

August 31, 2007

MEMORANDUM TO: Deborah A. Jackson, Chief
Technical Support Branch
Special Projects and Technical
Support Directorate
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

FROM: James A. Smith, Project Manager
Technical Support Branch
Special Projects and Technical
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Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
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SUBJECT: Minutes from August 23, 2007, Public Meeting on Part 70
Working Groups

The Nuclear Regulatory Commission (NRC) held a public workshop with the Nuclear Energy Institute and other stakeholders on August 23, 2007, to discuss certain implementation issues related to the implementation of subpart H of 10 CFR Part 70: 1) Part 70, Appendix A Reporting, 2) refinement of the definition of Uranium Solubility under part 70, 3) the 70.72 Facility Change Process, and 4) the possible Enforcement Policy Revisions. Working group members from the NRC as well as members from industry attended. Members of the public were invited to participate. The purpose of these meetings were to hold kick-off meetings for these small working groups to discuss any white papers that may have been developed or may need to be developed and to work out schedules for future meetings and communications.

The minutes from each of these working groups are attached. Also attached is a list of attendees.

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70.72 Facility changes and change process – Working Group

Attendees:

Steve Cowne

Jennifer Wheeler

Margie Kotzalas

Dave Hartland (phone)

Gerry Couture (phone)

August 23, 2007

Our guidance document will contain

1. Define the scope to what 70.72 applies (i.e., 70.72(a) is it only limited to items in the ISA?)
2. Guidance on implementing the criteria listed in 70.72(c), with the exception of 70.72(c)(4), which we believe is clear.
 - a. 70.72(c)(1)(i) Create new types....
 - b. 70.72(c)(1)(ii) Use new processes.....
 - c. 70.72(c)(2) Does not remove....equivalent...
 - d. 70.72(c)(3) Does not alter....
3. Expectations regarding level of rigor in documentation in the change evaluation.
4. Guidance on content and form of the “brief summary of all changes” as required by 70.72(d)(2).
5. Guidance for meeting the 70.72(d)(2) requirement to submit changes to the NRC annually within 30 days after the end of the calendar year (i.e., what to do if it's a hardship, should we consider rulemaking to make it more flexible?)

Our draft deliverable will be ready for review and concurrence.

April 2008

Our Working group schedule will be:

We will meet monthly, with the second meeting to be held in the NRC offices – Executive Boulevard Building - on September 25, 2007.

Work: Priority item 1. Define the scope to what 70.72 applies

Scope of Requirements to Research: - “change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel?”

Documents to look at for ideas:

1. 50.59 wording and guidance documents
 - a. Inspection Manual Part 9900 10 CFR Guidance, 10 CFR 50.59
 - b. RG 1.187 and NEI Guideline NEI 96-07
2. Inspection Procedure 88070, "Permanent Plant Modifications"
3. 10 CFR 830 (and implementing guidance documents)
4. 10 CFR 72.48
5. Statements of Consideration for 10 CFR Part 70 (Federal Register Vol. 65, No. 181, starting on page 56211, issued September 18, 2000)

Questions to think about:

What is common to all fuel cycle facilities – ISA – information upon which the NRC used to base its regulatory decision to issue a license – it may be called SAR or a "final" license application.

SNM activities must be in scope of 70.72. What other stuff is there?

Which licensing documents have its own change process (i.e., emergency plan, QA, etc.)? Could these documents then be out of scope of 70.72?

What is the right place to tie changes to licensing documents? Are licensing documents different from facility changes?

Goal for September 25, 2007, meeting: assemble, discuss, and toss out bad ideas. Develop into a straw-person. Have volunteer flesh it out for "finalization" during October meeting.

Action Items for September 25, 2007 meeting:

1. Review documents to identify "good words," applicable concepts or ideas that we can use. Send ideas to group members at least one week before the meeting.
2. Industry group members should speak with peers to get their ideas.

**PART 70 WORKING GROUP MEETING
AUGUST 23, 2007
MEETING SUMMARY**

ENFORCEMENT POLICY REVISION WORKING GROUP

Working Group Membership:

Steve Shilthelm	BWXT
Mike Boren	USEC
Nancy Parr	Westinghouse (not present)
John Nagy	NFS
Debbie Jackson	NRC HQ/FCSS - Chair (not present)
Dennis Morey	NRC HQ/FCSS - Acting chair
Chris Tripp	NRC HQ/FCSS
Amy Luebering	NRC HQ/FCSS
Manuel Crespo	NRC - Region II (telecon)

Summary

On June 23, 2007, staff from FCSS and Region II met with NEI representatives in a working group to discuss NRC enforcement policy related to fuel cycle facilities. The enforcement policy working group discussed currently pending enforcement policy revisions and attempted to reach a common understanding of industry concerns related to current efforts to risk inform NRC enforcement policy.

Mr. Shilthelm discussed the definition of minor v.s cited/non-cited violations. Industry is concerned that the LPR process is poorly defined and counts an NCV the same as a cited SLIV. The enforcement policy working group noted that LPR policy is a separate issue beyond the scope of enforcement policy change and that we would first need to fix the enforcement policy to be the way we wanted, then we could recommend changes to other things that flow from the policy (such as the LPR Program). The group noted that additional public notice may be required before expanding actions to issues beyond the scope of the current Part 70 working groups.

The group discussed the concept of failure within predicted frequency which is an important aspect of integrating subpart H into enforcement policy. The idea is that a failure that occurs within the frequency predicted by prior analysis need not be considered a violation of 70.61 but is still potentially a procedural violation. Therefore, failures within predicted frequency may be considered an aspect of a minor violation.

Mr. Morey summarized the proposed NRC EGM intended to provide guidance for violations related to failure to meet performance requirements. The working group continued the discussion of minor violations including various ways to refine the definition of minor violations at fuel cycle facilities. Mr. Crespo observed that some policy supplements contain definitions of minor violations. The working group agreed to add examples of minor violations to the proposed EGM. The working group also agreed

to develop additional guidance for minor violations which would later be included in the special topics section of the NRC enforcement policy including the following criteria:

1. Low safety significance
2. Non-repetitive
3. Placed in an approved CAP
4. Failure within predicted frequency in ISA or SAR

The group discussed self-identification and decided that self-identification was sufficiently accounted for in the current enforcement policy, specifically, in NCV determination process and as a specific factor in determination of escalation/mitigation. The group noted that self-identification is not a necessary criteria for a minor violation.

Ms. Luebering noted that an “approved CAP” is not defined and that we may need to identify criteria and methodology for approving a CAP.

Industry representatives agreed that the approach in the proposed EGM for categorizing SL I, II, and III violations is good.

Mr. Boren discussed the problem of distinguishing between actual and theoretical events, that is, between when a parameter is actually upset and when a control is lost but no parameter has been upset. NRC staff felt that this distinction was more related to reportability and that there was already guidance in enforcement space relative to determining the risk significance of issues. The group noted that this issue may be discussed further as a policy proposal is developed.

The working group discussed the consistency of Supplement VI with other Supplements (e.g., Supplement IV for Part 20 violations), and also discussed the “scope” of Supplement VI. Does or should Supplement VI apply to: (a) just violations involving 70.61 and IROFS, (b) any violations of Part 70, or (c) any violations of NRC requirements. The group decided that Supplement VI should be broadened to include (c). The group also agreed on the need to have two different supplements: one for facilities with an ISA (the new criteria would completely replace the old), and one for facilities without an ISA.

Proposed Future Actions

The group agreed on two actions as overall goals:

Prepare a draft EGM - short term action to revise and present an enforcement guidance memorandum that contains an expanded definition of minor violations based on ISA predictability and licensee correction action programs.

Prepare revisions to the Enforcement Policy - long term action to capture EGM information in the NRC enforcement policy with broad application to fuel cycle facilities including the expanded definition of minor violations.

Next Group Meeting

The working group plans to meet again in Rockville or Washington DC during the first two weeks of October.

Working Group for 10 CFR Part 70 Appendix A – Reportable Safety Events

Participants: NRC: Debbie Jackson
Alphonsa Gooden
Nilda Rivera

Industry: Clifton Farrell, NEI
Randy Schackelford, NFS
Robert Link (Areva)
Scott Murray, GE

The objective of the working group (WG) is to develop guidance to meet the requirements of 10 CFR Part 70, Appendix A and to identify what changes are needed to the regulations to achieve a common understanding of reports required under Appendix A. The goal shall include how each of the reports is to be evaluated in the inspection program.

Industry representatives discussed areas where the subjective language was vague and undefined in Appendix A. For reporting requirements, the urgency should be related to the significance or risk of an event and that credit should be given for corrective action programs. Examples were provided from the requirements where industry believes there are challenges in how the licensee's are meeting the requirements; areas of subjective interpretation, areas of inconsistency, areas requiring clarification and/or definitive guidance; and the lack of a consistent quantitative limit for chemical exposure such as for radiation exposure reporting. In addition, industry questioned the 30 mg uranium value (worker vs. public exposure limit). General reportability concerns were also discussed to include when does the reportability clock start (discovery or assessment); definition of an event; and does notification to site resident's office or Regional Office satisfy the reporting requirements for the NRC.

The industry representatives are proposing changes to the following sections of Appendix A of 10 CFR Part 70: (a)(2), (a)(5), (b)(4), b(5). Also, guidance needs to be developed on the following: (a)(3), (b)(1), (b)(2), (b)(3), (b)(4), and (c) [using pages 72-75 from NUREG-1022].

The WG discussed its possible products. The products identified were: (1) generic correspondence such as an information notice (IN) or a regulatory information summary (RIS); (2) an NEI document endorsed by the NRC; (3) rulemaking to revise Appendix A; and (4) a revision to NUREG-1520. The product may be one of the above mentioned or a combination depending on the complexity of the revisions to Appendix A.

The WG decided to have their public meetings via conference call every two weeks on Thursdays at 11:00 am Eastern Time (EST). The next meeting is scheduled for September 20, 2007, via bridge number provided by the NRC and posted on the NRC's public meeting website. The WG will meet at a designated location if a face-to-face meeting is necessary. Prior to the next meeting, the following action items will be performed:

1. The NRC WG sponsor, D. Jackson will locate background and/or historical documentation for Appendix A, including the statement of consideration (SOC).
2. Participants will review draft document entitled "Summary of 10 CFR Part 70 Appendix A Reporting Issues," authored by Christopher Tripp in June 2007 for discussion at the next meeting.
3. Industry sponsor, R. Link will provide (proposed changes vs. current requirements using NUREG-1022 format/matrix.
4. Industry sponsor, R. Link will provide proposed wording for reporting requirements.
5. The next Meeting Notice and bridge line for conference call will be coordinated by
D. Jackson/J. Smith.

Working Group for addressing Soluble Uranium Intake Criteria

Date: August 23, 2007

Participants: NRC: Peter Habighorst,
Yawar Faraz

Industry: Clifton Farrell, NEI
John Nagy, NFS
Richard Burklin (Areva-NP)

The subject working group (WG) was formed to explore whether numerical soluble uranium intake criteria can be established for a worker who may be potentially impacted by a high or intermediate consequence accident and an individual located outside a controlled area, such as a member of the public, by an intermediate consequence accident. Numerical criteria for these consequences are not contained in 10 CFR Part 70 or NUREG 1520. The WG will attempt to specify numerical soluble uranium intake values for terms in §70.61 such as "mild transient health effects to any individual located outside the controlled area" and "irreversible or other serious, long-lasting health effects to a worker."

The WG explored its possible products. Four options were identified: (1) generic correspondence such as an information notice (IN) or a regulatory information summary (RIS); (2) an NEI document endorsed by the NRC; (3) a new stand-alone NUREG; and (4) a revision to NUREG-1520. As an interim measure, the NUREGs may or may not be preceded by issuance of generic correspondence (i.e. IN or RIS). The goal is to prepare the first draft of the product by June 2008.

Mr. Burklin indicated that he had prepared a technical paper on the subject of soluble U intake limits with Ron Kathren and had submitted it to the Health Physics Society (HPS) about two weeks ago for publication in the HPS' monthly journal. The HPS journal's editors had accepted the paper and are expected to publish it in a future journal. Since the paper had not been published as yet, Mr. Burklin did not discuss its contents in any detail. However, he indicated that according to the paper, the soluble U limits used in ISA's are very conservative and can be relaxed. He added that once the paper is published he would be prepared to discuss its contents in a future WG meeting that would be open to the public.

The next WG meeting is tentatively scheduled for October 10, 2007, at the NFS satellite office in Rockville Maryland. Prior to the meeting, the following action items will be performed:

1. The NRC WG participants, in coordination with OGC, will review the bases, including the Statements of Consideration for the 2000 Part 70 rulemaking, for why a numerical value for soluble U intakes (30 milligrams) only exists for high consequences to the public (i.e. numerical criteria for intermediate consequences to a member of the public and workers and high consequences to workers are not contained in 10 CFR Part 70 or in NUREG-1520).

2. NRC will determine if OSHA and EPA have any soluble U intake criteria/guidelines and invite those agencies to attend the next WG meeting.
3. NRC will explore whether any international standards/criteria exist related to soluble U intakes.
4. All WG participants will review the August 1994 Pacific Northwest Laboratory (PNL) letter report on Uranium Hexafluoride Public Risk that was prepared for the Department of Energy and tied to NRC's initial certification of the gaseous diffusion plants (see ML072420288).
5. Mr. Faraz will prepare an overview of the PNL report and present it at the next WG meeting.
6. Mr. Burklin will prepare an overview of the paper he has prepared with Mr. Ron Kathren, after it is peer reviewed for publication in the Health Physics Journal, and present it at the WG meeting.
7. NRC and industry will solicit support from toxicology experts to review preliminary findings of the group or to make presentations on various standards.
8. Mr. Nagy will prepare an overview of NUREG-1391 and present it at the next WG meeting.
9. Industry will review and, if necessary, discuss with the National Academy of Sciences their work related to the health effects of depleted uranium (Project: BEST-K-04-02-A: *Toxicological and Radiologic Effects from Exposures to Depleted Uranium During and After Combat*).
10. NEI/Industry and NRC will explore establishing contracts involving experts that can review the available information and products developed by the WG on toxicology of soluble uranium.
11. Mr. Nagy will provide the NRC information concerning the venue of the next meeting for inclusion in a meeting notice that will be posted on the NRC's web page.

Meeting Attendees August 23, 2007, Part 70 Work Group Meeting

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