate Commission paper to provide the requested review of current regulatory analysis methodology. However, the staff concludes that the current regulatory analysis policy will not impede the implementation of voluntary initiatives. This is because voluntary initiatives are not subject to 10 CFR 50.109 review, since they are not backfits. The only case where backfitting considerations could be expected would be a case where a regulatory action was necessary because a voluntary industry initiative was not put in place or the industry had not completed an initiative for which they had previously made a commitment. In such a case the staff recommends that the current regulatory analysis methodology be continued. This would only be necessary for a regulatory action that was for enhanced safety since regulatory actions for adequate protection or to ensure compliance do not require a backfit analysis. In any event, the issue regarding credit given for voluntary industry initiatives in regulatory analyses would be moot since in these instances there would be either no, or inadequate, voluntary industry initiatives. If a change in policy for regulatory analysis methodology occurs during the formalization of the process for dealing with voluntary industry initiatives in lieu of regulatory action, it would be incorporated into the process.

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 Office of the Chief Information Officer has no objections to this paper.

CONCLUSIONS

(1) Voluntary industry initiatives will not be used in lieu of regulatory action where a question of adequate protection of public health and safety exists.

(2) Voluntary industry initiatives are an appropriate substitute for NRC regulatory action where the regulatory action to be taken is needed to meet existing requirements or for cases where a substantial increase in overall protection can be achieved with costs of implementation justifying the increased protection.

(3) The current regulatory framework does not preclude voluntary industry initiatives and existing regulatory processes can be used to support implementation of voluntary initiatives.

RECOMMENDATIONS

The Commission note that, unless directed otherwise, it is my intention to have the staff develop and formalize, with stakeholder contributions, a process with the elements outlined above for initiating and implementing voluntary industry initiatives within one year from the date of this paper.

Staff requests action within 10 days. Action will not be taken until the SRM is received. We consider this action to be within the delegated authority of

the EDO.

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Attachment: As stated

ATTACHMENT

SUBJECT: DSI-13, "THE ROLE OF THE INDUSTRY" - KEY POINTS FROM BREAKOUT SESSION II, "INDUSTRY INITIATIVES AS SUBSTITUTES FOR REGULATORY ACTION"

Breakout Session II, " Industry Initiatives as Substitutes for Regulatory Action," was held as part of a Stakeholders meeting on Tuesday, September 1, 1998, in Rosemont, Illinois. The session opened with introductory comments from Jack Roe, U.S. Nuclear Regulatory Commission (NRC); Carl Terry, Boiling Water Reactor Vessel Internals Program (BWRVIP); Frank Carr, Performance Demonstration Initiative (PDI); and Bob Hermann, NRC. The introductory comments were followed by a discussion of nine questions posed by the NRC to gather information from the industry. In the following material, the key points made by the introductory speakers, attendees, and panel members are summarized.

Introductory Comments

The NRC representative opened the session by stating the objective of the meeting, which was to obtain responses from stakeholders on the following two questions: (1) can industry initiatives be relied upon as adequate and effective substitutes for NRC regulatory activities and (2) can industry initiatives be relied upon to complement NRC activities in various areas, such as in the materials and non-power reactor fields? The ground rules for discussion during the session were laid: the three remaining introductory speakers were to comment, the panel would discuss the nine questions and topics, and the audience would then be invited to participate.

The BWRVIP Chairman summarized the BWR Vessel Internals Program (VIP), which serves as a framework for dealing with generic vessel internals degradation issues for BWR owners. The program was initiated in response to an increase in the amount of intergranular stress corrosion cracking issues in reactor vessel internals. Ongoing inspection mechanisms were not in place since most of these components are not covered by the ASME Code. Thus, the BWRVIP was formed. The Electric Power Research Institute (EPRI) acts as program manager for the project with heavy involvement of executive level management from the industry. The generic inspection criteria, repair criteria, and template for actions involving other components within the internals were created. The project prioritized what was important, established a framework for business, characterized the issues affecting internals and other components, and established generic inspection and repair approaches. It also established agreement with the NRC on how to deal with commitments that came out of the program. The project has been extremely successful; the key to its successes has been ongoing communication with the NRC and the public.

The PDI Chairman summarized the Performance Demonstration Initiative. This initiative involves all of the U.S. nuclear utilities. The initiative grew out of difficulties with the implementation of the provisions of ASME Section XI, Appendix VIII, regarding ultrasonic examinations. The PDI group has designed and built flaw specimens; its technical working groups developed specific methodology and samples acceptable to the ASME and NRC. Generic procedures were developed for such activities as detection and sizing. Currently, the piping and bolting portion of the program is finished and most of the work on the reactor vessel underclad and shell examinations is complete. Three more years are needed to address the remainder of activities regarding the reactor vessel nozzle shell and inner radius examinations and dissimilar metals examinations.

The NRC representative discussed NRC perspective on industry initiatives and how they tie to the regulatory process. Communication and consensus are considered the key, whether it takes place between NRC and the licensees, or within the industry groups themselves. Interaction between the industry and NRC staff, cooperative efforts in terms of resource management, and being aggressive with the issue are also important for a successful initiative. For example, the BWRVIP defined the issues from a system and risk perspective and was able to make commitments to the NRC for inspection programs. Regulatory controls are in place in terms of corrective actions and special processes under Appendix B programs. However, the use of commitments as the basis for the use of voluntary industry initiatives in lieu of regulatory actions raises some questions.

The NEI representative who served as the session Chairman stated that NEI's position was that an industry initiative should never be a substitute for regulatory action that passes the adequate protection standard or passes a backfit test that justifies a substantial increase in overall protection. This is not to say that a voluntary industry initiative could not complement such actions.

Participant Comments and Discussion of Nine Questions - Summary

Question #1: How do licensees intend to assure compliance with voluntary initiatives?

a. When considering voluntary initiatives, there is not a compliance issue. NRC does not have to determine compliance if an action is voluntary.

b. There are many industry guidelines that fit into Appendix B programs. Application of Appendix B programs provides mechanisms for onsite verification that the actions are being performed, consistent with implementing procedures for the voluntary initiatives, thus providing enforceability.

c. As a result of the BWRVIP process and formal interaction, NRC prepared a safety evaluation report (SER) of the VIP topical. Individual utilities can reference the topical and the staff's SER, and request plant-specific approval in instances where they do not conform with these documents.

d. There are many initiatives that are addressing safety issues to which licensees do commit, and then compliance is the same as for any other commitment.

Question #2: Commitment - what happens to an initiative if a licensee starts to back out?

a. There is adequate guidance relating to how to manage commitments. Licensees backing out of commitments is not something the industry can control, but that is something between the licensees and NRC.

b. Participants felt it is typical for licensees to try to get ahead of an issue and see if the resolution of a new issue cannot be handled outside of formal regulatory correspondence with the NRC. Licensees can volunteer to put information on the docket concerning what they are doing about an issue. Even if a licensee were to back out of commitments, Appendix B provisions would still apply.

c. Regarding commitment management guidelines, commitments have different gradations. The licensee bears the responsibility for fulfilling all commitments. If a licensee wants to back out of a commitment, it is the licensee's responsibility to notify the regulator.

Question #3:Must voluntary initiatives be documented in the final safely analysis report (FSAR)?

a. If the initiative changes the design, or changes a process that is already in the FSAR, the licensee has to document those changes in the FSAR.

b. The degree to which an initiative affects the information in the FSAR will be the deciding factor concerning whether or not that initiative needs to be reflected in the FSAR.

c. If there is a new requirement and the licensee is taking credit for some form of initiative, and the NRC thinks it is important enough that it issues an SER, then possibly that is the level of information that should be reflected back in the FSAR. That is consistent with NEI 96-07, "Guidelines for 50.59 Safety Evaluations." Under the provisions of 10 CFR 50.59, licensees should consider the information that is in the SER as part of the baseline information. Documenting how the licensee is meeting a formal regulatory requirement is supposed to be captured in the FSAR in some fashion.

d. Consider the draft guidelines on FSAR maintenance.

Question #4: If a regulatory action becomes necessary to ensure adequate protection, would an industry initiative be an adequate substitute for such an action?

a. It is not appropriate for NRC to displace a rulemaking action and rely on an industry initiative to ensure adequate protection.

b. An industry initiative is not a substitute for rulemaking. Industry groups should be working with the NRC on initiatives to complement the regulatory programs. The industry and NRC would save resources. NRC would still be determining the appropriate level of safety.

c. It was expressed that the idea of using an industry initiative as a substitute for rulemaking would be alarming to the "safe energy" community. NRC has an obligation to the public to allow the public to be able to gain access to certain levels of documentation. The public would not accept an industry initiative as a substitute for regulatory action.

d. NRC has to be very careful when it endorses an initiative that NRC does not move beyond what was adequate and add extra conditions to obtain increased margin.

Question #5: To what extent are NRC and licensee resources saved through the use of industry initiatives instead of regulatory actions such as generic letters, regulations, etc.?

a. If an industry initiative is really treated as a generic issue, the result is a net savings of resources for both industry and NRC.

b. Generic issues consume resources when there is inadequate planning. Industry has been given 30 days to respond to certain generic correspondence which is not usually enough time and requires immediate availability of resources. It was suggested that NRC work through NEI and let NEI set a time frame.

c. It was suggested that NRC apply regulations practically to the operating plant as well as to the design basis. When NRC issues a generic letter, the licensee is trying to answer a regulatory requirement and has to put the regulation to practical application. There might be a process for the licensee to talk to NRC before generic letters are issued so that the licensees truly know what NRC is seeking.

d. Some participants felt that docket submittal requests have increased; things that NRC never previously asked to put on the docket are now

being requested.

Question #6: Discussion of the process and general decision criteria to evaluate industry activities that would substitute for regulatory actions.

a. A participant emphasized that communication on issues is not binary, but in reality the answer to most issues is not "yes" or "no," but "maybe."

b. One participant suggested it may be appropriate to have more dialogue to gain an understanding of an issue. Sometimes what gets submitted is not what actually gets approved. It would be helpful if the process for voluntary industry initiatives recognized that.

c. The process suggests that the first step is an industry proposal. The process should reflect who is going to come up with the industry proposal or if NRC will take independent action.

d. A participant pointed out that NRC follow up activities are where the process can unravel to some extent. The licensees and NRC agree on what the initiatives are and what the actions are to be in the implementation, but through the inspection process, NRC may redefine what had been agreed on.

e. In the process, NRC should identify the things that are decided to be out of scope and do not need to be addressed. This provides guidance to the inspectors.

f. A participant suggested that the process ensure as much availability to the public as possible.

g. A participant suggested that definition of the criteria is important. Licensees would like to know the criteria upon which judgment is being made and some criteria for prioritization.

h. A participant suggested that scheduling and tracking of resources need to be included in the process.

Question #7: Are there similar processes that have been developed by other agencies or governments from which the NRC could learn?

a. One participant observed that the Finnish licensee interfaces with its regulatory agency during the whole period of an outage. The Finnish licensee plans and performs aggressive maintenance, and minimizes distractions.

b. Industry needs to have a partnership with NRC. Industry can identify a problem better with its own audits, surveys, or in its training.

c. It may be that an international committee of people, primarily from EPRI, can provide information on what is coming from certain initiatives for all of us to be more cognizant. It will give a better sense of what everyone is doing.

Question #8: Discussion of risk-informed, performance-based initiatives?

a. Participants felt that the biggest problem facing us right now in trying to make the regulations and the regulatory process more risk-informed is that the licensing basis for the plants is not risk-informed. The licensing basis is built upon deterministic analyses.

b. Regulations now in place certainly focus plant resources in the right areas from a safety perspective, but many of the requirements do not. NRC is somewhat limited as to how far it can go in making the process more risk-informed, as we might have to change some of the regulatory requirements. The NRC should make the inspection process more risk-informed and start focusing on the items that are of more risk significance. However, there are still a large set of requirements that are not risk-informed which licensees still have to comply with.

c. There are problems associated with comparing probabilistic risk assessments (PRAs) between plants.

d. The large-scale benefits of risk-informed changes associated with how we do business are not coming; but small, evolutionary ones are.

e. It is believed by some that engineering judgment is used in most industries except for the nuclear industry. Panels or teams involved in the process should be allowed to select on what and where to concentrate inspections.

f. The current licensing basis is deterministic and, therefore, would need to be changed to permit more risk-informed initiatives.

Question #9: Discussion of future industry initiatives.

a. A participant described considerations being undertaken by NEI. Industry has to learn what its priorities are before it can fully answer. It can only adopt risk-informed approaches to a certain point before the regulations will need to be changed. Industry has a task force that is looking at a plan of evaluating risk in a more integrated fashion. A team sponsored by NEI has identified 51 regulations in Part 50 that would have to be revised to allow them to be more risk-informed. The team expects to send a formal submittal to the agency seeking a pilot approach for three pilot plants. The team would like to develop a regulatory guide before anyone could apply the pilot approach. If NRC would grant exemption from the current Part 50 for the three plants and replace it with a revised Part 50, the licensee could work toward a

participatory rulemaking with NRC staff working directly with the pilot plants. When the staff is satisfied, then it would issue an SER, and the licensee could incorporate that, take the lessons learned, and start developing a regulatory guide for the rest of the industry. It was suggested that an advance notice of proposed rulemaking be published in order to notify the public.

b. A concern was expressed regarding what will happen to non-power reactors when considering these kinds of initiatives.

c. A concern was raised regarding whether a licensee can really expect some commitment to backing off on requirements or whether new ones are going to be added to the point where the risk-informed areas show that there are areas of greater concern.

d. The industry lacks the mechanisms to move rapidly from a plant-specific application to a generic approach to an issue. The industry needs to figure out how to move from those applications that are best started as pilot programs, and then move from lessons learned to industry-wide implementation.

e. It was suggested that, with open communication, NRC determine when there is a need for an industry initiative. NRC and industry should decide whether it is appropriate to tackle an issue as a pilot program or to jump directly to making it a generic one. They should consider the pros and cons and make sure the industry has the NRC's agreement with the approach.

General Comments

There was general concern over vocabulary definitions expressed throughout the session. Participants found that every question could be answered differently, based on the status or pedigree of the regulatory action. The definition of "voluntary initiative," "commitment," "regulatory action," and "compliance" as they relate to performance-based regulations needs to be clarified.