

POLICY ISSUE (Negative Consent)

July 5, 2001

SECY-01-0121

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 significant negative public comments that the staff received in response to the notice that was published in the *Federal Register* regarding the proposed guidelines for including industry initiatives in the regulatory process, and to request by negative consent Commission approval to notify all stakeholders that the proposal to implement a new industry initiative program and related guideline has been withdrawn based upon the staff's subsequent reevaluation.

SUMMARY:

In response to the June 28, 2000, staff requirement memorandum (SRM) to SECY-00-0016, the staff published the proposed guidelines for including industry initiatives in the regulatory process for public comments. Nearly all of the comments that the U. S. Nuclear Regulatory Commission (NRC) received from stakeholders in response to the *Federal Register* notice regarding the proposed guidelines, were negative. In general, the comments conveyed the stakeholders' opinion that the formal process described in the proposed guidelines should *not* be implemented. In addition, specific comments provided suggestions to improve the proposed guidelines in the event that they were implemented. To address the specific comments, the staff revised the guidelines to incorporate some of the suggested improvements within the previous structure and framework. As directed in the SRM to SECY-00-0116, the revised (final) guidelines are being provided to the Commission for their review (Attachment). The staff also evaluated whether a different approach would be more effective in resolving the stakeholders' comments and achieving the NRC's goals. After carefully considering the comments received from both industry and public stakeholders, and taking into account the existing process described in SECY-99-143, "Revisions to Generic Communication Program," the staff now

Contacts: Charles D. Petrone, NRR
301-415-1027

John R. Tappert, NRR
301-415-2236

recommends to the Commission that the proposed guidelines and the formal process described therein are not needed, and that the existing regulatory process, with minor revisions, is sufficient.

BACKGROUND:

The decision to develop guidelines for using industry initiatives in the regulatory process is an outgrowth of the Commission's Direction Setting Initiative (DSI) 13, which was published as part of SECY-97-303, "The Role of Industry (DSI-13) and Use of Industry Initiatives," dated December 31, 1997, and the associated staff requirements memorandum (SRM), which was issued on April 16, 1998. SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," forwarded to the Commission on March 2, 1999, proposed the development of NRC guidelines for crediting industry initiatives in lieu of taking regulatory action. 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 that existing regulatory processes can be used to support implementation of voluntary initiatives as long as such initiatives will not be used in lieu of regulatory action where a question of adequate protection exists. In addition, the SRM directed the staff to move forward, working with the industry and other stakeholders, in developing the guidelines for using industry initiatives.

This guideline was developed and provided to the Commission in SECY-00-0116, "Industry Initiatives in the Regulatory Process," on May 30, 2000. In response to the SRM issued on June 28, 2000, to SECY-00-0116, the staff revised the proposed guidelines as directed by the Commission and published them in the *Federal Register* on August 31, 2000 (65 FR 53050). The Commission also directed the staff to provide the final version of the guidelines to the Commission for review in the event that significant negative public comments were received regarding the proposed guidelines.

DISCUSSION:

Stakeholder Comments:

During the comment period, the staff received comments from 12 stakeholders. Of those 12, 9 stakeholders, including the Nuclear Energy Institute (NEI), reiterated their previously stated position that the guidelines were not needed because the current practice of addressing industry initiatives on an ad hoc basis is working satisfactorily. However, in the event that the staff elected to move forward with issuing the proposed guidelines, NEI and others provided specific recommendations to improve the guidelines. Of the three remaining stakeholders, the Tennessee Valley Authority (TVA), supported the guidelines as a means of operating more efficiently and effectively. TVA also provided specific recommendations for improving the guidelines. Another stakeholder, Public Citizen, opposed the proposed guidelines because it believes that industry initiatives are unenforceable, limit public participation, and provide an unacceptable substitute for needed regulatory action. The final stakeholder asked questions regarding the proposed guidelines, but did not indicate whether they supported or opposed the guidelines.

The major comments received from the external stakeholders are summarized as follows:

- (1) NEI believes that the proposed guidelines are not necessary, and that there is little value in developing a formalized, structured process regarding interactions that have historically worked well. NEI also contends that such a process would do nothing more than become a burdensome obstacle to open, candid, and necessary interactions between the NRC and its stakeholders. Further, NEI believes that industry initiatives should not be used as a substitute for required regulatory actions. Finally, NEI states that the NRC has the authority and responsibility to promulgate new or revised requirements that may be necessary to ensure adequate protection of public health and safety, and the NRC must continue to do so in order to maintain its standing as an objective and credible regulatory agency. In that regard, NEI believes that deferring to industry organizations or “applicable industry groups,” or creating the perception of doing so, under the auspices of the proposed guidelines, will quickly erode public confidence and trust. These NEI comments were endorsed by Commonwealth Edison Company (ComEd), Carolina Power and Light Company (CP&L), Southern Nuclear Operating Company (Southern Nuclear), South Carolina Electric and Gas Company (SCE&G), Entergy Operations, Inc. (Entergy), Nuclear Utility Backfitting and Reform Group (NUBARG), and Combustion Engineering Owners Group (CEOG).
- (2) The Westinghouse Owners Group (WOG) agreed with NEI, stating that there is no apparent need to formalize this process. WOG also stated that, “The primary motivation for the Industry to support the development of proposed guidelines for including industry initiatives in the regulatory process would be to preclude the issuance of NRC Bulletins and Generic Letters, and, in the process, optimize the actions necessary to address emerging issues. It can be argued that SECY-99-143, “Revisions to Generic Communication Program” already provides an improved level of discipline and consistency on how emerging issues should be addressed in the regulatory process.”
- (3) Public Citizen stated that it is “...categorically opposed to the regulatory retreat under way at the U.S. Nuclear Regulatory Commission (NRC) under the guise of voluntary industry initiatives (in lieu of regulation)...The NRC plans to supplant regulation with voluntary initiatives that are non-enforceable, remove the public from the process, and fail to address significant safety issues....Proposed guidelines will limit the ability of the public to meaningfully participate in the decisions that affect the health and safety of our families, homes, and communities....”

Staff Response to Comments:

The staff considered Comment 1, above, which is similar to the comments provided during previous interactions with the industry. The staff agrees that adequate protection issues should not be addressed using voluntary initiatives in lieu of the regulatory process. This is clearly stated in the proposed guidelines. Despite the improvements and clarifications made to the guidelines, industry stakeholders still believe that the proposed industry initiative process is less desirable than the existing ad hoc process. The staff previously argued in SECY-00-0116 that the proposed guidelines had sufficient flexibility to accommodate the concerns expressed by industry stakeholders. However, because the process relies so heavily on voluntary actions, the staff has concluded that implementing this process without the support of industry stakeholders would not be successful.

The staff also considered Comment 2. The staff agrees that the policy described in SECY-99-143 encourages greater stakeholder involvement in the generic communication process. For example, the process requires that the staff seek stakeholders' input prior to issuing generic letters. The staff has concluded that industry interactions in addressing future emerging issues can be handled on an ad hoc basis in the context of the generic communication process.

The staff also considered Comment 3. It is clear from the comments provided by Public Citizen and NEI that, although licensee commitments are an accepted part of the regulatory process, members of the public could perceive the industry initiative process as a means by which utilities could avoid regulation. Therefore, implementing the process could lead to the erosion of confidence in the regulatory process.

The question of enforceability has been a concern since the issue of formalizing the industry initiative process was first proposed. In the May 27, 1999, response to SECY-99-063, the Commission stated that it was not clear from SECY-98-224, SECY-99-007A, and SECY-99-063, how the staff plans to address enforcement in response to a licensee's failure to meet commitments associated with a voluntary initiative. The staff addressed this question in SECY-00-0116 by discussing the types of enforcement that are available for the various types of industry initiatives. Nonetheless, the staff's overall conclusion is that many industry initiatives that are implemented via a written commitment would not be enforceable. In the event that a licensee (or a group of licensees) failed to live up to a commitment, or to implement it in a timely manner, the staff's only option would be to determine whether there is a regulatory non-compliance and undertake enforcement actions, issue an order, or pursue rulemaking.

CONCLUSIONS:

Stakeholders perceive the industry initiative guidelines as imposing a burdensome obstacle to open and candid interactions. In view of the stakeholders' reluctance to embrace the proposed guidelines, the staff now believes that implementing this largely voluntary process would be ineffective. The difficulties in enforcing commitments and ensuring timely compliance argue for greater reliance on regulatory processes and less on industry initiatives. In addition, the implementation of the proposed industry initiative guidelines and process might give the public the impression that the NRC is encouraging the use of commitments at the expense of regulatory action. Revisions to the generic communication program described in SECY-99-143 have addressed past industry concerns regarding the inconsistency in the process for issuing generic communications. Taking these considerations into account, the staff has concluded that enhancing the internal NRC procedures for the generic communication process is preferable to implementing the proposed industry initiative guidelines and process. Also, by relying on the generic communications process, the NRC is more likely to be viewed as an effective and independent regulator, thereby increasing public confidence. Finally, by having a single process, the NRC is likely to be more effective and efficient.

RESOURCE IMPLICATIONS:

The balance of the small amount of resources planned for this activity (0.5 FTE and \$150K) will be reprogrammed to appropriate activities through the Planning Budget and Program Management (PBPM) process.

RECOMMENDATIONS AND FUTURE ACTIONS:

The staff requests the Commission's approval to notify all stakeholders that the proposal to implement a new industry initiative program and related guidelines has been withdrawn. NRC Inspection Manual Chapter 0720, "Nuclear Regulatory Commission Generic Communications Regarding Nuclear Reactor Issues" is currently being revised to encourage enhanced dialogue between the NRC and its stakeholders as part of the generic communication process. 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 Director of NRR.

COORDINATION:

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

The Office of the Chief Financial Officer has reviewed this paper for resource implications, and has no objections to its contents.

/RA/

William D. Travers
Executive Director
for Operations

Attachment:
Revised Draft—"Proposed Guidelines
for Implementing Industry
Initiatives in the Regulatory Process"

RESOURCE IMPLICATIONS:

The balance of the small amount of resources planned for this activity (0.5 FTE and \$150K) will be reprogrammed to appropriate activities through the Planning Budget and Program Management (PBPM) process.

RECOMMENDATIONS AND FUTURE ACTIONS:

The staff requests the Commission's approval to notify all stakeholders that the proposal to implement a new industry initiative program and related guidelines has been withdrawn. NRC Inspection Manual Chapter 0720, "Nuclear Regulatory Commission Generic Communications Regarding Nuclear Reactor Issues" is currently being revised to encourage enhanced dialogue between the NRC and its stakeholders as part of the generic communication process. 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 Director of NRR.

COORDINATION:

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

The Office of the Chief Financial Officer has reviewed this paper for resource implications, and has no objections to its contents.

/RA/

William D. Travers
Executive Director
for Operations

Attachment:
Revised Draft—"Proposed Guidelines
for Implementing Industry
Initiatives in the Regulatory Process"

ADAMS ACCESSION NUMBER: ML011630126 *See previous **concurrency official RECORD COPY**
 Publicly Available Non-Publicly Available Sensitive Non-Sensitive

OFFICE	REXB	Tech Editor	SC:REXB	BC:REXB	
NAME	CPetrone*	PKleene*	JTappert*	LMarsh*	
DATE	6/12/2001	6/18/2001	06/13/2001	6/13 /2001	
OFFICE	DD:DRIP	D:DRIP	D:DE	D:DSSA	
NAME	FGillespie	DMatthews*	JStrosnider*	GHolahan*	
DATE	6/ 13 /2001	06/26/2001	0 6 / 18 /2001	6/ 19 /2001	
OFFICE	D:DLPM	D:DIPM	OCIO	OCFO	OGC*
NAME	JZwolinski*	BBoger*	BShelton*	TPulliam*	STreby
DATE	6/20 /2001	6/18 /2001	6/20/2001	6/ 22/2001	06/26/2001
OFFICE	ADIP	PMAS	DD:NRR	D:NRR	OEDO
NAME	Rborchardt*	MJCase*	JJohnson	SCollins	WTravers
DATE	06/26/2001	06/26/2001	06/28/01	06/28/01	07/05/01

REVISED DRAFT
PROPOSED GUIDELINES FOR IMPLEMENTING
INDUSTRY INITIATIVES IN THE REGULATORY PROCESS

DEFINITIONS:

For the purposes of these guidelines, the following definitions should be used:

Applicable Industry Group (AIG): An industry group that undertakes to prepare an industry initiative. An AIG could include one or more Owners Groups, an industry organization such as the Nuclear Energy Institute (NEI) or the Electric Power Research Institute (EPRI), a group of licensees that is formally established to represent a particular group of reactors, a group of licensees who have reached a mutual agreement to speak on an issue as a single entity, or two or more licensees.

Stakeholder: The U.S. Nuclear Regulatory Commission (NRC), licensees, AIGs, vendors, consulting companies, State and local governments, the general public, and any other group that may be directly impacted by the NRC's decisions in the specific area of consideration.

Industry Initiative: For the purpose of these guidelines industry initiatives, are classified and defined by the following types. (Examples of each type are provided in the "Examples of Industry Initiatives" section of this document.)

Type 1: A Type 1 initiative is developed in response to an issue of potential safety concern that would complement regulatory actions within existing regulatory requirements. However, where it is determined that the safety concern involves the assurance of adequate protection, or other criteria described in Title 10, Section 50.109, of the *Code of Federal Regulations* (10 CFR 50.109), the NRC shall pursue rulemaking. In such a case, the Type 1 industry initiative may form the basis for an acceptable method of meeting the new regulation through endorsement in a regulatory guide.

Type 2: A Type 2 initiative is developed in response to a potential safety concern that is a potential cost-beneficial safety enhancement outside existing regulatory requirements. Such industry initiatives may be used to provide safety enhancements without the need for regulatory action. However, where it is determined that the proposed industry initiative is not effective in addressing the safety concern, the NRC may pursue rulemaking in accordance with the criteria described in 10 CFR 50.109.

Type 3: A Type 3 initiative is developed as an information-gathering mechanism, or a means to address issues of concern to the AIG that are not potential safety concerns, do not involve adequate protection issues, are outside existing regulatory requirements, and are not likely to yield cost-beneficial safety enhancements. These voluntary industry initiatives may be used by the AIG to address economic or efficiency issues.

PURPOSE:

This document presents the proposed guidelines for including industry initiatives in the regulatory process for nuclear power reactor licensees. These proposed guidelines are intended to ensure that future industry initiatives proposed by AIGs will 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, the NRC staff will address all related industry initiatives pursuant to these guidelines. The nature of issues that may be addressed through industry initiatives are very broad. Therefore, the following guidelines are intended to provide flexibility to allow the NRC 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. In addition, by promoting a consistent, controlled, and visible process, these guidelines are intended to ensure that safety is maintained, while providing for efficient and effective use of resources, reducing unnecessary regulatory burden, and enhancing public confidence.

It is important to note that these guidelines reference other existing NRC policies and procedures regarding generic communications, (SECY-99-14) 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. These guidelines are not intended 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:

This section describes the actions associated with each of the nine numbered steps indicated in the "Industry Initiatives Process" flowchart.

Step 1 - Issue Identification

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

However, it is important to note that some issues may fall within the scope of other NRC processes (e.g., allegations or petitions submitted pursuant to 10 CFR 2.206), and care should be taken to ensure that such issues are properly characterized and assigned to the appropriate process for dispositioning. Issues arising from allegations or petitions may be resolved in the longer term through the use of an industry initiative, but are not initially considered to be candidates for such an initiative.

Emerging issues should be documented, and the staff's preliminary evaluation of the technical and policy implications should be presented to the Executive Team (ET) of the NRC's Office of Nuclear Reactor Regulation (NRR) for review and initial dispositioning (see Step 2, below). The

staff's preliminary evaluation of the technical and policy implications of the emerging issue would include the following considerations (among others):

- whether the issue involves adequate protection
- whether there is an immediate safety concern
- which plants (types or specific plants) the issue could potentially involve
- the likelihood that one or more AIG(s) would pursue resolution through an industry initiative
- which type (1, 2, or 3) of industry initiative is appropriate
- what other regulatory process would be appropriate, if an industry initiative is not pursued
- which type(s) of staff work would be involved in resolving the issue (e.g., prior review and approval, monitoring, inspection, etc.)
- the estimate of staff resources that would be required for the industry initiative and other options
- whether a backfit potential is involved
- whether the issue involves an allegation or petition submitted pursuant to 10 CFR 2.206
- assessment against the outcome goals
- plans for stakeholder involvement
- options for how the plant(s) could resolve the issue
- the need for periodic reports to monitor licensee implementation of the industry initiative
- the need for Commission notification and followup

Similarly, issues identified by the industry or other stakeholders should be documented (e.g., letter to the Director of NRR), and then reviewed as above.

In developing an emerging issue, it may be appropriate for the staff 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. Notices regarding any meetings and/or workshops should be issued in a timely manner, and the meetings and/or workshops should be open to allow public participation (see "Public Participation," below).

Step 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 to warrant either meeting with the AIG(s) and other stakeholders to present the NRC staff's views regarding the appropriateness of addressing an emerging issue as an industry initiative, or immediately pursuing regulatory action, if justified (see Step 4, below). The staff's evaluation, as presented to the NRR ET, should include the following details, to the extent possible:

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

In the early stages of issue development, additional information may be necessary to fully characterize or quantify the issue, and 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 Step 3, below), (2) pursue the issue on an expedited basis (see Step 4, below), or (3) pursue the issue via an industry initiative (see Step 5, below).

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 the guidelines herein, many issues can be addressed through an industry initiative. However, issues that involve matters of adequate protection shall not be addressed via the process provided in these guidelines.

Step 3 - NRR ET Decision Not to 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 staff should inform the AIG(s) and other interested stakeholders (in writing) of the decision and its bases.

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

Step 4 - NRR ET Decision to Pursue Issue Resolution on an Expedited Basis

Some issues may need to be handled in a more expeditious manner than is possible with 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 an issue requires expedited action, the approaches that may be taken could include activating the Regulatory Response Group (RRG) of the appropriate owners group, issuing orders, or issuing a bulletin, as described in SECY-99-143. The staff may defer formal regulatory actions while the appropriate 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.

Step 5 - NRR ET Decision to Establish an Industry Initiative

If an expedited resolution is unnecessary and the NRR ET decides to pursue the issue through an industry initiative, the NRR Director would send a letter to the identified AIG(s) and other interested stakeholders. These letters will describe the issue, provide appropriate references and background information, identify the NRC contact for the issue (see "Project Management," below), and propose to schedule an initial public meeting or workshop to share information regarding the issue. The AIG(s) would be invited to evaluate the issue and to develop a proposal to address 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 public would be informed of meetings and/or workshops held on the 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 receive individual views regarding the possible options for resolving the issue. These interactions would include the NRC, AIG(s), and other stakeholders, with the objective of developing a better understanding of the issue, and establishing an industry initiative action plan with tasks, milestones, required resources, and responsible parties, to be utilized in resolving the issue. The industry initiative action plan should provide the basis for pursuing the issue as an industry initiative, as well as the need for licensee commitments (as appropriate) to the industry initiative. The staff should establish its own industry initiative action task plan, as well as an industry initiative communications plan. Schedules should be established to resolve the issue within a time frame that is consistent with its significance.

In some cases, it may be necessary to gather additional information to develop a better understanding of 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 they may require some affirmative action on the part of the NRC. Any NRC activities to gather 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 the consideration of the Paperwork Reduction

Act, and will be coordinated with the NRC's Offices of the Chief Information Officer (OCIO) and the General Counsel (OGC).

Possible approaches to resolving the issue could include such actions as developing and implementing an industry program, issuing voluntary license amendments, revising industry guideline documents, modifying codes and standards, or creating a generic safety issue (GSI). The intent would be to resolve the issue in the most efficient and effective manner.

Step 6 - Regulatory Acceptance of the Proposed Industry Initiative

If the NRR ET finds that the industry initiative action and communications plans developed in Step 5 are acceptable, those plans will be implemented as described in Steps 8 and 9.

If the NRR ET finds that the industry initiative action and/or communications plans developed in Step 5 are unacceptable, the issues leading to rejection of the plan(s) should be publicly 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 Step 7, below).

The staff's acceptance or rejection of a proposed industry initiative will be reported on the NRC's Web page.

Step 7 - Determine Appropriate Regulatory Action

If the staff does not accept the AIG's proposed actions, an individual licensee in the AIG does not commit to the industry initiative, or AIG member licensees fail to implement the committed-to actions, the staff may independently take action. After having determined that the issue involves either a needed safety enhancement and/or compliance with existing rules and/or regulations, the staff should take regulatory actions (e.g., rulemaking, issuing appropriate generic communications or, orders, etc.) to appropriately address the issue, as needed. Any regulatory actions taken would be determined in a manner that is 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 (however, this does not apply where an individual licensee fails to commit to, or fails to implement, the industry initiative). The public should be kept informed, through public meetings or other appropriate media, while the staff develops these regulatory actions.

Step 8 - Implementation of Industry Initiative

Once approved, the industry initiative action and communications plans developed in Step 5 should be implemented by the AIG(s) and monitored by the staff as appropriate. 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 should be monitored via periodic reviews and public meetings with the AIG(s) and other stakeholders. NRC acceptance of the industry initiative and associated action and

communications plans should be documented in a regulatory issue summary (RIS), in accordance with SECY-99-143 (see "Communications Plan," below). The public should be kept informed of the progress in completing the industry initiative action plan as outlined in the industry initiative communications plan, and should be encouraged to provide input (see "Public Participation," below).

Step 9 - Inspection and/or Monitoring and Enforcement

The need for inspection should be determined in a manner that is consistent with the NRC's Reactor Oversight Process, as described in Inspection Manual Chapter 2515. An inspection plan will be established on a case-by-case basis, consistent with the requirements associated with implementing the industry initiative and the revised risk-informed NRC inspection program as described in the NRC's Inspection Manual Chapter 2515. The inspection plan should include a decision-making process regarding 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. It is expected that many licensee activities will already be adequately covered by the existing inspection and oversight program.

Licensee activities implemented as a result of an industry initiative may or may not be enforceable, depending upon the nature of the issue being addressed. Initiative-related licensee actions that are necessary to maintain compliance with an existing regulatory requirement would be enforceable. By contrast, if an industry initiative program addresses issues that are outside the scope of current regulatory requirements, or the initiative is intended 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, the staff will take appropriate enforcement actions, if any, consistent with the guidance described below, when appropriate.

Specific Enforcement Guidance

Type 1: Actions taken to address Type 1 industry initiatives may require a licensee to make a written commitment to the NRC, or to make changes to programs, procedures, or technical specifications as mandated by regulatory requirements. If a licensee fails to meet the written commitment, the NRC may conclude that the industry initiative was not effective, and that there may be a need to take regulatory action (e.g., order, rulemaking) to resolve the concern. If a licensee fails to follow programs, procedures, and technical specifications that are mandated by regulatory requirements, that licensee may be subject to enforcement under the NRC's revised reactor oversight process and enforcement policy.

Type 2: Actions taken to address Type 2 industry initiatives are developed and implemented by licensees outside the scope of existing regulatory requirements, and they are documented in written commitments. If the licensee fails to meet its written commitments, the NRC may conclude that the industry initiative process was ineffective, and that there may be a need for regulatory action (e.g., order, rulemaking) to address the safety concern.

Type 3: The NRC will neither inspect nor enforce Type 3 industry initiatives.

OTHER ITEMS

Project Management

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

A lead technical reviewer (LTR) will also be assigned from either the NRR's 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

It is essential to ensure that all stakeholders have an opportunity to participate. As such, the staff 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 regarding the industry initiative action plan, and to participate in all NRC-sponsored meetings and/or workshops relating to the industry initiative. At a minimum, notices regarding any meetings and/or workshops would be posted on the NRC's Web page in a timely manner, and the meetings and/or workshops would be open to the public to allow participation. The industry initiative LPM will be responsible for encouraging interested stakeholders to participate in the process of considering the industry initiative, and exchanging relevant information with the staff and the AIG(s) while the industry initiative action and communications plans are being developed and implemented.

The staff will disclose to the public all information supplied by or obtained from the 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 the 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

The NRC staff will develop a communications plan for each issue that is being addressed by an industry initiative. The objectives of this industry initiative communications plan are to make the industry initiative visible to all stakeholders, and to allow easy access to relevant information. Guidance to the staff in this communications plan would include the use of the Agencywide Documents Access and Management System (ADAMS) and an NRC industry initiative Web page, which includes:

- a summary of the issue
- meeting announcements and summaries and/or transcripts
- non-proprietary versions of submitted reports and staff evaluations
- action plans
- generic communications (e.g., regulatory issue summaries)
- 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
- a final resolution summary

Primary responsibility for implementing the communications plan will belong to the assigned LPM, who will also maintain the NRC's industry initiative Web page.

Fees

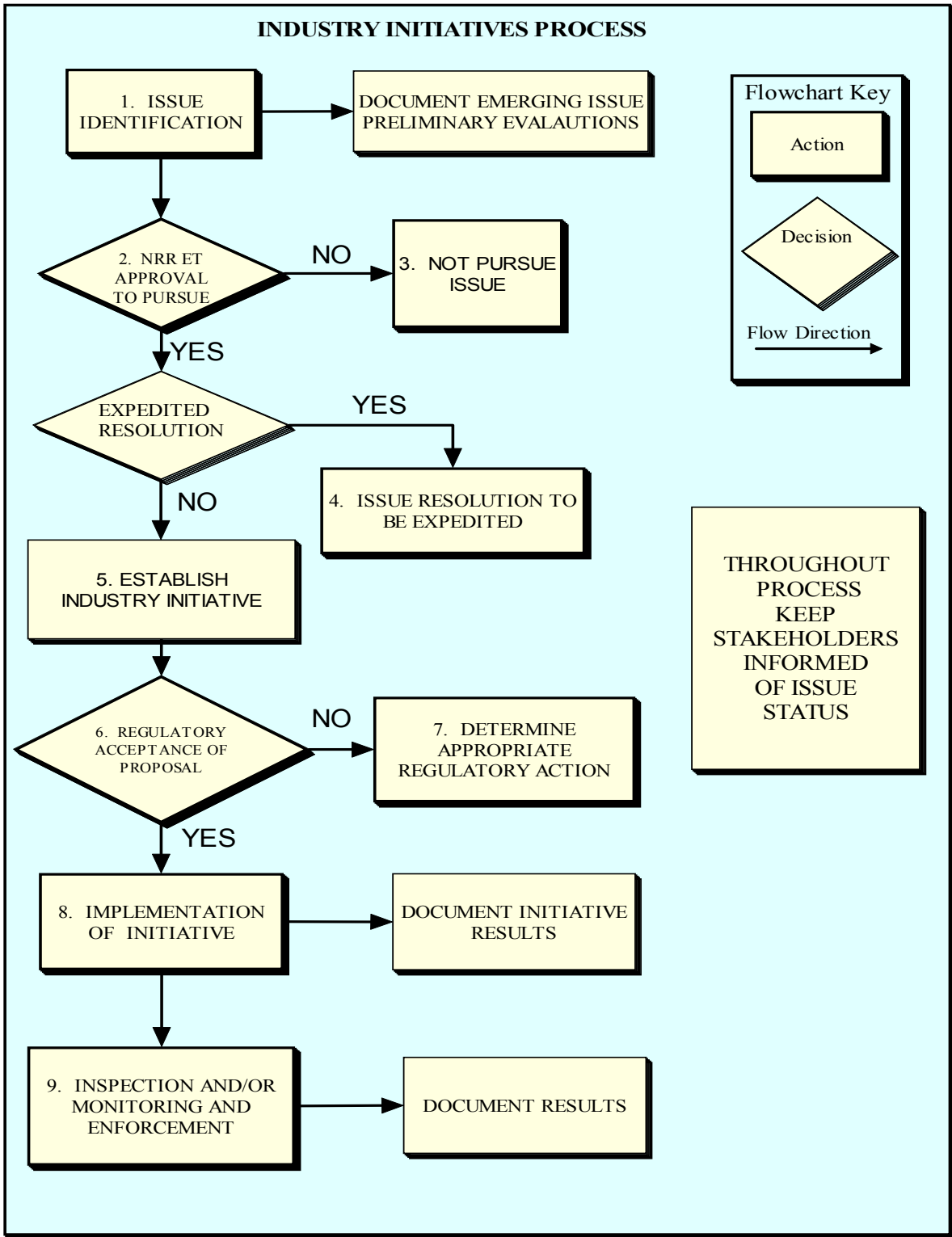
The agency's fee process, in accordance with 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended," allows the exemption of fees for reviews under 10 CFR 170.11(a)(12), "Exemptions." Specifically, this paragraph includes the following statement:

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, NEI-99-04, "Guidelines for Managing NRC Commitments" referenced therein, provide recommended actions for licensees' management, implementation, and documentation of commitments (Sections 2, 3, 4, and 5). These guidelines were found to be acceptable by the staff. Related correspondence would be made publicly available, as appropriate.



EXAMPLES OF INDUSTRY INITIATIVES

Type 1 Industry Initiative Examples

A Type 1 example of an existing program that complements 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, initially to address the potential consequences of intergranular stress corrosion cracking (IGSCC) in the BWR core shroud. The project subsequently expanded in scope to address all BWR safety-related austenitic stainless steel and Alloy 600 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 on which components are safety-related, actions taken to inspect, evaluate, and repair these components are covered by the individual licensees' quality assurance (QA) programs, as governed by Appendix B to 10 CFR Part 50.

A second example of a Type 1 industry initiative 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's 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 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.

Type 2 Industry Initiative Example

An example of a Type 2 industry initiative is the NEI guidelines that have been provided to licensees to address shutdown risks. This risk-significant issue is not explicitly addressed 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 3 Industry Initiative Examples

A Type 3 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 stakeholder 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 3 industry initiative is one developed for information gathering purposes. In some cases, it may be necessary to collect additional information to develop a better understanding of 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.