



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 5, 2004

MEMORANDUM TO: Melanie Galloway, Section Chief
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FROM: Patricia Silva, ISA Coordinator 
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SUBJECT: MEETING SUMMARY OF THE FCSS STAFF WORKSHOP ON
INTEGRATED SAFETY ANALYSIS, MARCH 23, 2004

On March 23, 2004, the Division of Fuel Cycle Safety and Safeguards (FCSS) conducted the first in a series of staff workshops on Integrated Safety Analysis (ISA) Summary reviews. The workshops are in support of the development of future interim staff guidance (ISG) to clarify the ISA portions of the Standard Review Plan (SRP). The resolutions to the issues discussed in the workshops will form the ISGs. These staff level workshops will be held bi-weekly until June, when the next ISA workshop for industry is anticipated to be held.

The topics for discussion on the agenda were those that resulted from the ISA industry workshop in September 2003. Specific questions in these areas were raised and discussed. In addition to those topics, questions and comments on the ISA review expectations, requesting additional information, and reviewing supplemental information were also discussed which identified new questions/issues for further discussion in a future workshop. The workshop was well attended by about 25 staff, who were not hesitant to ask questions, provide feedback, and raise issues. Overall, it was a positive indication of the level of involvement that is necessary to successfully develop the ISGs. The workshop slide presentation and a table of the issues are in Attachments 1 and Attachment 2, respectively. Note that time did not allow completion of the entire slide presentation. Areas yet to be discussed are administrative controls, baseline design criteria and technical evaluation reports (TERs).

Workshop Details

The highlights from each discussion topic follows.

Commission Position

Based on the regulations and the SRP, the Commission position is that what the applicant submits to us is what we must either grant, grant with conditions or deny. Some staff felt that there seems to be more emphasis from management on granting applications, less emphasis on granting with conditions, and not much emphasis on denying an application. It wasn't clear if

applicants are aware of the three options and it was suggested that somehow that be reinforced to the applicant. Comments were made that although the regulations state that the ISA summary is required for NRC approval, there seems to be no implication on ISA denial. Staff cited an example concerning a licensee that submitted an ISA summary in 2002 and is currently operating under Subpart H. However, NRC cannot inspect against the requirements of Subpart H until the ISA summary and license are approved. The same licensee has also submitted an update to their yet-approved ISA summary.

Review Expectations

One of the review expectations for the ISA summary is to not look for scientific precision. This was an issue of much debate because of confusion over how much accuracy is needed and at what threshold. Some staff felt that more guidance or explanation in this area was necessary because the applicants are focusing on numbers. One staff member felt that we are spending too much time verifying the accuracy of numbers and calculations when the focus should be on whether the applicant has identified all of their credible accident sequences. The ISA summary may not show accident sequences that fall below the threshold (low consequence). If the reviewer identifies an accident sequence they feel may be a high or intermediate consequence they should make this part of their on-site review. It was the general consensus that this a very gray area and because the SRP is only guidance, it will ultimately come down to the judgement of the reviewer. It was concluded that since the vertical slice approach is intended to be the more detailed review, however, for the overall review, reviewers shouldn't be doing a lot of verification of numbers. Of more importance than specific numbers is reviewing the methodology and the assumptions that the applicant made.

Review of supplemental information

A staff member had a question about what should be done in the case where the licensee chooses not to submit to NRC information that is classified or proprietary and therefore not docketed. The staff member was reminded that only if the information was used in the safety evaluation is it necessary to be docketed. If the information is needed and the applicant is not cooperative, a request for some negotiated form of the information can be made with the understanding that if not submitted, the applicant could face denial.

In continuing with the discussion of supplemental information, clarification was requested on management expectations for the number of RAIs. The expectation is that we should be doing an acceptance review and asking the applicant to re-submit if the application is not up to par. In addition, conference calls are being encouraged to keep the number of RAIs to one. A few staff members gave examples of how conference calls with the licensee discussing draft RAIs and draft RAI responses drastically reduced the number of RAIs.

Existing Programs

The ISA summary is not to focus on the adequacy of approved existing programs however, the licensees feel that NRC is re-reviewing existing programs that have already been approved. A comment was made that maybe the licensee was being premature in their observation and based on NRC review of amendments, assumed the same level of detail for the ISA summaries. There was confusion among the staff on how exactly existing programs relate to management measures. One staff member thought that there was an implication from this expectation that a detailed review of management measures wasn't necessary. Another staffer commented that once the management measures are approved, we shouldn't be reviewing them again but in the case of a new applicant that might not have all of their management

measures identified, it may be necessary. Other staff felt that the licensee was being misled to believe that reviewers would not look at existing programs to make sure everything is integrated. As an example, staff noted that one licensee in particular already decided that it was not feasible to just look at Chapter 3 of the SRP and thus the licensee made the decision to amend the license to comply with Subpart H. However, for the most part the problem is that licensees don't think they should have to amend the license to comply with Subpart H. One comment was that because the ISA is only one part of 10 CFR 70.62, the licensee must also establish safety programs to meet the performance requirements and, therefore, reviewers may have to look at safety programs in some degree of detail. This sparked a debate as far as how much information regarding safety programs was necessary. Some staff felt that the regulation was designed to give the licensee more flexibility so there wasn't a "right amount" of information that is acceptable. Others expressed that regardless of that fact, safety programs needed to be identified in sufficient detail. For situations where reviewers have to look into programs to make findings, a commenter felt that it was a gray area and was confused on where to draw the line. Staff felt that the SRP is not clear on how an ISA review alone is different than reviewing an amendment.

The bottom line for including a review of existing programs for the ISA summary is that it may be necessary to ensure compliance with the new subpart H, but should not be the focus of the ISA Summary review.

Management Measures

The licensee expressed concern at the industry workshop that management measures were a huge burden because they are in addition to identifying IROFS and could be a money issue. A number of staff members felt that if the licensee did not properly approach management measures it could be a burden, but overall management measures should not be a burden. One comment was that licensees may be avoiding identifying some IROFS so that in the case that they fail, they won't have violations. An IROFS failure isn't automatically a violation, but it could be which is the other part of them taking on that burden. A few staff thought that there is licensee reluctance because they perceive that management measures and IROFS have significant cost increases, which isn't always the case. The staff indicated the need for clarification on why management measures would be a burden.

Initiating Frequency

Initiating frequency is evaluated independent of IROFS. Some licensees have been using circular logic i.e., event can't happen because of the physical features of plant (not IROFS) and taking credit for that. The question was posed on whether or not we can use items such as structure, ventilation, alarms, etc. in evaluating initiating frequencies. There were comments that credit shouldn't be taken for an active system unless it is an IROFS and there were comments that credit shouldn't be taken for a passive system. Some staff thought that guidance may be necessary for clarification, while other staff thought it was a judgement call. Based on the discussions, it seemed to be on a case by case basis but more specific licensee examples are necessary to make a determination.

Items Relied on for Safety

The goal for IROFS is that they be uniquely identified to perform the safety function. A staffer commented that this wasn't a very good goal, because since the IROFS won't be used on a regular basis, it may not work when needed. The question of what to do with information on defense in depth was posed. It was the general consensus that it's not necessary to look at

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defense-in-depth for existing facilities because it is a baseline design criteria in 70.64 and really only applies to new facilities. Existing facilities are required to have it in place, but the defense-in-depth feature can be changed at their will.

Attachments:

1. NRC Integrated Safety Analysis Workshop Slides
2. Table of Questions/Issues

cc: R. Pierson, FCSS
J. Holonich, FCSS

NRC Integrated Safety Analysis Workshop

Agenda

- ISA Summary Reviews
 - Regulations
 - Standard Review Plan
 - Expectations
- Specific Topics for Discussion
 - Existing Programs
 - Low Consequence Accidents
 - Management Measures
 - Initiating Frequency
 - IROFS
 - Administrative Controls
 - Baseline Design Criteria
- Technical Evaluation Reports

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Integrated Safety Analysis Summary Reviews

Regulatory Framework

- Fundamental regulatory philosophy: **Safe operation of a nuclear facility is the responsibility of the licensee**
- Regulations provide standards established to protect public health and safety
- Guidance documents contain information that helps achieve compliance with regulations

Commission Position

- Part 51 Statement of Considerations

So far as the Commission action is concerned, the available alternatives are to grant the application, grant the application subject to certain conditions, or deny the application

...the Commission has an obligation to...perform the requisite safety and environmental analyses, the Commission has no power to compel an applicant to come forward, to prepare and submit a totally different proposal

Application of Commission Position

- The reviews of ISAs must judge regulatory acceptability consistent with Commission mission

Types of ISA Summaries

- New processes at existing facilities or new facilities requiring an amendment to an existing license or a new license
- Processes at existing facilities or entire site-wide summaries for existing facilities which do not require an amendment or license
- Updates to approved ISA summaries

Review Expectations

- Review should be consistent with Commission framework
- Not looking for scientific precision
- Conduct the initial review at a high level
- Detailed look on a targeted basis to confirm application of ISA methodology

Aspects of Review

- Assumptions are justified and reasonable
- Methods are properly applied
- Evaluate whether the licensee demonstrates that the approach meets the codified requirements
- Request for information issued when information is needed to determine compliance with regulatory requirements

Standard Review Plan

- Consistency of depth and breadth of reviews
- Guidance for reviewers (and licensees) on ways to comply with regulations
- Alternatives may be acceptable
- Alternatives need to demonstrate compliance with the regulations
- May necessitate a more involved review

Overview of Review

- Review is not intended to be a detailed evaluation of all aspects of the ISA Summary, ISA and supporting documentation
- SRP provides one way for licensees to show compliance with 10 CFR Part 70, Subpart H
- The Technical Evaluation Report (TER) will be used to support findings on the licensee's ISA summary

ISA Summary Review

- ...provide reasonable assurance that the applicant has performed a systematic evaluation of the hazards and has identified credible accident sequences, IROFS and management measures that satisfy the performance requirements of 10 CFR 70.61
- Review is of the approach or methodology and sample verification that it was implemented
- Statement of Considerations for draft rule “by evaluating the **ISA methodology and ISA summary**, supplemented by reviewing the ISA and other information, **as needed...**”

Review of Supplemental Information

- Documents include the ISA and supporting documentation
- This review is for a targeted portion of the information and is used to confirm the basis for calculations, components, and conclusions of the safety program
- Inspections provide continuing insights into details supporting the ISA Summary and changes to the ISA Summary

Review Procedure

- Conduct review in an efficient and effective manner that is within the regulatory framework
- Prepare the draft TER identifying gaps in drawing regulatory conclusions
- Prepare RAIs to obtain information needed to close these gaps
- Conduct conference calls with the licensee to ensure an understanding of the information requested
- Complete final TER with conclusions on compliance with Part 70, Subpart H

Fallout from the Previous Workshop and Miscellaneous Working Groups

Existing Programs

- ISA Summary reviews of existing facilities or processes should not focus on the adequacy of approved existing programs such as radiation protection and nuclear criticality safety
- ISA Summary reviews of new facilities should ensure that such programs are acceptable as part of the license application review process
- ISA Summary reviews of a new process(es) at existing facilities should ensure that the existing approved programs adequately cover the new process(es)

Low Consequence Accidents

- Consequences that fall below the threshold of “intermediate” are not regulated under Subpart H
- Low consequence accidents are captured under Part 20 and Emergency Planning

Management Measures

- Management measures are not IROFS
- Be sure that the accident is being prevented or mitigated by the IROFS identified not the management measure
- Management measures should be a self correcting process for ensuring IROFS are maintained available and reliable

- Are management measures a huge burden?

Initiating Frequency

- Evaluated independent of IROFS

- Can we use items such as structure, ventilation, alarms, etc. in evaluating initiating frequencies?

Items Relied on for Safety

- Independent of the initiating event and independent of other IROFS
- Uniquely identified to perform the safety function for new process(es) or facility
- Available and reliable
- Records maintained on failures
- What do we do with information on defense-in-depth?

Administrative Controls

- Procedures or training are not administrative controls
- Administrative controls apply to human actions
- Procedures and training are part of management measures

- Augmented versus enhanced – What's the difference?

Baseline Design Criteria

- Is the applicable building code for a particular geological area good enough to meet highly unlikely?
- Definition of “new process(es) or facility”
- Definition of “challenges to IROFS”
- Level of detail of review of BDCs and degree to which they must be explicitly identified in application/amendment requests

Technical Evaluation Report Format

Overview of the TER

- Identifies whether the ISA Summary and supporting documentation provides reasonable assurance that the IROFS, managements and programmatic commitments, if properly implemented, will meet the performance requirements
- The TER documents whether the ISA Summary complies with Subpart H

Outline of the Technical Evaluation Report (TER)

1.0 Introduction

2.0 Review of ISA Summary

2.1 General description of the site

2.2 General description of the facility

2.3 Description of facility processes, hazards, and types of accident sequences

2.4 Demonstration of compliance with performance requirements

Outline of the TER (con't)

2.5 Description of the ISA team qualifications and ISA methods

2.6 Descriptive list of IROFS

2.7 Description of acute chemical exposure standards used

2.8 Descriptive list of sole IROFS

2.9 Definition of the terms “credible,” “unlikely,” and “highly unlikely”

3.0 Overall Conclusion

Findings Concerning Compliance

- Findings should be made concerning any specific requirements in 10 CFR Part 70 that address the nine elements in the ISA Summary
- Findings should be limited to a finding of reasonable assurance that a process having the IROFS, as described in the ISA Summary, is capable of meeting the requirements if properly implemented, operated, and maintained

Table of Questions/Issues

- Are management measures a huge burden?
- Can we use items such as structure, ventilation, alarms, etc in evaluation initiating frequencies?
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- What do we do with information on defense-in-depth?
- What impact is there if we deny approval of the ISA Summary?
- With respect to review expectations, how much accuracy is needed?
- With respect to the review of existing programs, the licensee feels that they don't have to amend their license to comply with subpart H, however, it may be necessary depending on the situation.
- What is the "right amount" of information on safety programs in the license?
- Who signs the ISA Summary approval letter (that goes out with the TER)?