

POLICY ISSUE
(NEGATIVE CONSENT)

May 30, 2000

SECY-00-0116

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: INDUSTRY INITIATIVES IN THE REGULATORY PROCESS

PURPOSE:

To inform the Commission of the NRC staff's development of proposed guidelines for including industry initiatives in the regulatory process and to request Commission approval to issue the proposed guidelines for public comment.

SUMMARY:

In response to the staff requirements memorandum (SRM) issued on May 27, 1999, to SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," and to stakeholders' comments, the staff, working with stakeholders, has developed the attached proposed guidelines for including industry initiatives in the regulatory process. (The term "voluntary industry initiatives," previously used in SECY-99-063, has been superseded by the term "industry initiatives," in the proposed guidelines, in response to stakeholder comments.) The guidelines are intended to provide a level of discipline and consistency in the way industry initiatives are included in the regulatory process. They also provide for visibility of the process and appropriate participation by all stakeholders.

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Use of the proposed guidelines is consistent with existing regulatory processes. The guidelines identify to the public that: (1) the use of industry initiatives in the regulatory process can provide effective and efficient use of resources and resolution of issues, (2) industry initiatives will be controlled and monitored by the staff so as to provide reasonable assurance that the health and safety of the public will be maintained, (3) the industry initiative will be conducted in compliance with the Commission's regulations, as applicable, and (4) the industry initiative will not be inimical to the common defense and security.

This paper provides a summary of the background associated with this subject, a discussion of examples of past industry initiatives and how they have been included in the regulatory process, a discussion of stakeholders' comments and how they are addressed in the proposed guidelines, a review of guidance provided in the Commission's SRM associated with SECY-99-063, and a discussion of how that guidance is addressed in the proposed guidelines.

The proposed guidelines are consistent with SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," dated March 2, 1999; however, one of the NRC's stakeholders (the Nuclear Energy Institute - NEI) has suggested that no guidelines are necessary. After considering the needs of all stakeholders, the staff believes that the guidelines are appropriate. They contain substantial additional detail and reflect the staff's recommended approach for including industry initiatives in the regulatory process. The staff believes that it is also appropriate to provide these proposed guidelines to the Commission for review prior to publication in the Federal Register for final public comment.

BACKGROUND:

The decision to develop guidelines for use of industry initiatives in the regulatory process is an outgrowth of the Commission's Direction Setting Initiative (DSI) 13, "The Role of Industry (DSI-13)' and Use of Industry Initiatives" (SECY-97-303), dated December 31, 1997, and the associated SRM issued on April 16, 1998. In accordance with the SRM, a public meeting on DSI-13 was held in Rosemont, Illinois, on September 1, 1998, and input was received from the attending stakeholders. This input was used in developing the subsequent SECY-99-063.

SECY-99-063 and Associated SRM

On March 2, 1999, the staff forwarded to the Commission SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," which, based on the input received from the DSI-13 meeting, proposed the development of NRC guidelines for crediting voluntary industry initiatives (VIIs) in lieu of taking regulatory action. It listed the areas to be addressed in these guidelines, and presented the findings of a staff assessment concerning how VIIs, including risk-informed, performance-based VIIs, may be used in lieu of, or to complement, regulatory actions. The guidelines would contain definitions of different categories of voluntary actions that parallel the criteria for regulatory action given in 10 CFR 50.109. The staff concluded that the current regulatory framework does not preclude implementation of VIIs and that such industry initiatives, except in cases in which adequate protection is concerned, can be accepted in lieu of, or complementary to, regulatory actions.

The staff also concluded that the current regulatory policy would not impede the implementation of VIIs because such industry initiatives, if successfully implemented, would preclude the need for regulatory actions involving formal backfit considerations and value/impact considerations, since the actions would be voluntary by the industry rather than

new NRC regulatory actions. The only case where backfitting considerations could be formally addressed would be where a regulatory action was cost-justified because a VII was not put in place, was not effective, or the industry had not completed an industry initiative to which it had previously committed. In this case, the staff recommended that the current regulatory policy be continued.

On May 27, 1999, the Commission issued an SRM approving the staff's recommendations in SECY-99-063, and agreed that the current regulatory framework does not preclude voluntary industry initiatives and existing regulatory processes can be used to support implementation of voluntary initiatives. The SRM directed the staff to move forward, working with the industry and other stakeholders, in developing the guidelines for using VIIs. The SRM set a due date of May 31, 2000, for providing the proposed guidelines to the Commission for review prior to staff implementation.

In order to keep the public and other interested stakeholders informed of the staff's actions in developing these proposed guidelines, the staff established a web page at <http://www.nrc.gov/NRC/REACTOR/VII/index.html>, which has electronic copies of all relevant background materials; meeting notices, summaries, and transcripts; letters to and from the industry; and, milestones for this subject. Further, the staff has actively encouraged the involvement of external stakeholders, including NEI, the industry, and the public in developing the proposed guidelines.

DISCUSSION:

For the purpose of these guidelines, there are two types of industry initiatives, Type 1 and Type 2. Type 1 industry initiatives are broken down into two subparts. A description follows:

- Type 1: those developed by the applicable industry group(s) (AIGs)⁽¹⁾ in response to some issue of potential regulatory concern (a) to substitute for or complement regulatory actions for issues within existing regulatory requirements, or (b) which are potential cost beneficial safety enhancement issues outside existing regulatory requirements;
- Type 2: those that are initiated and developed by the AIG(s) to address issues of concern to the applicable industry group but that are outside existing regulatory requirements and are not cost beneficial safety enhancements, or that are used as an information gathering mechanism.

The staff has been advocating the use of industry initiatives for several years, and the industry has responded favorably by forming specialized working groups to address specific technical issues of interest. As such, to date, methods for interaction between the staff and these industry working groups have developed in an *ad hoc* manner and have generally been quite successful. However, if these interactions are to become an integral part of the regulatory process, the Commission has determined, in its policy guidance detailed in the SRM to SECY-99-063, that developing and implementing guidelines for industry initiatives is appropriate.

The proposed guidelines have been developed to ensure that future industry initiatives would be treated and evaluated in a consistent and predictable manner. This would allow industry

⁽¹⁾ An AIG could be the members of one or more Owners Groups, an industry organization such as NEI or the Electric Power Research Institute (EPRI), or two or more licensees.

initiatives to play an important role in achieving the NRC's regulatory goals of maintaining safety, reducing unnecessary regulatory burden, improving efficiency, effectiveness, and realism, and improving public confidence. The proposed guidelines are detailed in Attachment A. Some examples of the two types of industry initiatives are contained in Attachment B. Attachment C describes the meetings and communications that the staff had with the various stakeholders on this subject.

The examples in Attachment B illustrate the range of approaches that can be taken when addressing issues through industry initiatives. In the case of the Boiling Water Reactor Vessel and Internals Project (BWRVIP), a program was developed and implemented that provides an acceptable method of complying with 10 CFR Part 50, Appendix B, with regard to managing the degradation of safety-related BWR components. In this case all BWR licensees committed to implement the BWRVIP program, and the NRC has the option of performing inspection of these activities relative to 10 CFR Part 50, Appendix B.

In the case of shutdown risk, the staff had completed an analysis indicating that industry actions could be justified as a cost-beneficial safety enhancement; however, the Commission concluded that rulemaking should not proceed given the initiatives taken by the industry to maintain an acceptable level of risk during shutdown conditions. Licensee implementation of commitments in this area is not enforceable, but NRC monitoring provides a basis for determining if future regulatory action becomes necessary.

As for the new NEI-97-06 steam generator industry initiative, it will result in voluntary and enforceable changes to plant technical specifications. As illustrated by these examples, a wide range of approaches can be taken in using industry initiatives in the regulatory process. This includes the methods of implementation and the options available for NRC monitoring, inspection and enforcement.

Stakeholder Comments

The major comments received from external stakeholders in general, and NEI in particular, are summarized as follows:

- (1) Guidelines for including industry initiatives in the regulatory process are not necessary. NEI pointed out that there is a history of NRC crediting industry initiatives albeit on a somewhat informal or *ad hoc* basis. NEI indicated that this process had worked quite successfully and that this success was largely due to the flexibility that has existed in the way in which different issues have been resolved. NEI indicated that, although the staff may want to develop guidelines for their own use, the industry did not believe such guidelines are necessary and that care should be taken if guidelines are developed to avoid losing the existing flexibility in the way industry initiatives can be used to address issues.
- (2) The title "*voluntary* industry initiatives" (emphasis added) may be a misnomer since it was not clear that many industry initiatives are truly voluntary. NEI noted that, in many cases, an industry initiative must be taken in order to maintain compliance with existing regulations or that the industry felt compelled to take action to avoid issuance of a generic letter or other regulatory action.
- (3) In the event that there is a basis for issuing a generic communication on an issue, NRC should proceed with issuing that generic communication, notwithstanding industry

initiatives to address the issue. However, it was also stressed that interaction on the issue with the industry should begin early and that information or perspectives provided by the industry could be useful in preparing the generic communication. During discussions in a breakout session on VIIs at the Regulatory Information Conference in April 2000, a representative of the New England Coalition on Nuclear Pollution indicated that he agreed with this comment but also stressed the need for making information readily available to all stakeholders.

- (4) Any guidelines that are developed should be consistent with the guidance related to generic communications, i.e., SECY-99-143, "Revisions to Generic Communication Program."

The staff considered comment 1, above, and concluded that it was appropriate to continue with the development of guidelines for including industry initiatives in the regulatory framework, based on the need to consider all stakeholders and a desire for a consistent process. However, the staff agrees that flexibility needs to be maintained regarding the ways in which industry initiatives can be credited in the regulatory process. The preceding discussion on examples of successful industry initiatives illustrates the variety of approaches that have been used in the past and the need to provide for flexible approaches in this process. The proposed guidelines are not prescriptive and are intended to provide maximum flexibility in addressing issues.

Regarding comment 2, the staff concluded that a better title for the subject of the guidelines would be industry initiatives, thereby eliminating any debate regarding the voluntary or involuntary nature of industry initiatives. Therefore, the adjective "voluntary" has been dropped from the proposed guidelines and from other discussions in this SECY, except where appropriate for historical accuracy.

Regarding comment number 3, industry has previously asserted that it is best able to identify the most effective and efficient resolution to emerging issues, and that resolution of such issues would be more timely and resource efficient if the staff were to solicit industry support directly rather than issuing a generic communication to initiate industry action. SECY-99-143, "Revisions to Generic Communication Program," dated May 26, 1999, acknowledges the value of early interaction with industry on potential generic issues and encourages the use of industry initiatives. Notwithstanding the industry initiative option, there may be cases where, based on the significance and urgency of an issue, the decision on the part of industry to not address an issue through an industry initiative, or the need to take action to facilitate or complement an industry initiative, it may be desirable to issue a generic communication or take other appropriate regulatory action.

The staff was also sensitive to the non-industry stakeholders input, and the need for such stakeholders to be kept informed through ready access to associated information, and to have the opportunity for participation, consistent with existing rules and agency procedures. In this regard, it is noted that, if the staff decides not to issue a generic communication based on crediting an industry initiative, this could eliminate an opportunity for public comment. However, in reality, there are situations where industry initiatives preempt the need for issuing a generic communication. The proposed guidelines encourage the use of public communications (web pages and Federal Register notices) and provide an opportunity for stakeholders to provide comments at public meetings in which the NRC and industry discuss possible approaches to resolving issues. The guidelines also rely on existing processes and opportunities for stakeholders participation in cases where the industry initiative includes some regulatory action

such as NRC approval of voluntary license amendment requests or modifications to rules or regulatory guidance.

Regarding comment number 4, above, the attached guidelines are consistent with the most recent guidance on generic communications.

Commission SRM Items

As indicated in the "Background" section of this paper, the Commission SRM in response to SECY-99-063 identified several specific subjects to be addressed by the staff in the development of the proposed guidelines. The manner in which the proposed guidelines address each of these issues is discussed below.

Ensure guidance accounts for the tracking of commitments consistent with existing regulatory processes.

In response to this direction, the proposed guidelines incorporate directly by reference the guidelines in SECY-00-0045, "Acceptance of NEI 99-04, 'Guidelines for Managing NRC Commitments,'" dated February 22, 2000. The NEI guidelines provide recommended actions for licensees' management, implementation and documentation of commitments (Sections 2, 3, 4 and 5). The guidelines were found acceptable by the staff.

Ensure guidance accounts for inspection and enforcement of voluntary initiatives that are implemented in lieu of regulatory requirements consistent with the proposed reactor oversight process improvements and clearly communicated to our stakeholders.

The guidelines state that inspection and monitoring will be established on a case-by-case basis, depending on the nature of the industry initiative. As illustrated by the examples discussed in Attachment B, some industry initiatives will result in activities that fall within the inspection process, while others may be monitored to determine whether or not any additional regulatory action is necessary. Inspection activities and focus would be consistent with the new Reactor Oversight Process. The proposed guidelines contain specifics on the types of actions that could result from various industry initiatives and how they would be treated, consistent with existing enforcement policy.

Address how plants that do not fully commit to a particular voluntary industry initiative, and are therefore not subject to any related enforcement, will be handled.

The proposed guidelines specifically address the process to follow in the event that a licensee does not commit to an industry initiative or commitments made under an industry initiative are not appropriately implemented. The process would require evaluation either in the context of existing enforcement policy, if appropriate, or an assessment of the need for additional regulatory action.

Include the agency's decision-making process in pursuing and endorsing a particular voluntary initiative (e.g., whether this is a staff action or Commission decision).

The proposed guidelines would place the decision for pursuing an issue and endorsing a proposed industry initiative with NRR senior management, and it is expected that Commission decisions would not be required in most cases. If multiple AIGs individually submit separate

initiatives regarding the same issue, all industry initiatives will be addressed pursuant to these guidelines. However, in some cases, such as those in which the staff decides to pursue rulemaking rather than endorse an industry initiative, or the industry requests rulemaking as part of their industry initiative, the Commission would be involved through existing processes. The staff would remain sensitive to possible policy issues arising out of proposed industry initiatives, and would bring these to the Commission.

Make it clear to the public that substituting voluntary industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, will be controlled and monitored so as to ensure plant safety is not compromised, and does not represent a reduction in NRC's commitment to safety and sound regulation.

As previously stated, there are several arguments supporting the idea that crediting industry initiatives in lieu of regulatory action can provide an effective and efficient resolution of an issue. Many issues have already been successfully resolved by this process, engaging the industry early on issues should expedite their resolution, and the industry should be in the best position to develop resolution of technical issues. As discussed above, the proposed guidelines provide for stakeholder participation as well as making information relative to particular industry initiatives readily available. This is consistent with the communications plan for industry initiatives, as described in the proposed guidelines. Issuing the proposed guidelines for public comment will provide the opportunity for any stakeholder concerns to be brought to the staff's attention, and these concerns will be addressed before the guidelines are issued in final form.

The staff should determine to what extent the process will apply to non-power reactors, decommissioning reactors, and materials and other licensees.

At present, these proposed guidelines apply only to operating commercial nuclear power reactor licensees, but could be extended in the future to apply to non-power reactors, decommissioning reactors, and materials and other licensees. As experience is gained, it may be appropriate to extend the industry initiative approach to fuel-cycle licensees.

Other Aspects of the Proposed Industry Initiatives Guidelines

In addition to laying out a process, the proposed guidelines provide specific discussions regarding NRC project management issues; public participation and the elements of a communications plan that should be developed for each industry initiative; fees; tracking of commitments; inspection and/or monitoring; enforcement guidelines; and, resource planning. As indicated by some of the foregoing, the approach taken by the staff in developing the proposed guidelines was to use existing processes to the extent possible. Therefore, the primary purpose of the discussions on these topics is to provide guidance and perspective on how industry initiatives fit within the existing processes and regulatory framework.

Related Staff Activities

It should be noted that the staff is currently in the process of recommending a revision to the NRC policy concerning the treatment of industry initiatives in regulatory analyses. The revision is consistent with the staff's proposal as presented in SECY-99-178, "Treatment of Voluntary Initiatives in Regulatory Analyses," which was approved by the Commission in an SRM dated August 26, 1999. In general, the new policy would require, under certain circumstances, the preparation of best estimate cost benefit results based on measured credit for industry

initiatives. The amount of credit is to be determined by how well the industry initiative satisfies the guidelines developed therein. Guidance on this new policy will be available in an update to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, which should be available by August 2000.

RESOURCE IMPLICATIONS:

Thus far, approximately 1.0 FTE have been expended on the development of the proposed guidelines for industry initiatives, and it is expected that an additional 0.5 FTE in FY-2000 (already budgeted) will be needed to address stakeholder comments and finalize the guidelines. The impact that implementation of the guidelines will have cannot be quantified since the nature and number of issues and related industry initiatives that may arise in the future is not known, *a priori*. However, when compared to the historical practice of issuing generic letters or bulletins, it is expected that addressing issues through industry initiatives would, overall, save resources for both the NRC and the industry. Most industry initiatives would address issues generically, rather than on a plant-specific basis, and staff experience is that the generic approach saves resources. Industry initiatives also allow the nuclear power reactor industry more flexibility in the selection of the schedule and technical approach for addressing the issue. Further, since industry and other members of the public would be involved at an earlier stage in addressing an issue, the staff expects better communication and more timely identification of appropriate actions to address emerging issues. This would also save resources and would improve timeliness of actions.

It should be noted that resources would still be required for industry and NRC staff to effectively address issues, although not as much as would be expended by individual licensees and the staff in addressing issues on a plant-specific basis. 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 industry initiatives, which could involve such activities as program and procedure changes and training. NRC staff would remain responsible for reviewing the industry submittals, as appropriate, and may also expend resources in order to verify effective implementation of industry initiatives.

The proposed guidelines include important activities to assure that resource expenditures are effectively managed. The staff has concluded that effective utilization of industry initiatives would require coordinated action with the industry to provide timely identification of resources necessary to support the budgeting process. Therefore, the guidelines provide for two public meetings each year to review the status of ongoing industry initiatives and to identify future potential industry initiatives. This could be an additional agenda item on pre-existing meetings with industry groups and representatives. Additional meetings may be needed to address emerging issues. In addition, the guidelines provide for use of the "add/shed" process as part of Planning, Budgeting and Performance Management (PBPM) in order to assure that resources are expended on those issues that maintain safety and provide maximum leverage to reducing unnecessary burden, improving public confidence and increasing efficiency, effectiveness and realism.

Fees:

The agency's fee process, in accordance with 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of

1954, as Amended,” allows for the exempting of fees for reviews under §170.11(a)(12), Exemptions. Specifically, this paragraph states that:

No application fees, license fees, renewal fees, or inspection fees shall be required for: A performance assessment or evaluation for which the licensee volunteers at the NRC's request and which is selected by the NRC.

The staff is recommending no change to this process, since the staff believes that overall savings effected by the use of industry initiatives will offset the costs of review. Accordingly, there would be no licensee-specific charges associated with the generic staff review of an industry initiative.

CONCLUSIONS:

The staff has completed the development of proposed guidelines for including industry initiatives in the regulatory process. The guidelines provide flexibility in the form that industry initiatives might take while making optimal use of existing regulatory processes to provide a framework for the efficient and effective use of industry initiatives to resolve issues and maintain safety. The guidelines provide for public participation in the process and for making information related to industry initiatives readily available to all stakeholders.

Interactions by the staff with industry groups or other members of the public in carrying out the steps described in this paper will be carried out in such a manner as to fall outside of the requirements of the Federal Advisory Committee Act (FACA). Staff will consult with the Office of the General Counsel (OGC) if any questions arise regarding the application of FACA to such interactions.

RECOMMENDATIONS AND FUTURE ACTIONS

Staff requests the Commission’s approval to issue the proposed guidelines for public comment. Staff requests action within ten days. Action will not be taken until the SRM is received. Staff consider this action to be within the delegated authority of the Director of NRR.

After considering further stakeholder comments, staff will communicate the final, revised guidelines in a generic communication and implement them for future industry initiatives. The final guidelines will be distributed by Agency-approved means (e.g., internally by NRR office letter, and externally by a regulatory issue summary) and posted on the NRC’s web page. Expected milestones are:

Commission Approval to Issue Guidelines for Public Comment	July 31, 2000
Guidelines Issued for 45-day Public Comment	August 31, 2000
Comments Resolved and Final Guidelines Issued	January 5, 2001

Commission approval of the final industry initiatives guidelines would only be sought if they are substantially different from the attached proposed guidelines.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections to its content.

The Commissioners

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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 reviewed this paper for information technology/information management implications and has no objections.

/RA by Carl J. Paperiello Acting For/

William D. Travers
Executive Director
For Operations

Attachments: Attachment A, Process and Guidelines
Attachment B, Discussion and Examples of Industry Initiatives
Attachment C, Summary of Meetings and Communications With Stakeholders

letter, and externally by a regulatory issue summary) and posted on the NRC's web page. Expected milestones are:

Commission Approval to Issue Guidelines for Public Comment	July 31, 2000
Guidelines Issued for 45-day Public Comment	August 31, 2000
Comments Resolved and Final Guidelines Issued	January 5, 2001

Commission approval of the final industry initiatives guidelines would only be sought if they are substantially different from the attached proposed guidelines.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections to its content.

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 reviewed this paper for information technology/information management implications and has no objections.

/RA by Carl J. Paperiello Acting For/
 William D. Travers
 Executive Director
 For Operations

Attachments: Attachment A, Process and Guidelines
 Attachment B, Discussion and Examples of Industry Initiatives
 Attachment C, Summary of Meetings and Communications With Stakeholders

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PROPOSED GUIDELINES FOR IMPLEMENTING INDUSTRY INITIATIVES IN THE REGULATORY PROCESS

PURPOSE:

To provide proposed guidelines for including industry initiatives involving nuclear power reactor licensees in the regulatory process. These proposed guidelines are intended to ensure that future industry initiatives proposed by applicable industry groups (AIGs)⁽¹⁾ would be treated and evaluated in a consistent and controlled manner that is visible and open to all stakeholders. If multiple AIGs individually submit separate initiatives regarding the same issue, all industry initiatives will be addressed pursuant to these guidelines. The nature of issues that may be addressed through industry initiatives are very broad. Therefore, it is intended that the following guidelines provide flexibility in allowing the staff, AIGs, and other stakeholders to interact in pursuing industry initiatives. However, these guidelines provide the staff with a structured framework for processing issues from their identification through implementation to resolution. It is intended that, by promoting a consistent, controlled and visible process, these guidelines will assure that safety is maintained while providing for efficient and effective use of resources, reduced unnecessary regulatory burden and enhanced public confidence.

In addition, it is important to note that these guidelines reference other existing NRC policies and procedures (e.g., generic communications, SECY-99-143; commitment tracking, SECY-00-0045; inspection/oversight, SECY-00-0049; enforcement policy, SECY-00-0061 and SECY-99-219; commitment policy, SECY-98-224; and, fees policy, 10 CFR Parts 170 and 171, among others). It is not the intent of these guidelines to create any new policies or procedures in those areas. The most recent version of the applicable NRC policies and procedures should be utilized when implementing these guidelines.

DESCRIPTION OF INDUSTRY INITIATIVES PROCESS

The following describes the actions associated with each numbered step indicated in the "Industry Initiatives Process" flowchart (page A-11, of the guidelines).

Box 1 - ISSUE IDENTIFICATION

There are many ways that an emerging issue, potentially suitable for being addressed via an industry initiative, may be identified. These include the NRC staff being informed by the AIG(s), the public, another government entity (domestic or foreign), through the staff's own investigations (e.g., inspection, event assessment, or research studies), or other means. It is intended that a broad range of information sources be considered in identifying issues of concern.

However, it is important to note that some issues may fall into other NRC processes (e.g., allegations or petitions submitted pursuant to 10 CFR 2.206), and care should be taken to make sure that such issues are properly characterized and assigned to the appropriate process for

⁽¹⁾ An AIG could be the members of one or more Owners Groups, an industry organization such as the Nuclear Energy Institute (NEI) or the Electric Power Research Institute (EPRI), or two or more licensees.

dispositioning. Issues arising from allegations or petitions may be resolved in the longer term by use of an industry initiative, but are not initially considered to be candidates for an industry initiative.

Emerging issues should be documented and the staff's preliminary evaluation of the technical and policy implications presented to the Office of Nuclear Reactor Regulation's (NRR) Executive Team (ET) for review and initial dispositioning (see Box 2, below). The staff's preliminary evaluation of the technical and policy implications of the emerging issue would include items such as:

- (a) whether or not the issue is an adequate protection issue,
- (b) whether or not there is an immediate safety concern,
- (c) which plants (types or specific plants) could the issue potentially involve,
- (d) the likelihood that AIG(s) would pursue resolution through an industry initiative,
- (e) if AIG(s) decide that the issue is appropriate for resolution through an industry initiative, should the resolution be handled through a Type 1 or Type 2 industry initiative⁽²⁾,
- (f) if an industry initiative is not pursued, what other regulatory process would be appropriate,
- (g) types of staff work that would be involved in resolving the issue (e.g., prior review and approval, monitoring, inspection, etc.),
- (h) estimate of staff resources required for industry initiative and other options,
- (i) whether or not a backfit potential is involved,
- (j) whether or not the issue involves an allegation or petition submitted pursuant to 10 CFR 2.206,
- (k) assessment against the outcome goals,
- (l) plans for stakeholder involvement,
- (m) options for how the plants could resolve the issue,
- (n) need for periodic reports to monitor licensee implementation of industry initiative, and
- (o) need for Commission notification and followup.

Other items would be included, as appropriate. Similarly, issues that the industry or other stakeholders identify should be documented (e.g., letter to the Director of NRR), then reviewed as above.

⁽²⁾ For the purpose of these guidelines, there are two types of industry initiatives, Type 1 and Type 2. Type 1 industry initiatives are broken down into two subparts. Industry initiatives are defined as:

Type 1: those developed by AIG(s) in response to some issue of potential regulatory concern (a) to substitute for or complement regulatory actions for issues within existing regulatory requirements, or (b) which are potential cost beneficial safety enhancement issues outside existing regulatory requirements;

Type 2: those that are initiated and developed by AIG(s) to address issues of concern to the applicable industry group but that are outside existing regulatory requirements and are not cost beneficial safety enhancements, or that are used as an information gathering mechanism.

In developing an emerging issue, it may be appropriate to hold public meetings and/or workshops to obtain additional information and individual views regarding the issue from appropriate stakeholders. However, meetings and/or workshops held during this phase of the process should be primarily for the purpose of understanding the issue in order to facilitate the rest of the process presented in these guidelines, and should not involve significant commitments of staff resources.

The public should be notified of the issue, either by press release, generic communication, weekly highlight, or other appropriate media. At a minimum, any meetings and/or workshops should be noticed in a timely manner and open to the public to allow public participation (see Public Participation, below).

Box 2 - NRR ET APPROVAL TO PURSUE ISSUE

The staff's initial evaluation of the issue is reviewed by the NRR ET to ensure that the emerging issue is of sufficient importance either to meet with the AIG(s) and other stakeholders to present the NRC staff's views on the appropriateness of addressing an emerging issue as an industry initiative, or to immediately pursue regulatory action, if justified (see Box 4, below). The staff's evaluation, as presented to the NRR ET, should include, to the extent possible:

- 1) identification of applicable regulatory requirements (e.g., regulations, technical specifications, design bases, commitments),
- 2) safety significance from both a deterministic and probabilistic risk assessment perspectives,
- 3) limitations in the amount of information available or ability to characterize the issue,
- 4) an assessment of the impact of the industry initiatives on other NRC organizations and a discussion of how those organizations will be involved in the further evaluation of the industry initiative, and
- 5) staff recommendations.

It is recognized that, in the early stages of issue development, additional information may be necessary to fully characterize or quantify the issue, and that the information presented at this stage may be somewhat preliminary and qualitative in nature. The NRR ET will render a decision on whether to: (1) not pursue the issue (see Box 3, below), (2) pursue the issue on an expedited basis (see Box 4, below) or, (3) pursue the issue via an industry initiative.

Consistent with the definitions provided in SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," SECY-99-143, "Revisions to Generic Communication Program," and these guidelines, many issues can be addressed through an industry initiative. However, those issues that involve matters of adequate protection shall not be addressed via the process provided in these guidelines.

Box 3 - NOT PURSUE ISSUE

The NRR ET may decide that the issue does not need to be pursued. This decision would consider both the safety significance and the existing regulatory bases, and should be documented in a memorandum from the sponsoring organization (e.g., division) to the Director, NRR. If the issue is one identified by an AIG or other stakeholder, the AIG(s) and other interested stakeholders should be informed in writing of the decision and its bases.

The NRR decision to not pursue an issue at this time would not preclude the AIG(s) or individual licensees from pursuing an issue through other avenues.

Box 4 - PURSUE ISSUE RESOLUTION ON AN EXPEDITED BASIS

Some issues may need to be handled in a more expeditious manner than is possible by an industry initiative. Some considerations that may be taken into account when determining the urgency of an issue may include the level of risk involved and the need for prompt corrective action. In the event that the NRR ET determines that the issue requires expedited action, approaches could be taken that include activation of the appropriate Owners Group's Regulatory Response Group (RRG), issuance of orders, or issuance of a bulletin, as described in SECY-99-143. The staff may defer formal regulatory actions while the appropriate Owners Group's RRG is activated to address the issue. The AIG(s), stakeholders and the public are kept informed through public meetings or other appropriate media, as described in the Communications Plan, below.

Box 5 - ESTABLISH INDUSTRY INITIATIVE

If an expedited resolution is unnecessary and the NRR ET determines to pursue the issue through an industry initiative, a letter would be sent from the NRR Director to the identified AIG(s) and other interested stakeholders. These letters will include a description of the issue, provide appropriate references and background information, identify the NRC contact for the issue (see Project Management, below), and propose that an initial public meeting or workshop be scheduled to share information on the issue. The AIG(s) would be invited to evaluate the issue and to develop a proposal for addressing the issue, which would be presented to the staff and other stakeholders at the proposed initial public meeting/workshop. Stakeholders would be invited to provide individual views regarding the issue and any proposed actions. The staff will need to evaluate the AIG's proposal, and any stakeholders comments or proposals, before any further meetings and/or workshops on the issue are held.

The public would be informed of meetings and/or workshops held on this issue, and would be encouraged to attend and/or provide input (see Public Participation, below).

Since many different approaches may be used to resolve the issue, multiple meetings and/or workshops may be needed at this point in the process in order to exchange information, present proposals from the stakeholders, and to receive individual views on the possible options for resolution of the issue. These interactions would include the NRC, AIG(s) and other stakeholders. The objectives are to better understand the issue, and to establish an industry initiative action plan with tasks, milestones, resources required, and responsible parties, to be utilized by the AIG(s) in pursuing issue resolution. The AIG(s) industry initiative action plan should provide the basis for pursuing the issue as an industry initiative, and the need, as appropriate, for licensee commitments to the industry initiative. The staff should establish its own industry initiative action task plan. An industry initiative communications plan should also be developed by the staff. Schedules should be established consistent with the significance of the issue.

In some cases, it may be necessary to collect additional information to better understand the significance of an emerging issue and how to address it in an efficient and effective manner. Information needs could be addressed in the industry initiative action and communication plans, or may require some affirmative action on the part of NRC. Any NRC activities to collect information would be conducted in accordance with the guidance provided in SECY-99-143 and

the applicable rules and regulations referenced therein. Any voluntary information collections are subject to Paperwork Reduction Act considerations and will be coordinated with the Offices of the Chief Information Officer (OCIO) and the General Counsel (OGC).

Possible approaches to resolving the issue could include actions such as development and implementation of an industry program, voluntary license amendments, revision of industry guideline documents, modifications to codes and standards, or creation of a Generic Safety Issue (GSI). In general, the intent would be to accomplish the issue resolution in the most efficient and effective manner.

Box 6 - REGULATORY ACCEPTANCE OF THE PROPOSED INDUSTRY INITIATIVE

The NRC staff should consider the proposed industry initiative action and communications plans developed in Box 5 as part of the Planning, Budgeting and Performance Management (PBPM) “add/shed” budgeting process. The review should consider the background of the issue and the details of the industry initiative action and communications plans that have been developed, including the proposed actions, milestones, resources and responsible parties. The review should address how the industry initiative action and communications plans supports the NRC’s goals of maintaining safety, reducing unnecessary burden, improving public confidence, and enhancing efficiency and effectiveness, and should be documented.

If the industry initiative action and communications plans developed in Box 5 are found acceptable by the NRR ET, implementation of the industry initiative action and communications plans will proceed as described in Boxes 8 and 9.

If the industry initiative action and/or communications plans developed in Box 5 are found unacceptable, the issues leading to rejection of the industry initiative action and/or communications plans should be publically communicated to the AIG(s) and other stakeholders. If an acceptably revised industry initiative action and/or communications plans cannot be developed, the NRC will consider the need for further regulatory action (see Box 7, below).

The staff’s acceptance or rejection of a proposed industry initiative will be published in the Federal Register and placed on the NRC’s web page.

Box 7 - DETERMINE APPROPRIATE REGULATORY ACTION

If the staff does not accept the AIG’s proposed actions to be taken, an individual licensee in the AIG does not commit to the industry initiative, or if AIG member licensees fail to implement the committed-to actions, the NRC staff may independently take action. After having determined that the Type 1 industry initiative issue involves either a needed safety enhancement and/or compliance with existing Rules and/or regulations, the staff should take regulatory actions (e.g., rule-making, issuing appropriate generic communications, orders, etc.) to appropriately address this issue, as needed. Any regulatory actions taken would be determined consistent with existing Regulations and NRC policy and procedures. For items requiring a backfit analysis per 10 CFR 50.109, crediting of the industry initiative would follow the position in NUREG/BR-0058, Revision 3, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” or the latest applicable guidance. The public should be kept informed, through public meetings or other appropriate media, while the staff develops these regulatory actions.

Box 8 - IMPLEMENTATION OF INDUSTRY INITIATIVE

Once approved, the industry initiative action and communications plans developed in Box 6 should be implemented by the AIG(s) and monitored by the staff. The milestones in the AIG's industry initiative action plan should be documented in the staff's task action plan, tracked in the NRR Director's Quarterly Status Report (DQSR), and incorporated into the NRR Operating Plan, as appropriate. The industry initiative action plan milestones would be monitored via periodic reviews and through periodic public meetings with the AIG(s) and other stakeholders. NRC acceptance of the industry initiative and associated action and communications plans would be documented in a Federal Register notice and a Regulatory Issue Summary (RIS), in accordance with SECY-99-143 (see Communications Plan, below). The public would be kept informed of the progress in completing the industry initiative action plan as outlined in the industry initiative communications plan, and would be encouraged to provide input (see Public Participation, below).

Box 9 - INSPECTION AND/OR MONITORING AND ENFORCEMENT

Resolution of Type 1a industry initiative issues may require that AIG member licensees implement changes in their programs, technical specifications, or take other actions as established in the industry initiative plan. Inspection and/or monitoring of implementation of these activities would depend on the nature of the activities the AIG(s) implement to address the issue. Enforcement would be available if violations of regulatory requirements occur.

Resolution of Type 1b industry initiative issues would involve NRC re-assessment of the issue, and of the efficacy of an industry initiative to address the issue. Inspection and/or monitoring of implementation of these activities would depend on the nature of the activities the AIG(s) implement to address the issue. Enforcement would be available if violations of regulatory requirements occur.

Type 2 industry initiatives involve industry actions outside existing regulatory requirements that are not cost beneficial safety enhancements, or that are used as an information gathering mechanism, and the need for NRC overview is not anticipated, and enforcement action will not be available.

The need for inspection and/or monitoring should be determined consistent with the NRC's Reactor Oversight Process, as described in Inspection Manual Chapter 2515. An inspection and/or monitoring plan will be established on a case-by-case basis, consistent with the requirements associated with implementation of the issue and the revised risk-informed NRC inspection program, as described in the NRC's Inspection Manual 2515. The inspection and/or monitoring plan would include a decision making process on whether to alter the baseline inspection program or develop a temporary instruction (TI) that will look at risk significance, resources, cornerstone attributes, performance indicator (PI) implications, etc., in determining whether additional inspections are needed. Special inspections or monitoring of the progress may not be necessary, and in most cases it is expected that it will not be, based on the nature of the actions taken. For example, it is expected that many licensee activities will already be adequately covered by the existing inspection and oversight program. Inspections may be performed either by resident or regional inspectors or special teams to determine if regulatory requirements are met. Monitoring may be performed by either inspectors or NRR project managers (PMs), wherein they would determine that licensees have taken actions committed to be performed as part of the industry initiative. Documentation of inspections or monitoring activities should be in accordance with the NRC Inspection Manual.

If a specific licensee, or the industry group in general, fails to adequately implement the agreed upon actions, this would be addressed by NRC in the context of existing enforcement policy and/or additional regulatory action consistent with the guidance above. Additional discussion on enforcement is found below in the section “Enforcement Guidelines Consistent with Reactor Oversight Process Improvements.”

OTHER ITEMS

Project Management

Once it has been decided to pursue resolution of an issue via an industry initiative, a lead project manager (LPM) from either NRR’s Division of Licensing Project Management (DLPM) or Division of Regulatory Improvement Programs (DRIP), as appropriate, should be appointed. The LPM will be responsible for (1) facilitating staff review of the industry initiative, (2) assuring that activities described above are accomplished, and (3) acting as the staff’s point of contact between the AIG(s), other stakeholders, and other interested members of the public.

A lead technical reviewer (LTR) will also be assigned, from either the Division of Engineering (DE), Division of Systems Safety and Analysis (DSSA), Division of Inspection Programs Management (DIPM), or DRIP, as appropriate. The LTR will be responsible for coordinating the technical review of the industry initiative.

Public Participation

Ensuring that all stakeholders have an opportunity to participate is essential. As such, the industry initiative communications plan (see below) should be developed to ensure that stakeholders will be notified of the issue, either by press release, generic communication, or other appropriate media. The stakeholders will be given an opportunity to provide their individual views on the industry initiative action plan, and to participate in all NRC-sponsored meetings and/or workshops on the industry initiative. At a minimum, any meetings and/or workshops would be noticed on the NRC’s web pages in a timely manner and open to the public to allow public participation. The industry initiative LPM will be responsible for encouraging interested stakeholders to participate in the process for consideration of the industry initiative, exchanging relevant information with the staff and the AIG(s) while the industry initiative action and communications plans are being developed, and then implemented.

The staff will disclose to the public all information supplied by or obtained from industry, subject to relevant Freedom of Information Act (FOIA) and Privacy Act exceptions, in support of the industry initiative. The NRC will also disclose all information supplied by or obtained from industry (subject to relevant FOIA/Privacy Act exceptions) that it uses to assess (1) the quality of implementation of the industry initiative by licensees and (2) the effectiveness of the industry initiative in resolving the underlying issues. This disclosure typically will be through the public docketing process.

Communications Plan

A communications plan will be developed by the NRC staff for each issue that is being addressed by an industry initiative. The objective of this industry initiative communications plan is to make the industry initiative visible to all stakeholders and to allow easy access to relevant

information. Guidance to the staff in this communication plan would include the use of the ADAMS system and an NRC industry initiative web page, that includes:

- (1) a summary of the issue;
- (2) meeting announcements and summaries and/or transcripts;
- (3) non-proprietary versions of submitted reports and staff evaluations;
- (4) action plans;
- (5) generic communications (e.g., regulatory issues summaries);
- (6) periodic status reports, press releases, weekly highlights, and/or, other appropriate media, issued in a timely manner to facilitate public participation in the regulatory process; and,
- (7) a final resolution summary.

Primary responsibility for implementation of the communications plan will be that of the assigned LPM. The NRC industry initiative web page will be maintained by the assigned LPM.

Resource Planning, Including Semi-Annual Meetings to Identify Potential Industry Initiatives:

To effectively and efficiently delineate expected resource needs and expenditures for industry initiatives, the staff should publicly meet on a regular basis (approximately twice annually) with industry groups and other stakeholders to obtain information on the status of ongoing and potential future industry initiatives. This could be an additional agenda item on pre-existing public meetings with industry groups and representatives, and will be noticed accordingly. Additional noticed public meetings could be needed to address emerging or unanticipated issues. The purpose of these regularly scheduled public meetings is to provide the NRC staff with information that will support budgeting and resource planning, and any required staff resource reallocations. The LPM would have primary responsibility for scheduling, conducting, and documenting these meetings. NRC should address its resource needs using the “add/shed” process as part of the PBPM process in order to prioritize resource expenditures.

Fees:

The agency’s fee process, in accordance with 10 CFR Part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended,” allows for the exempting of fees for reviews under §170.11(a)(12), Exemptions. Specifically, this paragraph states that:

No application fees, license fees, renewal fees, or inspection fees shall be required for: A performance assessment or evaluation for which the licensee volunteers at the NRC's request and which is selected by the NRC.

There would be no licensee-specific charges associated with the generic staff review of an industry initiative.

Tracking of Commitments Consistent with Existing Regulatory Processes:

Tracking of licensee commitments made in accordance with the industry initiative action plan, if any, will be handled by the individual licensee’s NRR PM and the industry initiative LPM in accordance with SECY-00-0045. The NEI guidelines, referenced therein, provide

recommended actions for licensees' management, implementation and documentation of commitments (Sections 2, 3, 4 and 5). The guidelines were found acceptable by the staff. Related correspondence would be made publically available, as appropriate.

Enforcement Guidelines Consistent with Reactor Oversight Process Improvements:

Licensee activities implemented as the result of an industry initiative may or may not be enforceable, depending upon the nature of the issue being addressed. Licensee actions resulting from an industry initiative that are necessary to maintain compliance with an existing regulatory requirement would be enforceable. If an industry initiative program addresses issues outside current regulatory requirements, or is for information gathering, it is not enforceable. If it is determined that licensees are not implementing the industry initiative products as they have committed to, appropriate enforcement actions, if any, consistent with the guidance described below, will be taken by the staff, when appropriate.

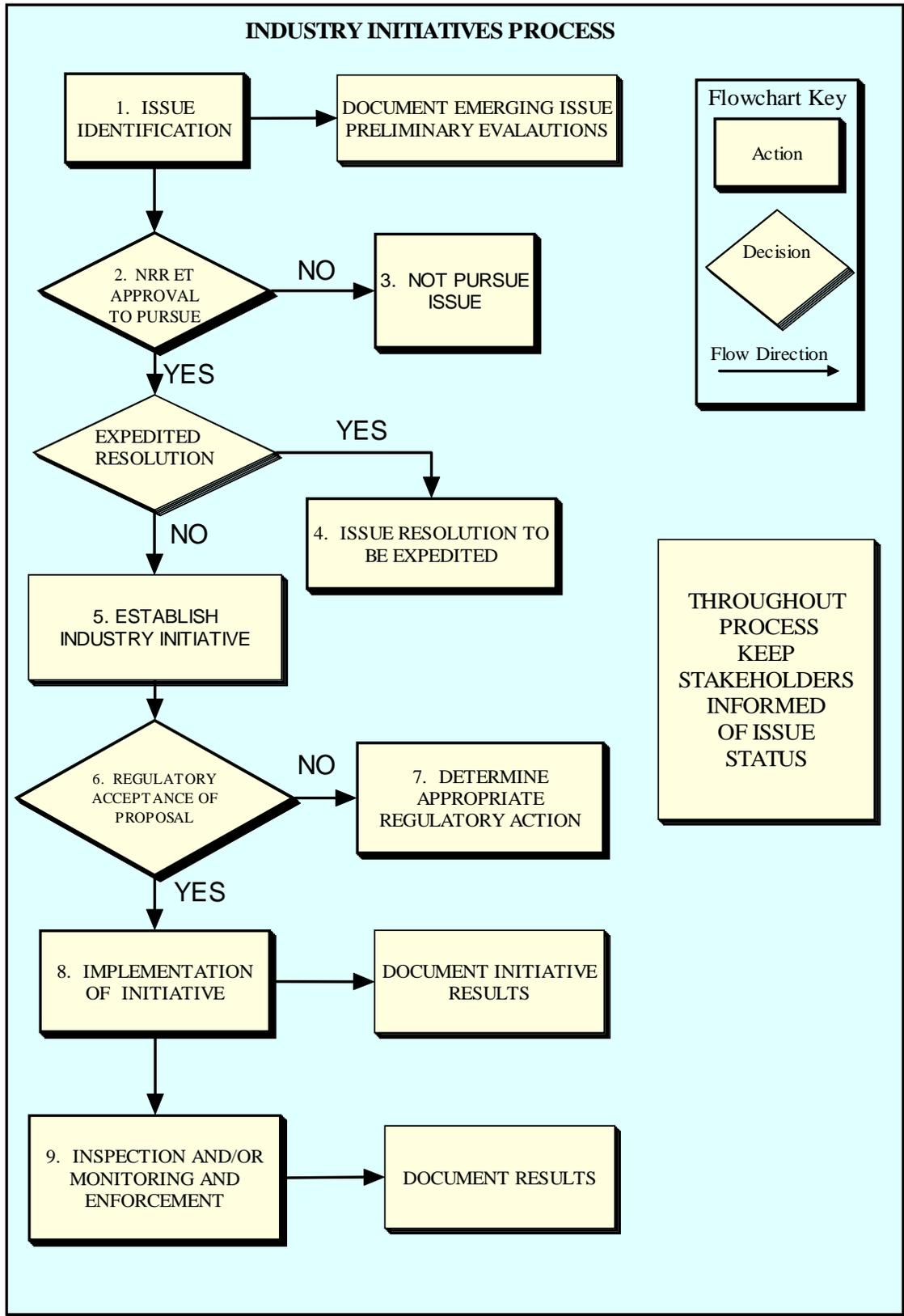
Proposed Enforcement Guidelines for Licensees for Industry Initiatives *

<u>Type of Industry Initiative</u>	<u>Industry Action</u>	<u>Enforcement Guidance</u>
I.a. Industry initiatives to address issues that substitute for or complement regulatory actions for issues within existing regulatory requirements (e.g., BWRVIP, NEI SG Guidelines).	AIG(s) develop and implement program, with associated licensee commitments, that is included in appropriate documents (e.g., technical specifications, updated final safety analysis report, and/or plant procedures), and controlled by applicable regulatory requirements (e.g., 10 CFR Part 50, Appendix B program, 10 CFR 50.59, or Section 182 of the Atomic Energy Act), if any.	If licensee does not implement the activities resulting from the industry initiative, and its actions are not consistent with applicable regulatory requirements, if any, enforcement is available. The severity of the violations would be established consistent with revised reactor oversight process and the enforcement policy.

Proposed Enforcement Guidelines for Licensees for Industry Initiatives *

<u>Type of Industry Initiative</u>	<u>Industry Action</u>	<u>Enforcement Guidance</u>
1.b. Industry initiatives to address potential cost beneficial safety enhancement issues outside existing regulatory requirements (e.g., shutdown risks, severe accident management).	AIG(s) develop and implement program, with associated licensee commitments.	Commitment to industry initiative by licensee is only link to NRC. Deviation or re-direction from committed program would cause NRC re-assessment of issue, and of the efficacy of an industry initiative to address the issue. Orders or rule-making are available as an option if 10 CFR 50.109 criteria for backfitting as a safety enhancement are satisfied; if reasonable assurance criteria are undermined, there is no need to further satisfy backfit criteria. Credit for industry initiative would be considered in a backfit analysis, consistent with Commission guidance to SECY-99-178, "Treatment of Voluntary Initiatives in Regulatory Analysis," dated May 21, 1999.
2. Industry initiatives for issues that are outside of regulatory requirements, not cost beneficial safety enhancements, or that are used as an information gathering mechanism.	AIG(s) develop and implement program.	No NRC overview or enforcement expected to be needed on program.

* Issues that involve adequate protection are outside the scope of industry initiatives.



DISCUSSION AND EXAMPLES OF INDUSTRY INITIATIVES

Definition of Industry Initiatives:

For the purpose of these guidelines, there are two types of industry initiatives, Type 1 and Type 2. Type 1 industry initiatives are broken down into two subparts. A description follows:

- Type 1: those developed by the applicable industry group(s)⁽¹⁾ in response to some issue of potential regulatory concern (a) to substitute for or complement regulatory actions for issues within existing regulatory requirements, or (b) which are potential cost beneficial safety enhancement issues outside existing regulatory requirements;
- Type 2: those that are initiated and developed by the AIG(s) to address issues of concern to the applicable industry group but that are outside existing regulatory requirements and are not cost beneficial safety enhancements, or that are used as an information gathering mechanism.

Type 1 Industry Initiative Examples:

A Type 1a example of an existing program that compliments existing regulatory requirements via an industry initiative is the Boiling Water Reactor Vessel and Internals Project (BWRVIP). This program, in which all U.S. BWR licensees participate, was instituted in 1994 to address, initially, the potential consequences of intergranular stress corrosion cracking (IGSCC) in the BWR core shroud. It subsequently expanded in scope to address all BWR austenitic stainless steel and Alloy 600 safety-related components, the reactor vessel, and safety-related piping. This industry-led program developed, in safety-significance priority, approximately 50 generic industry guidelines for inspection scope and frequency, flaw evaluation, and mitigation and repair. All BWR owners committed to adhere to the program or inform the staff of any plant-specific deviations. Further, since the BWRVIP representatives agreed which components are safety-related, actions taken to inspect, evaluate, and repair these components are covered by the individual licensee's 10 CFR Part 50, Appendix B, quality assurance (QA) program.

A second Type 1a industry initiative example is the framework for managing steam generator (SG) tube integrity associated with NEI-97-06, "Steam Generator Program Guidelines." This industry initiative will involve license amendments by all pressurized water reactor (PWR) licensees to change from deterministic to performance-based technical specifications. In response to the staff's ongoing regulatory development effort, the PWR industry focused its efforts on improving existing SG inspection guidance and developing additional guidelines on other programmatic elements related to SG tube integrity. The industry's efforts to improve industry guidance culminated in the NEI 97-06 industry initiative, developed through the NEI Nuclear Strategic Issues Advisory Committee, which establishes a framework for structuring and strengthening existing SG programs. This industry initiative discusses regulatory interfaces, licensee responsibilities, and a protocol for revising referenced guidelines. It also

⁽¹⁾ An applicable industry group (AIG) could be the members of one or more Owners Groups, an industry organization such as the Nuclear Energy Institute (NEI) or the Electric Power Research Institute (EPRI), or two or more licensees.

defines the performance criteria that licensees shall use to measure tube integrity. It should be noted that the final staff review of NEI-97-06 is still in progress.

An example of a Type 1b industry initiative is the NEI guidelines that have been provided to licensees to address shutdown risks. This risk-significant issue is not explicitly required by existing regulations. The staff found this issue to be valid for backfitting as a safety enhancement pursuant to 10 CFR 50.109. The rulemaking was discontinued since the Commission concluded that existing industry practices provide an adequate level of safety. No enforcement would presently be appropriate.

Type 2 Industry Initiative Examples:

A Type 2 industry initiative addresses issues that are not related to a regulatory requirement and do not address a safety concern (e.g., productivity, balance of plant system performance, or resource management). An example is site access authorization, in which industry representatives determined that a common approach would be beneficial. In this case, the staff and stakeholders participants agreed that a commitment to the NRC regarding the industry initiative was unnecessary, and inspections and enforcement are not applicable.

A second example of a Type 2 industry initiative is one developed for information gathering purposes. In some cases, it may be necessary to collect additional information to better understand the significance of an emerging issue and how to address it in an efficient and effective manner. In this case, the information that is collected would be included in the industry initiative action plan. Alternately, any NRC activities to collect information would be conducted in accordance with the guidance provided in SECY-99-143, "Revisions to Generic Communication Program," and the applicable rules and regulations referenced therein.

SUMMARY OF MEETINGS AND COMMUNICATIONS WITH STAKEHOLDERS

The NRC staff has had discussions on this subject at several public meetings with members of the industry, the Nuclear Energy Institute (NEI) and other interested stakeholders, as described below. These discussions focused mainly on the intent and usage of voluntary industry initiatives (VIIs). The staff issued a Federal Register notice (FRN) and requested comments from interested stakeholders, up to and including proposing guidelines *in toto*. No response to the FRN was received. Other than written comments from NEI, no written input was received from the stakeholders on specifics to be included in the proposed guidelines. The staff established a web page at <http://www.nrc.gov/NRC/REACTOR/VII/index.html>, which has electronic copies of all relevant background materials; meeting notices, summaries, and transcripts; letters to and from the industry; and, milestones for this subject.

September 1, 1998, Public Meeting on DSI-13:

The decision to develop guidelines for crediting voluntary industry initiatives in lieu of regulatory action is an outgrowth of the Commission's Direction Setting Initiative (DSI) 13, "The Role of Industry (DSI-13)' and Use of Industry Initiatives," dated December 31, 1997, and the associated SRM issued on April 16, 1998. In accordance with this SRM, a public stakeholders meeting on DSI-13 was held in Rosemont, Illinois, on September 1, 1998, and input was received from the attending stakeholders. This input was utilized in the development of the subsequent SECY-99-063.

July 13, 1999, Internal Stakeholders Meeting:

On July 13, 1999, members of the NRC staff from the Office of Nuclear Reactor Regulation (NRR), Office of Enforcement (OE), Office of the General Counsel (OGC), Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Nuclear Regulatory Research (RES) met to broadly discuss various guidelines to allow the initial drafting of a regulatory framework that supports the implementation of voluntary industry initiatives. Specifically, the topic of developing an inspection program and enforcement of a licensee's failure to meet commitments associated with a voluntary industry initiative were examined. The emphasis of the meeting was focused on three areas: defining types of voluntary industry initiatives; industry developing a program with commitments that is included in the updated final safety analysis report and made part of licensees' Appendix B QA Program; enforcement guidelines predicated on 10 CFR Part 50, Appendix B, 10 CFR 50.59, Section 182 of the Atomic Energy Act, and Enforcement Guidance Memorandums 98-006 and 98-002(T).

September 8, 1999, Internal Stakeholders Meeting:

On September 8, 1999, members of the NRC staff from NRR, OE, OGC, NMSS, RES, Office of the Chief Financial Officer and the Advisory Committee on Reactor Safeguards attended a second internal NRC stakeholders meeting to specifically determine guidelines to allow the drafting of an initial regulatory framework that supports the implementation of VIIs. The meeting focused on the nine areas specified in SECY-99-063: definition and initiation of voluntary industry initiatives, identification of staff role, fee management, developing an operating plan, tracking of licensee commitments, generating inspection/monitoring guidelines, developing enforcement procedures, and public participation. On the basis of this discussion,

the staff developed an outline of possible guidelines to use for discussion purposes with external stakeholders.

October 27, 1999, Public Meeting:

A public meeting was held on October 27, 1999, in Rosemont, Illinois, with interested stakeholders, including NEI and Owners Groups management representatives, and is summarized in a meeting summary dated November 18, 1999. At the request of NEI, an additional stakeholders meeting was held at the NRC Headquarters on December 21, 1999. Both of these meetings were noticed and discussed in advance with NEI and other stakeholders.

Although the attendance at the October meeting was relatively small (seven external stakeholders), the panel at the meeting included management representatives from NRC, NEI, and two nuclear utilities, representing two industry groups. Other participants included a vendor representative and two industry consultants. A representative from the Nuclear Energy Information Services, who had previously planned to participate as a panel member, was unable to be at the meeting.

December 13, 1999, Federal Register Notice:

On December 13, 1999, the NRC issued a Federal Register notice (FRN) (64 FR 69574) “... *soliciting additional stakeholder comments from interested parties on both the technical and regulatory aspects related to the development of guidelines to allow the drafting of a regulatory framework that supports the implementation of [VIIIs],*” from interested stakeholders, by January 15, 2000. The response date was chosen in order to allow the staff time to incorporate any comments received into the proposed guidelines. No comments were received in response to the FRN.

December 21, 1999, Public Meeting:

Seven external stakeholders also participated in the December 21, 1999, meeting, held in Rockville, Maryland. Participants in this meeting included management representatives from NRC, NEI and the Electric Power Research Institute (EPRI), as well as representatives from utilities and vendors. Discussions at both the October and December meetings focused largely on the general concept and philosophy of crediting VIIIs in lieu of regulatory action, and was less focused on the specific details to be included in the guidelines. During the December 21, 1999, meeting, NEI and EPRI representatives provided a one-page flow chart outlining a proposed process for crediting industry initiatives, which was included in the meeting summary, dated February 3, 2000. The NRC staff indicated during this meeting that they would review this flow chart and provide comments, which were provided to NEI by letter dated February 9, 2000.

February 2 and February 6, 2000, Telephone Conversations:

On February 2 and February 6, 2000, the staff had telephone conversations with NEI regarding NEI's position on the staff's proposal to develop guidelines for crediting VIIIs in lieu of regulatory action. The staff documented these telephone conversations in a letter to NEI dated February 11, 2000. During the February 6, 2000, telephone conversation, NEI stated that they would provide a letter stating NEI's position on this subject during a February 17, 2000, meeting at the NRC's Headquarters in Rockville, Maryland.

February 17, 2000, NEI Letter:

NEI's February 17, 2000, letter, stated that NEI believes that VIIs ". . .*should not be a substitute for regulatory action.*" Further, this letter stated that "[in] the stakeholder discussions held to-date, NRC suggested voluntary industry initiatives could be used as an alternative to NRC imposing new regulatory requirements by issuing a generic letter. To suggest that industry pursue a voluntary initiative in such a case is counterproductive and circumvents the provisions of the backfitting rule. We believe that if NRC has determined that regulatory action is warranted, then NRC should proceed with rulemaking."

February 17, 2000, Meeting:

The February 17, 2000, meeting, was at NEI's request, and is documented in a meeting summary dated April 7, 2000. During this meeting, NEI, in response to a staff question as to whether the NRC should be developing VII guidelines, stated that guidelines should not be developed since there is no value perceived by NEI ". . .*in putting forward a formalized, structured process on something that has historically worked very well*" in an *ad hoc* manner. Views were exchanged regarding the merits of a formalized process that would ensure that future industry initiatives proposed by the industry are treated and evaluated in a known manner, thus allowing future VIIs to play a major role in achieving the NRC's regulatory goals of maintaining safety; reducing unnecessary regulatory burden; improving efficiency, effectiveness, and realism; and improving public confidence.

During the October 27 and December 21, 1999, and the February 17, 2000, meetings, NRC management suggested that interested stakeholders in general, and NEI in particular, consider proposing a set of guidelines in response to the December 13, 1999, FRN, up to and including proposed guidelines *in toto*. The staff also noted that it could propose a revised schedule to the Commission if the industry needed more time to develop such guidelines. Notwithstanding the above, the NRC did not receive any additional comments in response to the FRN.

March 28, 2000, Regulatory Information Conference (RIC 2000) Break-out Session:

On March 28, 2000, there was an industry initiatives break-out session during the NRC's Twelfth Annual Regulatory Information Conference. The panel included participants from the staff, industry, NEI, the American Nuclear Society, the New England Coalition on Nuclear Pollution, and General Electric, and there was active participation from the attendees in the audience. The staff gave an overview of the history of the issue to date, then opened the floor to questions and comments.

A concern was raised on the enforceability of VIIs. It was agreed that enforcement depends on the specifics of the VII, and that the guidelines need appropriate flexibility. A second concern was stated regarding public confidence. It was felt that replacing regulatory actions with VIIs could decrease public confidence in the staff's ability to regulate safety. However, it was acknowledged that guidelines which codify wide dissemination of information, including reducing the amount of information held as proprietary on the VII subject, could increase overall public confidence.

Finally, it was stated that increased reliance on the usage of industry codes and standards could be a complementary adjunct to the VII process. The staff encouraged all interested stakeholders to provide any additional comments or input to the staff; however, as of the date of this paper, no further input was received.