

March 7, 2005

MEMORANDUM TO: Robert C. Pierson, Director
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

THRU: Melanie A. Galloway, Chief **/RA/**
Technical Support Group
Division of Fuel Cycle Safety
and Safeguards, NMSS

FROM: Kim E. Hammer, Nuclear Process Engineer **/RA/**
Technical Support Group
Division of Fuel Cycle Safety
and Safeguards

SUBJECT: FEBRUARY 22, 2005, SUMMARY OF THIRD INTEGRATED
SAFETY ANALYSIS WORKSHOP

On February 22, 2005, U.S. Nuclear Regulatory Commission (NRC) staff met with members of industry and the public in the Third Integrated Safety Analysis (ISA) Workshop. The purpose of this workshop was to have discussions regarding ISA issues for nuclear fuel cycle facilities under 10 CFR Part 70, Subpart H. The summary of the workshop is attached and includes the list of attendees, meeting agenda and slide presentations. This summary contains no proprietary or classified information.

Attachment: Summary of Third ISA Workshop

cc: Meeting Attendees (external to NRC)

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FCSS r/f FCFB r/f SPB r/f TSG r/f RPierson JHolonich
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OFFICE	TSG		TSG		FCSS		
NAME	KHammer		WSmith		MGalloway		
DATE	03/ 07 /05		03/07 /05		03/ 07 /05		

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Summary of the Third Integrated Safety Analysis (ISA) Workshop

Dates: February 22, 2005

Place: NRC Auditorium, Rockville, MD

Attendees: See Enclosure 1

Purpose:

The purpose of this workshop was to discuss ISA issues for nuclear fuel cycle facilities under 10 CFR Part 70, Subpart H with industry. This workshop was a Category 3 Meeting with the public invited to participate during the discussion and at designated points on the agenda. The meeting agenda is contained in Enclosure 2.

Discussion:

Welcome/Introduction/Opening Remarks

NRC welcoming remarks thanked everyone for attending, encouraged attendees to participate in discussions, discussed ground rules for this workshop, reviewed the agenda, and initiated a “parking lot” for new issues. NRC defined ground rules for the Workshop: (1) the format was a brief presentation followed by general discussion on the topic, (2) comments from anyone in the audience were acceptable at any time, (3) this is an open public meeting so no proprietary or classified information should be provided, and (4) the discussion should be generic (i.e., specific topic but general that it should not be based on a specific licensing issue). The agenda of the meeting was determined from: (1) issues raised at the last Workshop, (2) issues identified by NRC during reviews of ISA Summary submittals, and (3) issues identified by industry representatives. Issues identified during the Workshop that needed further action were to be placed in a “parking lot” list of follow-up items. All attendees introduced themselves, were requested to sign the attendees list, and were requested to complete a meeting comment form for feedback on workshop conduct and focus.

NRC introductory remarks: (1) provided more details on the purpose of the workshop; (2) re-iterated the NRC fundamental regulatory philosophy; and (3) reviewed 10 CFR Part 70, Subpart H issues, requirements, and regulations (See Enclosure 3a).

NRC opening remarks were provided by the Director of Nuclear Materials Safety and Safeguards (NMSS), the Deputy Director of Fuel Cycle Safety and Safeguards (FCSS), and Section Chief of the Technical Support Group (TSG).

NMSS Director’s comments: (1) encouraged the commitment of today’s resources to address ISA issues as an investment in the future, (2) warned of the difficulties ahead in a continuously maturing regulatory environment, and (3) acknowledged the value of this workshop as the appropriate means to ensure continuous improvement.

Attachment

FCSS Deputy Director's comments: (1) iterated the enormous investment ISA represents to both the NRC and industry, (2) commended the Industry progress on ISA becoming living documents, (3) recognized that the process was still maturing, and (4) hoped this workshop would garner more cooperation between NRC and Industry.

TSG Section Chief's comments: (1) challenged attendees to engage with the NRC on ISA issues and to strive for better risk-informed performance-based regulations and inspections, (2) re-iterated that the agenda of this workshop is flexible, and (3) reminded all that NRC is here to listen.

Industry opening remarks were provided by Clifton Farrell of the Nuclear Energy Institute, who noted that: (1) Industry was pleased with the results of the last workshop, (2) Industry needed improved guidelines for inspection and enforcement, (3) Industry was dissatisfied with the timeliness of the Interim Staff Guidance (ISG) document review and issuance, and (4) Industry questioned the value of the ISG documents to current licensees.

Session 1 - ISA Inspection

Presentation - Licensing Issues

NRC presented information regarding licensing issues (see Enclosure 3b).

No questions or comments were raised.

Presentation - Status of ISA Reviews

NRC presented information on the status of ISA reviews (see Enclosure 3c).

No questions or comments were raised.

Presentation - Inspection of 10 CFR Part 70 Subpart H Requirements

NRC presented information regarding inspection of 10 CFR part 70 Subpart H requirements (see Enclosure 3d).

Regarding an Industry question about expectations for inspection of administrative controls, NRC indicated that: (1) review of training and (2) inspection of configuration management would be the focal point for inspection of administrative controls. However, other areas are always open to inspection.

Regarding an Industry question on inspector response to discovery of an incomplete ISA, NRC indicated that identification of ISA concerns by inspectors would be referred to NRC Headquarters.

An Industry question was raised regarding applicability of the inspection discussion to nuclear criticality safety inspections. NRC indicated that: (1) criticality inspections are performed per Inspection Procedure (IP) 88015, (2) inspections follow a graded approach per Inspection Manual (IM) Chapter 2600, (3) NUREG-1600 is the basis for inspection reviews, and

(4) changes are addressed by IP 88015.

Regarding an industry question as to what scenarios are considered in an inspection, NRC indicated that all scenarios can be considered, even those not included in the ISA Summary.

An Industry request was made to have Industry involvement in Inspection Manual revisions for ISA. NRC indicated that: (1) revisions of the IM chapters are in the process of NRC review, (2) the IM chapters will be provided for public comment when internal reviews have been completed, and (3) NRC will hold a workshop with Industry to discuss comments.

An Industry comment was made regarding the need for overall objectives, basis, and intent of the inspection procedures. NRC indicated that the comment would be considered and such information may be provided in future revisions.

An Industry comment was made regarding the status of new enforcement procedures incorporating ISA policy. NRC indicated that issuance of the new enforcement procedures for public comment was imminent.

An Industry question was raised regarding whether enforcement practices are driven by the Inspection Manual or driven by the enforcement policy (NUREG-1600). NRC indicated that enforcement practices are driven by the enforcement policy.

An Industry question was raised regarding enforcement policy with respect to failures in safety systems that are not IROFS. NRC indicated enforcement would depend on whether the failures resulted in an increased risk.

An Industry comment was made that a future workshop could be devoted to enforcement policy. NRC indicated it would consider the need for a workshop on enforcement as the inspection activities are implemented. The workshop may center on how best to focus NRC policy in the right way to get the wanted results.

An industry comment was made that the NRC enforcement policy needed revision to account for the new ISA environment.

An Industry question was raised regarding the amount of effort/discipline that should be expended for a given risk. NRC indicated that the amount should be high for high risks and be low for low risks. A follow-on Industry question was raised regarding the appropriate treatment of "small" failures. NRC indicated that all failures must be included in the ISA and this will drive whether the failure is in the ISA Summary.

Session 2 - Interim Staff Guidance (ISGs)

Presentation - Follow-up September 2003 and July 2004 Workshops

NRC presented information following-up on previous two ISA workshops (see Enclosure 3e).

No questions or comments were raised.

Presentation - Summary of ISG Status

NRC presented information summarizing ISG status (see Enclosure 3f).

An Industry comment was made regarding the apparent difficulty of issuing Initiating Event Frequencies (ISG-9) before Qualitative Criteria for Evaluation of Likelihood (ISG-1) is issued because of their interrelationship. NRC indicated that: (1) this situation was recognized early in the scheduling process, and (2) a decision was made to focus resources on ISG-9 first with the expectation that later issuance of ISG-1 may require revision of ISG-9.

Two Industry comments were made regarding the intent and value of all ISG documents.

Industry commented that the general intent of the ISGs needed clarification. NRC indicated that the general intent of all ISG documents includes: (1) providing acceptable methods for achieving performance requirements, and (2) filling the gaps in the standard review plan, but does not include new requirements.

Industry commented on the value of issuing ISG documents at this point in time. NRC indicated that timeliness of comments on drafts of ISGs is important.

Presentation - Natural Phenomena Hazards (ISG-08)

NRC presented information on natural phenomena hazards (ISG-08) (see Enclosure 3g).

An Industry question was raised regarding the wording in ISG-8 about “any new nuclear process or facility,” indicating construction requirements of a nuclear power plant are to be followed. NRC explained that “nuclear facility” was intended as broader than nuclear power plants, to include fuel cycle facilities.

An Industry comment was made regarding the need for guidance to address facilities built to 1950's requirements including examples from evaluations already done. NRC indicated that the draft ISG-8 will address this issue.

Presentation - Qualitative Criteria for Evaluation of Likelihood (ISG-01)

NRC presented information on qualitative criteria for evaluation of likelihood (ISG-01) (see Enclosure 3h).

An industry comment was made regarding the value of ISG-01 at this time and how this ISG-01 is different from what was addressed at previous workshops. NRC indicated that: (1) this ISG is essentially the same as the guidance that was addressed at previous workshops; (2) this ISG is guidance for Industry and is not a required approach; (3) this approach benefits Industry with a better evaluation method; (4) this thought process identifies those parameters that should become performance parameters, and (5) a reasonably well done double contingency analysis (ISG-3) should lead licensees to meet the performance requirements.

Presentation - Justification for the Minimum Margin of Subcriticality (MoS) for Safety (ISG-10)

NRC presented information on justification for the minimum margin of subcriticality (MoS) for safety (ISG-10) (see Enclosure 3i).

Regarding a question about why existing code validations are no longer adequate, NRC clarified that: (1) past validations were performed involving processes that were well known and conservative margins of subcriticality were prescribed to ensure adequate margin, (2) current validations are for new processes that are not as well known, (3) Industry desires narrowing of margins for greater operating and design flexibility, and (4) these changes have increased risk requiring greater understanding of the uncertainty involved in the MoS of these processes.

Regarding a question as to whether the NRC is justified in questioning licensed safety parameters, NRC indicated that licensees' underlying analyses can be the subject of inspections or licensing renewal reviews.

In response to a question of whether a specific licensed facility would need to submit license amendments after the final version of ISG-10, NRC indicated that: (1) experience gained in the licensing process of the facility had been incorporated into ISG-10, and (2) specific facility had addressed the technical issues of ISG-10.

The Industry commented regarding whether the ISG process is the proper regulatory vehicle for this subject matter and whether the content of ISG-10 should be vetted through the national consensus standards process. NRC indicated that these issues will be addressed.

The Industry questioned whether NRC was ignoring standards because ISG-10 appears not to follow the guidance of those documents. NRC indicated that: (1) ANS 8.1 requires all computer usage for determining criticality safety limits to be validated via providing a bias and bias uncertainty to ensure that the calculated k-effective provided has a 95/95 confidence level, and (2) ANSI standards contain only generic guidance and do not say how much margin or how to justify it. NRC requested Industry to provide specific examples of where the standards provide more detail.

Session 3 - NRC Experience with ISA for New License Applications

Presentation - Experience with ISA for New Applications

NRC presented information on its experience with ISA for new applications (see Enclosure 3j).

No questions or comments were raised.

Session 4 - Subpart H/ISA Review and Status

Presentation - Subpart H/ISA Review and Implementation

NRC presented information regarding Subpart H/ISA Review and Implementation (see Enclosure 3k).

Regarding a question on the qualifications of NRC contractors who have performed ISA

reviews, NRC indicated the contractor had been provided extensive ISA training, both formal and one-on-one, to ensure qualifications.

Presentation - Review of Annual Change Submittals

NRC presented information regarding review of annual change submittals (see Enclosure 3l).

No questions or comments were raised.

Presentation - Potential Benefits of ISA

NRC presented information regarding potential benefits of ISA (see Enclosure 3m).

Regarding a question on the boundaries on safety programs changes under 10 CFR Part 70.72. NRC indicated that: (1) boundaries are set by the facilities, and (2) facilities can be inspected at any time to ensure 10 CFR Part 70.72 compliance.

Presentation - Industry Comments

Industry comments addressed the successes and concerns identified since the last workshop and provided future expectations.

Successes included: (1) benefits of the facility vertical slice ISA reviews performed during the past year, (2) ISA on-site reviews and focus group meetings, (3) reference facility visits, (4) staff willingness to communicate and “connect the dots” for the licensees, and (5) communication in general with the NRC.

Concerns included: (1) lack of guidance on application of qualitative verses quantitative methodologies, (2) need for enforcement policy/protocol reform to be consistent with risk-informed performance-based ISA policy, (3) need for NRC to act as one regulator, (4) lack of standard exemptions for criticality accident alarm systems, and (5) observation that ISG documents are becoming an institution unto themselves.

Future expectations included: (1) reviewing the intent of the ISG documents, (2) revising Standard Review Plans (SRPs) if new expectations are identified, (3) revising guidance on 10 CFR 70.24, Criticality Accident Alarm Systems (CAAS), to including examples of risk-informed exemptions, (3) reforming enforcement policy consistent with risk-informed performance-based, ISA policy, (4) giving ISA review schedules precedence over ISG schedules, and (5)initiating follow-up session to this workshop in 12-16 months.

Next Steps

1. Inspection Programs
 - a. Industry and NRC agreed to work jointly – Contact point is Region II
 - b. New procedures will be out for public comment in 6-8 weeks
 - c. Inspection workshop schedule anticipated late May
2. Enforcement Policy
 - a. NRC will engage Industry – Contact point is Wil Smith
 - b. NRC has action item to discuss and get back to Industry
3. ISG-10
 - a. ISA workshop is not the appropriate forum for ISG-10 topics
 - b. NRC will consider whether an ISG is the appropriate communication vehicle
 - c. If an ISG is appropriate, then an NCS workshop may be valuable

Parking Lot Issues

During the workshop, some issues were placed in the parking lot for future consideration. These issues were:

- Overhaul (Understand Intent) of the Inspection Strategy
- Future NRC/NEI Interaction On Inspection
 - Comments/Workshop
 - Discuss Protocol of how to do Comments/Workshop before start (In Region II)
- Enforcement Strategy (NUREG-1600)
 - Use of Corrective Action Plan
 - Significance Determination Process
 - Supplement (Examples)
 - Violations of administrative controls
 - Treatment of IROFS/non-IROFS controls
- Inspection and Enforcement Programs
 - Programs need to focus on Risk-Significant
 - Match-up inspection program with enforcement program
- ISG-09: Initiating Event Frequencies
 - Finalization of ISG-09 while receiving comments on ISG-01
 - ISG-09 and ISG-01 are inter-linked
- ISG-08: Natural Phenomena Hazards
 - Will be sent out for public comment
 - Provide examples of “connecting dots” in ISG
 - Difference in guidance for new/old facilities
 - New facilities – to meet BDC, use accepted practices
 - New processes in existing buildings
 - Guidance needed in ISG
 - What are staff’s expectations?
- General to all ISG Documents
 - Intent of the ISGs
 - Acceptable Methods
 - Fill in the gap in Standard Review Plans
 - Not to make new requirements

- Value of ISG documents at this point in time
- ISG-01: Qualitative Criteria for Evaluation of Likelihood
 - Need qualitative example without using index method
 - As an example, put double contingency argument in ISG
 - As an example, put 10 CFR Part 76 certification lessons learned in ISG
- ISG-10: Justification for the Minimum Margin of Subcriticality for Safety
 - If this is the right communication vehicle?
 - Should this be vetted with the standards process?
- Subpart H – NRC Experience
 - Annual Update
 - NRC/Industry need to work together to determine what is needed
 - Benefits
 - Clarity of license application changes under 10 CFR 70.72
- Subpart H – Industry
 - Current Concerns
 - 70.24 – CAAS Exemptions
 - Generic exemption because standards and rulemaking are not consistent
 - NRC suggested Industry consider a rulemaking petition outlining the technical considerations
 - Future Expectations
 - Next ISG Workshop in about 12-16 months
 - SRP vs. ISG
 - Accelerate ISG schedule or stop?
 - ISG-01, Qualitative Criteria for Evaluation of Likelihood
 - NRC suggested that it would be helpful if Industry provides text changes with comments

Enclosures:

1. Meeting Attendee List
2. Meeting Agenda
3. ISA Workshop Slides

**UNITED STATES
NUCLEAR REGULATORY COMMISSION
THIRD INTEGRATED SAFETY ANALYSIS WORKSHOP
ATTENDEE LIST**

<u>NAME</u>	<u>ORG.</u>
Melanie Galloway	NRC
Billy Gleaves	NRC
Chris Tripp	NRC
Bill Troskoski	NRC
Rex Wescott	NRC
Fred Burrows	NRC
Mary Adams	NRC
Brian Smith	NRC
Kevin Morrissey	NRC
Harry Felsher	NRC
Gary Janosko	NRC
Norma G. Santos	NRC
Tamara Powell	NRC
Joseph Holonich	NRC
Mike Lamastria	NRC
Kevin Ramsey	NRC
Bob Lukes	NRC
Kim Hammer	NRC
Michael Markley	NRC
Daniel Rich	NRC
James Smith	NRC
Wilkins Smith	NRC
Anne T. Boland	NRC/RGN II
William Gloersen	NRC/RGN II
Craig Hrabal	NRC
Nick Baxter	NRC
Diana Diaz	NRC
Stu Magruder	NRC
Greg Morell	NRC
Matt Langschwager	NRC
Robert K. Johnson	NRC
Tom Cox	NRC
Dennis Galvin	NRC
Jay Henson	NRC/RGN II
Deborah Seymour	NRC/RGN II
Garrett Smith	DOE National Nuclear Security Administration
Clifton Farrell	Nuclear Energy Institute
Don Williams	Oak Ridge National Laboratory

US NRC ATTENDEE LIST CONT'D

Tomoho Yamada	Japan Nuclear Energy Safety Organization
Leoner Tomen	Numeric Assoc.
Brandon O'Donnell	Industry
Charlie Holman	Industry
Gary Kaplan	Industry
John W. Nagy	Industry
Jennifer Wheeler	Industry
Jim R. Clark	James R. Clark & Associates
Jason Bolling	Industry
Jim Heath	Industry
Les Duncan	Industry
Leah Morrell	Industry
Brian Kidd	Industry
Steve Schilthelm	Industry
Calvin Manning	Industry
Robert Link	Industry
Jon Russell	Center for Nuclear Waste and Regulatory Analysis
M. J. Kerrigan	Kerrigan & Associates, Inc.
Peter Hastings	Industry
Chris Monetta	Industry

**Integrated Safety Analysis Workshop
US Nuclear Regulatory Commission
Rockville, Maryland
February 22, 2005**

Purpose: This workshop is sponsored by the Division of Fuel Cycle Safety & Safeguards and the Region II Division of Fuel Facility Inspection. The workshop is being held as part of the NRC staff's initiative to continuously improve the processes for 10 CFR 70 licensing and inspection actions. Discussions should focus on broad licensing, inspection, guidance, and implementation issues. Participants are encouraged to interact with the NRC staff and with colleagues to discuss more effective and efficient communication, methods, and processes.

AGENDA

- 8:00 am Welcome, Introduction and Opening Remarks
- NRC Staff
- Industry Representatives
- 8:15 am Workshop Purpose and ISA Review Status
- NRC Staff
- Industry Representatives
- 8:30 am **Session 1 - ISA Inspection**
Objective: Communication and discussion of the current and planned inspection of licensee Implementation of the Subpart H requirements for process safety information, ISA (including IROFS), and management measures.
[This session will consist of a presentation by Region II inspection staff, with extensive discussions and question-and-answer (Q&A) periods]
Expected topics include:
- Inspection Manual Chapters and Procedures
- Current Licensee Inspection
- New Facilities/Construction Inspection
- Enforcement Issues
- Stakeholder Comments
- Questions/Discussion
- 10:00 am Break
- 10:20 am **Session 2 - Interim Staff Guidance (ISGs):**
Objective: Communication and discussion of the purpose, key features, review comments, and plans for ISGs.
[This session will consist of brief presentations by FCSS and licensee or applicant (optional) staff on the ISG status, reviewer comments, and issues, with extensive discussions and Q&A as appropriate.]
Planned discussion topics:
- Summary of ISG Status

- ISG-08 Natural Phenomena Hazards
- ISG-01 Methods for Qualitative Evaluation of Likelihood
- ISG-10 Justification for Minimum Margin of Subcriticality for Safety
- Questions/Discussion

12:15 am	Lunch
1:00 pm	<p>Session 3: NRC Experience with ISA for New License Applications Objective: Communication and discussion of the lessons learned on new license applications. [This session will consist of a presentation by FCSS staff, with a brief Q&A period.]</p>
1:20 pm	<p>Session 4: Subpart H/ISA Review and Implementation Objective: Assessment of Subpart H implementation and identification, communication, and discussion of the issues. [This session will consist of brief presentations by NRC/licensee/applicant staff , with extensive NRC and stakeholder panel discussions and Q&A]</p> <p>NRC - ISA Review</p> <ul style="list-style-type: none"> - Review of Annual Change Submittals - Potential Benefits of ISA <p>Industry Assessment of Subpart H Implementation</p> <ul style="list-style-type: none"> - Successes - Current Concerns - Future Expectations
3:00 pm	Break/Industry and NRC Caucuses on Issues
3:30 pm	Resume Session 4 - Discussion of Subpart H/ISA Review and Implementation Issues
5:00 pm	Summary of Workshop Progress, Issues, Next Steps, and Expectations
5:20 pm	Adjourn