

POLICY ISSUE NOTATION VOTE

June 30, 2012

SECY-12-0091

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: COMPLETENESS AND QUALITY OF INTEGRATED SAFETY
ANALYSES

PURPOSE:

The purpose of this paper is to provide the Commission with recommendations regarding the development of standards by technical societies and the use of peer reviews to ensure the completeness and quality of the integrated safety analyses (ISAs). This paper is in response to the Staff Requirements Memorandum (SRM) M111101B, "Information Briefing on the Fuel Cycle Oversight Program," dated November 10, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML113140227).

BACKGROUND:

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," requires licensees to establish and maintain a safety program that demonstrates compliance with the requirements of 10 CFR 70.61, "Performance Requirements." The safety program is composed of three elements: process safety information, an ISA, and management measures. An ISA is a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level. As used here, "integrated" means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical hazards. An ISA also describes the licensee's management measures which provide reasonable assurance that the IROFS are available and reliable to

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perform their function when needed. An ISA summary provides a synopsis of the results of the ISA and contains the information specified in 10 CFR 70.65(b). The ISA summary (but not the ISA) is submitted for U.S Nuclear Regulatory Commission (NRC) review and approval, and must list all IROFS identified in the ISA. NRC inspectors use ISA summaries to help focus their facility inspections on the dominant hazards, accident scenarios and safety controls, and principal management measures. The ISAs are kept onsite and are available for NRC inspection.

As part of the implementation of Subpart H to 10 CFR Part 70, the NRC staff issued NUREG-1513, "Integrated Safety Analysis Guidance Document (May 2001)." NUREG-1513 provides guidance to NRC fuel cycle licensees and applicants on how to perform an ISA and document the results. In developing NUREG-1513, the NRC staff relied on information from various sources, giving particular weight to "Guidelines for Hazard Evaluation Procedures" (2nd Edition) developed by the American Institute of Chemical Engineers (AIChE). In addition, NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility (Rev. 1 May 2010)," contains guidance to evaluate the likelihood of accident sequences and NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook (March 1998)," describes consequence evaluation methods.

Subpart H to 10 CFR Part 70 became effective on October 18, 2000, and provided existing licensees 4 years to complete their ISAs. During the development of the initial ISAs, licensees encountered areas where more NRC guidance was needed. The NRC staff also identified areas for improvement after reviewing the completeness and quality of the initial ISA summary submittals. The NRC staff conducted public ISA workshops in September 2003, July 2004, and February 2005 to discuss the implementation of the 10 CFR Part 70 Subpart H requirements, obtain industry comments and feedback, and identify areas that needed additional guidance. In June 2005, the NRC staff published additional guidance in several interim staff guidance (ISG) documents. The treatment of common cause failures and human error were among the areas addressed in these 2005 ISGs, specifically FCSS-ISG-01, "Methods for Qualitative Evaluation of Likelihood." These ISGs were formally incorporated into Revision 1 of NUREG-1520 as Appendix B to Chapter 3, "Qualitative Criteria for Evaluation of Likelihood," and Appendix E to Chapter 3, "Human Factors Engineering for Personnel Activities."

DISCUSSION:

The NRC staff developed options for Commission consideration regarding the development of standards by technical societies and the use of peer reviews to ensure the completeness and quality of ISAs. In developing these options, the NRC staff engaged representatives from the Nuclear Energy Institute (NEI) and fuel cycle industry, and members of the public in a public meeting on March 29, 2012. The NRC staff also engaged representatives from the American Nuclear Society (ANS) in a conference call on April 17, 2012. The NRC staff used these interactions and information provided in an NEI letter, dated April 17, 2012 (ADAMS Accession No. ML12109A107), to inform the options and recommendations presented in this Commission paper.

Specifically, NEI stated in its letter that the fuel cycle industry does not support development of an ISA standard because industry relies on existing industry standards to inform facility-specific ISA methodologies (e.g., AIChE's "Guidelines for Risk Based Process Safety," and ANS-8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors").

However, during the April 17, 2012 conference call, ANS representatives expressed support for the development of an ISA standard. Regarding the use of peer reviews, NEI stated in its letter that, in some cases, fuel cycle facilities are in direct competition with one another and therefore, for proprietary reasons, peer reviews of fuel cycle facilities by other fuel cycle facilities are not and cannot be conducted. Based on this NEI input, the NRC staff's view is that such a voluntary initiative supporting peer reviews is unlikely.

Options for ISA Standards

Option 1 – Request that ANS Develop an ISA Standard. If ANS were to agree to the request, the ISA standard would be developed by a working group formed by the Nuclear Facilities Standards Committee (NFSC) of the ANS. The standard would include recommendations for common cause failure, human error, and accident sequence screening in addition to other topics needed to prepare a complete ISA standard. The NRC staff would initiate the ISA standard development process by preparing a letter of interest to the Chair of the NFSC of the ANS that would describe the need for a quality standard and request that NFSC consider developing an ISA standard. Subsequently, the Chair of the NFSC of the ANS would send a Project Initiation and Notification System (PINS) report to the members of the NFSC for approval. If the PINS report is approved by the members of the NFSC, the NFSC would create a working group to write the ISA standard. Once the ISA standard is complete, the NRC staff would engage stakeholders in the process of endorsing it using a Regulatory Guide.

Option 2 – Improve Guidance in NUREG-1513. Revise NUREG-1513 by converting it into a detailed handbook for performing ISAs. The revised guidance would specify recommended ISA tasks and methods needed to achieve ISA completeness and quality. The ISA handbook would provide guidance at a level of detail similar to NUREG/CR-2300, “[Probabilistic Risk Assessment (PRA)] Procedures Guide: A Guide to the Performance of [PRA] for Nuclear Power Plants,” and would reference existing guidance from the AIChE on process hazard analysis and applicable NRC guidance on PRA. In revising NUREG-1513, the NRC staff would solicit comments from stakeholders, including experienced ISA practitioners.

Option 3 – Improve Guidance in NUREG-1520. Improve NUREG-1520 review guidance on selected ISA topics, such as common cause failure, human error, and accident sequence screening. Such improved guidance would enhance the completeness and quality of the ISAs because the NRC staff would focus its reviews of licensee ISA programs on these three elements, which have been identified as important to assuring completeness and quality. While guidance documents are not binding, licensees may formally commit and therefore be bound to following specific guidance documents as conditions of their licenses. Licensee submittals and NRC staff reviews would benefit from expanded NRC guidance. Thus, if the ISA related guidance is enhanced in areas where ISA consistency or completeness has been lacking, the NRC staff can contribute to improving ISAs. This option would expand the scope of the revisions to NUREG-1520 that are currently being planned while still engaging stakeholders.

Option 4 – Status Quo. Rely on the NRC's existing oversight process, licensing reviews using current NRC guidance, and current licensee corrective action programs to improve ISA quality in areas identified by these processes. Additionally, planned periodic revisions to NUREG-1520 and other NRC guidance documents would be based on review of ISA related submittals and lessons learned. NRC ISA guidance would continue to improve and be available to increase the completeness and quality of future ISA submittals.

A discussion of the pros and cons for these options on ISA standards is enclosed with this Commission paper.

Options for ISA Peer Reviews

Option 1 – Revise the Regulations to Require Licensees to Perform Peer Reviews. Licensees would be required to perform peer reviews of the full contents of their ISAs using either qualified internal or independent experts to enhance their quality. Peer reviews could, in principle, enhance ISA completeness and quality by having ISAs reviewed by persons independent of those who performed the original analysis, but who are qualified in the relevant disciplines. A backfit analysis would be necessary to impose the requirement. It should be noted that the power reactor industry is not currently required by regulation or order to obtain peer reviews on its PRAs.

Option 2 – Current Practice. Continue to use existing licensing practices that can enhance ISA quality similar to peer reviews. Such practices include the NRC staff review of the annual ISA summary updates for changes that do not require preapproval under 10 CFR 70.72. As required by 10 CFR 70.72, licensees annually submit a brief summary of all changes to the records that demonstrate compliance with the elements of the safety program and the revised pages of the ISA summary. If any changes require preapproval, a licensee must submit a license amendment request. In addition to these annual NRC reviews, some licensees voluntarily have peer reviews performed by (1) foreign counterparts in the same parent company, (2) employees that are not responsible for conducting or maintaining the ISAs, (3) employees who have experience at other facilities to gain risk insights, or (4) independent consultants. Each of these reviews is performed by qualified independent reviewers. However, such voluntary peer reviews are not conducted using NRC-mandated standards.

A discussion of the pros and cons for these options on ISA peer reviews is enclosed with this Commission paper.

RECOMMENDATION:

The NRC staff recommends Options 1 (Request that ANS Develop an ISA Standard) and 3 (Improve Guidance in NUREG-1520) for ISA standards. For ISA peer reviews, the NRC staff recommends Option 2 (Current Practice).

The NRC staff recommends Options 1 and 3 for the ISA standard because their implementation would enhance the completeness and quality of ISAs and these options are not mutually exclusive. The NRC staff could request ISA standard development while working to improve the guidance in NUREG-1520. The ISA standard, however, would only be developed if it is supported by the ANS.

The NRC staff recommends Option 2 (Current Practice) for ISA peer reviews because the standard and improved guidance in NUREG-1520 (i.e., the recommendation for the ISA standard) is more cost effective and efficient and would directly improve the completeness and quality of ISAs.

The NRC staff recognizes the burden that these recommendations may have on licensees and the cumulative effects of regulation which include actions such as revised guidance. In order to

minimize the burden these recommendations may have on licensees, the NRC staff will prioritize their implementation (if approved by the Commission) considering factors such as the NRC strategic goals, and internal and external stakeholder interests.

RESOURCES AND SCHEDULE:

The tables below show the estimated cumulative resources/full-time equivalents (FTE) to carry out each option and the estimated timeline to complete each option for the ISA standards and ISA peer reviews, respectively. These resources would fall under the Fuel Facilities Business Line. The resources in fiscal years (FY) 2012 through 2014 would be reallocated from other activities such as the development of Regulatory Guides for fuel cycle facilities and planned improvements to the licensing and oversight processes. The resources in FY 2015 would be requested as part of the budget formulation process.

ISA Standards	Cumulative Resources	Completion Timeline
Option 1 – Request that ANS Develop an ISA Standard	0.6 FTE	FY 2015
Option 2 – Improve Guidance in NUREG-1513	2 FTE	FY 2015
Option 3 – Improve Guidance in NUREG-1520	0.4 FTE	FY 2015
Option 4 – Status Quo	0 FTE	N/A

The total of resources needed for the NRC staff's recommendation on ISA standards (i.e., Options 1 and 3) is 1 FTE.

ISA Peer Reviews	Cumulative Resources	Completion Timeline
Option 1 – Revise the Regulations to Require Licensees to Perform Peer Reviews	3 FTE	FY 2015
Option 2 – Current Practice	0 FTE	N/A

COORDINATION:

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

/RA/

R. W. Borchardt
Executive Director
for Operations

Enclosure:

[Pros and Cons for the Options on Integrated Safety Analysis Standards and Peer Reviews](#)

Pros and Cons for the Options on Integrated Safety Analysis Standards and Peer Reviews

The NRC staff developed options for Commission consideration regarding the development of standards by technical societies and the use of peer reviews to ensure the completeness and quality of the integrated safety analyses (ISAs). The NRC staff included in these options (1) soliciting a formal ISA industry consensus standard from the American Nuclear Society (ANS), and (2) establishing an NRC requirement that licensees obtain independent peer reviews for the ISAs of all plant processes. In addition, options that would have the same objective as an industry standard and mandatory peer review, but would be more efficiently targeted on identified issues, are also described. The pros and cons of each option are presented below.

The NRC staff licensing reviews approve licensee methods for performing and maintaining ISAs. NRC staff reviews the application of ISA methods to specific processes, but often reviews only a selected subset of processes, due to their very large number. NRC staff reviews have found licensee ISA methods to be of sufficient quality to provide reasonable assurance of adequate protection.

Facilities using ISAs change over time. NRC staff monitors licensee maintenance of ISA quality through inspections and licensee event reports, and by its review of the annual updates of ISA Summaries. Problems with ISA completeness and quality have been identified and corrected. Thus, although the quality of ISAs is generally adequate, there are opportunities for enhancement.

Options for ISA Standards

Option 1 – Request that ANS Develop an ISA Standard

ANS representatives expressed support for the development of an ISA standard. If ANS were to agree to the request, the ISA standard would be developed by a working group formed by the Nuclear Facilities Standards Committee (NFSC) of the ANS. The standard would include recommendations for common cause failure, human error, and accident sequence screening in addition to other topics needed to prepare a complete ISA standard. The NRC staff would initiate the ISA standard development process by preparing a letter of interest to the Chair of the NFSC of the ANS that would describe the need for a quality standard and request that NFSC consider developing an ISA standard. Subsequently, the Chair of the NFSC of the ANS would send a Project Initiation and Notification System (PINS) report to the members of the NFSC for approval. If the PINS report is approved by the members of the NFSC, the NFSC would create a working group to write the ISA standard. Once the ISA standard is complete, the NRC staff would engage stakeholders in the process of endorsing it using a Regulatory Guide.

Pros: A standard could be useful to current and future licensees for the purpose of developing an ISA that ensures the safety objectives of the regulations, including completeness. A standard would specify what must be done to perform quality ISAs. The standard could go beyond current industry guidance that relies on handbooks for chemical safety process hazard analysis, which do not address all regulatory objectives of the ISA.

The standard would identify which ISA elements are necessary to assure ISA quality, and would be based on a consensus among a broad representation of experts.

The cost to the NRC would be low, since the working group for a standard typically only has one member from the NRC.

Cons: The standard would not result in retroactive upgrades or ensure increased quality for existing ISAs because the licensees would not be required to follow the standard, unless incorporated by regulation or license condition.

The development of a draft standard could take 2 to 3 years once a working group is formed.

Option 2 – Improve Guidance in NUREG-1513

Revise NUREG-1513 by converting it into a detailed handbook for performing ISAs. The revised guidance would specify recommended ISA tasks and methods needed to achieve ISA completeness and quality. The ISA handbook would provide guidance at a level of detail similar to NUREG/CR-2300, “[Probabilistic Risk Assessment (PRA)] Procedures Guide: A Guide to the Performance of [PRA] for Nuclear Power Plants,” and would reference existing guidance from the American Institute of Chemical Engineers on process hazard analysis and applicable NRC guidance on PRA. In revising NUREG-1513, the NRC staff would solicit comments from stakeholders, including experienced ISA practitioners.

Pro: The improved guidance would facilitate future ISA reviews by addressing areas for improvement in ISA completeness and quality through detailed recommendations.

Cons: The guidance may not result in retroactive upgrades or ensure increased quality for existing ISAs because the licensees would not be required to follow the guidance, unless incorporated by regulation.

The extensive revisions to NUREG-1513 would be more costly and take more time than Option 3 (improved guidance in selected areas).

NUREG-1513 would not be a formal industry consensus standard.

Option 3 – Improve Guidance in NUREG-1520

Improve NUREG-1520 review guidance on selected ISA topics, such as common cause failure, human error, and accident sequence screening. Such improved guidance would enhance the completeness and quality of the ISAs because the NRC staff would focus its reviews of licensee ISA programs on these three elements, which have been identified as important to assuring completeness and quality. While guidance documents are not binding, licensees may formally commit and therefore be bound to following specific guidance documents as conditions of their licenses. Licensee submittals and NRC staff reviews would benefit from expanded NRC guidance. Thus, if the ISA related guidance is enhanced in areas where ISA consistency or completeness has been lacking, the NRC staff can contribute to improving ISAs. This option would expand the scope of the revisions to NUREG-1520 that are currently being planned.

Pros: Focused guidance on selected ISA topics would facilitate current reviews and make inspection efforts more effective, efficient, and consistent. The expense of preparing detailed guidance on elements of ISAs where current guidance is sufficient would be avoided.

The NRC staff has already planned and budgeted for a revision to NUREG-1520. This option would be integrated into these plans with little additional cost.

The improved guidance would be a more efficient use of resources than Options 1 and 2, because it would focus on areas which experience shows are keys to achieving high quality ISAs.

Cons: The guidance, although available to industry, would be for NRC staff reviewers. In contrast, an industry standard would include recommendations for industry performance.

The licensees would not be required to follow the guidance, unless they make a commitment that is included by a license condition.

The NRC staff could not enforce recommendations in the guidance unless the guidance was specifically adopted in the licensee's ISA.

Option 4 – Status Quo

Rely on the NRC's existing oversight process, licensing reviews using current NRC guidance, and current licensee corrective action programs to improve ISA quality in areas identified by these processes. Additionally, planned periodic revisions to NUREG-1520 and other NRC guidance documents would be based on review of ISA related submittals and lessons learned. NRC ISA guidance would continue to improve and be available to increase the completeness and quality of future ISA submittals.

Pro: No additional costs. This would utilize existing guidance on ISA methods and planned new guidance (e.g., Revision 2 to NUREG-1520).

Con: Current plans for new guidance on ISA review are focused on specific regulatory issues rather than on enhancing overall ISA quality. The planned NUREG-1520 revisions may be limited in addressing the identified areas for improvement in ISA quality; namely, common cause failure, human error, and accident sequence screening.

Options for ISA Peer Reviews

Option 1 – Revise the Regulations to Require Licensees to Perform Peer Reviews

Licensees would be required to perform peer reviews of the full contents of their ISAs using either qualified internal or independent experts to enhance their quality. Peer reviews could, in principle, enhance ISA completeness and quality by having ISAs reviewed by persons independent of those who performed the original analysis, but who are qualified in the relevant disciplines. A backfit analysis would be necessary to impose the requirement. It should be noted that the power reactor industry is not currently required by regulation or order to obtain peer reviews on its PRAs.

Pro: All processes would be reviewed by independent third parties. In order to ensure completeness and high quality, the licensee's peer review would be able to use NRC guidance that did not exist at the time of the original ISA summary submittals. Each successive periodic peer review would thus be utilizing the most up to date NUREG-1520 in addition to providing an independent review of the licensee's analyses.

This would be a significant enhancement since current ISAs are based on the guidance published at the time of the original submittal.

Con: The rulemaking process could take at least 3 years, and fuel cycle licensees would then be subject to more stringent requirements regarding peer review of safety analyses than their counterparts in the power reactor industry.

Option 2 – Current Practice

Continue to use existing licensing practices that can enhance ISA quality similar to peer reviews. Such practices include the NRC staff review of the annual ISA summary updates for changes that do not require preapproval under 10 CFR 70.72. As required by 10 CFR 70.72, licensees annually submit a brief summary of all changes to the records that demonstrate compliance with the elements of the safety program and the revised pages of the ISA summary. If any changes require preapproval, a licensee must submit a license amendment request. In addition to these annual NRC reviews, some licensees voluntarily have peer reviews performed by (1) foreign counterparts in the same parent company, (2) employees that are not responsible for conducting or maintaining the ISAs, (3) employees who have experience at other facilities to gain risk insights, or (4) independent consultants. Each of these reviews is performed by qualified independent reviewers. However, such voluntary peer reviews are not conducted using NRC-mandated standards.

Pros: Periodic ISA audits conducted by NRC licensing and inspection staff provide regular opportunities for ISA quality enhancement.

Some licensees perform internal peer reviews voluntarily. These internal peer reviews can be more efficient than reviews by personnel unfamiliar with the facilities because fuel cycle facilities tend to differ from one another much more so than nuclear power reactors.

No additional cost to the NRC.

Cons: The NRC staff reviews of annual ISA summary updates do not provide the same benefits as a peer review because they are limited to consideration of the safety implications of changes made to the ISA summary in the previous year.

There is no guidance or standard on how fuel cycle licensees perform internal or independent peer reviews.