UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

May 9, 2001

MEMORANDUM TO: ACRS/ACNW Members

FROM: Michael Markley, Senior Staff Engineer
ACRS

SUBJECT: CERTIFICATION OF THE MINUTES OF THE ACRS/ACNW JOINT SUBCOMMITTEE MEETING ON MATTERS RELATED TO THE DEVELOPMENT OF RISK-INFORMED REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS, JANUARY 19, 2001, ROCKVILLE, MARYLAND

The minutes of the subject meeting, issued March 7, 2001, have been certified as the official record of the proceedings of that meeting. A copy of the certified minutes is attached.

Attachment: As stated

cc: via E-mail
J. Larkins
J. Lyons
ACRS Staff Engineers
ACRS Fellows

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D.C. 20555-0001

MEMORANDUM TO: Michael T. Markley, Senior Staff Engineer

FROM: B. John Garrick, ACNW

SUBJECT: CERTIFICATION OF THE SUMMARY/MINUTES OF THE ACRS/ACNW JOINT SUBCOMMITTEE MEETING ON MATTERS RELATED TO THE DEVELOPMENT OF RISK-INFORMED REGULATION IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS, JANUARY 19, 2001, ROCKVILLE, MARYLAND

I do hereby certify that, to the best of my knowledge and belief, the minutes of the subject meeting on January 19, 2000, are an accurate record of the proceedings for that meeting.

4/19/01

B. John Garrick, Co-Chairman Date

CERTIFIED

CERTIFIED BY:
B. John Garrick - 4/19/01

Date: 3/7/01

CERTIFIED MINUTES OF THE
ACRS/ACNW JOINT SUBCOMMITTEE MEETING
JANUARY 19, 2001
ROCKVILLE, MARYLAND

INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) Joint Subcommittee of the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) met on January 19, 2001, at 11545 Rockville Pike, Rockville, MD, in Room T-2B3. The purpose of this meeting was to discuss risk assessment methods associated with Integrated Safety Analysis (ISA) and the status of risk-informed activities in the Office of Nuclear Material Safety and Safeguards (NMSS). The Joint Subcommittee also discussed risk analysis methods associated with the Department of Energy (DOE) Integrated Safety Management (ISM) program.

The entire meeting was open to public attendance. Mr. Michael T. Markley was the cognizant ACRS/ACNW staff engineer for this meeting. The meeting was convened at 8:30 a.m. and adjourned at 3:30 p.m.

ATTENDEES

ACRS/ACNW Members

J. Garrick, Chairman, ACNW
T. Kress, Co-Chairman, ACRS
M. Levenson, ACNW
M. Markley, ACRS Staff

Principal NRC Speakers

T. Cox, NMSS*
D. Damon, NMSS
L. Kokaiko, NMSS

Industry Presentation

R. Beedle, NEI
J. Brons, NEI
F. Killar, NEI

Department of Energy Presentation

T. Wyka, DOE

Participation by Members of the Public

D. Goldbach, Westinghouse Electric Corporation

NMSS Office of Nuclear Material Safety and Safeguards
NEI Nuclear Energy Institute

There were approximately 16 members of the public in attendance at this meeting. A complete list of attendees is in the ACRS/ACNW Office File, and will be made available upon request. The presentation slides and handouts used during the meeting are attached to the office copy of these minutes.

OPENING REMARKS BY THE SUBCOMMITTEE CHAIRMAN

Dr. B. John Garrick, Co-Chairman of the ACRS/ACNW Joint Subcommittee convened the meeting at 8:30 a.m. He introduced Dr. Kress as the Co-Chairman of the Joint Subcommittee as well as the ACRS/ACNW Members in attendance. He stated that the purpose of this meeting was to discuss risk assessment methods associated with Integrated Safety Analysis (ISA) and the status of risk-informed activities in the Office of Nuclear Material Safety and Safeguards (NMSS). The Joint Subcommittee also discussed risk analysis methods associated with the Department of Energy (DOE) Integrated Safety Management (ISM) program.

Dr. Garrick stated that the Subcommittee had received no written comments from members of the public but noted that Mr. Donald Goldbach of Westinghouse Electric Corporation had requested an opportunity to participate via telephone. He informed the audience that the Joint Subcommittee was accommodating that request.

DISCUSSION OF AGENDA ITEMS

NRC Presentation

Mr. Thomas Cox, NMSS, provided a brief presentation on the revised 10 CFR Part 70 and current licensing status. Mr. Dennis Damon, NMSS, discussed the requirements for licensees to submit ISA Summaries in accordance with 10 CFR Part 70. Mr. Lawrence Kokajko, NMSS described the mission and activities of the NMSS Risk Task Group including plans to develop case studies for risk-informed applications in NMSS. Significant points raised during the presentations include:

Revised 10 CFR Part 70

- Revised 10 CFR Part 70 requires licensees to perform an ISA identifying "items relied on for safety" to prevent and mitigate accidents. The rule requires that measures be established to ensure that these items are available and reliable and that performance requirements be established for each type of accident identified in the ISA.

- On April 18, 2001, licensees are required to submit their plans describing the ISA approach, the processes to be analyzed, and schedule for completing the analyses for each process.

- On October 18, 2004, licensees are required to complete an ISA, correct performance deficiencies, and submit an ISA Summary for NRC approval.

- Standard Review Plan (NUREG-1520), Chapter 3 provides guidance for the staff's review of ISA Summaries. In parallel, NEI is developing guidance on the preparation of ISA Summaries, including proposed treatment of previously submitted ISA material.

ISA Required by Revised 10 CFR Part 70

- The proposed rule requires that licensee ISA's identify radiological and chemical hazards, accident sequences, consequences and likelihood, and items relied on for safety (IROFS).

- Acceptance criteria for evaluation of potential accidents against performance requirements include completeness of accident identification, correctness of consequence evaluations, and adequacy of likelihood evaluations. SRP Chapter 3 provides staff review guidance. Appendix A of Chapter 3 provides an example of an analysis evaluation method (accident sequence evaluation table and likelihood method evaluation) for IROFS.

- Draft NUREG-1513 describes how to do an ISA including hazard evaluation and accident identification methods including flow charts for risk analysis method selection, e.g., fault trees, event trees, HAZOP, What-If Checklists, etc. NUREG/CR-6410, "Nuclear Fuel Cycle Accident Analysis Handbook," provides detailed guidance for consequence evaluation.

- All processes must be maintained subcritical in accordance with ANSI/ANS 8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

- The staff discussed three examples of how the ISA method could be applied using Appendix A of SRP Chapter 3: 1) a double-wall toxic chemical line, using accident sequences, 2) overloading a uranium transfer cart, using administrative controls and passive engineered design, and 3) criticality mass control for a liquid chemical process, using a combination of administrative controls, engineered container size, and event sequence evaluation.

NMSS Risk Task Group

- In SECY-99-100, the Commission approved the staff's proposed framework for risk-informed regulation in NMSS. The Commission also directed the staff to develop material and waste safety goals analogous to the NRC Safety Goals for reactors.

- The Risk Task Group (RTG) is coordinating the integration and linkage of the NRC Strategic Plan and associated objectives in the Nuclear Materials and Nuclear waste Strategic Arenas into the Risk-Informed Regulation Implementation Plan. The RTG is also coordinating development of risk-informed training programs. A key feature of the proposed training programs will be the use of case studies to illustrate and test regulatory applications that are amenable to the use of risk information.

- Screening criteria for case studies include questions related to maintaining or improving safety, improving the efficiency or effectiveness of the regulatory approach, reducing regulatory burden, helping to effectively communicate regulatory positions or approaches. The screening criteria also question the availability and sufficiency of analytical models and whether a risk-informed approach can be realized at a reasonable cost to the NRC, licensee, or applicant.

- The RTG also plans to assist the NMSS technical divisions in its implementation and review of risk-informed initiatives, e.g., Yucca Mountain Review Plan, Mallinkrodt Lessons Learned, BWXT ISA, etc.

Industry Presentation

Messrs. Ralph Beedle and Jack Brons of the Nuclear Energy Institute (NEI) provided a brief presentation on the ISA process and offered comments on the Joint Subcommittee discussions. They also discussed an NEI-sponsored assessment entitled, "Assessment of Nuclear Criticality Safety and Emergency Preparedness at U.S. Nuclear Fuel Plants." Mr. Felix Killar, NEI, provided supporting discussion. Significant points made during the presentation include:

- NEI representatives stated that ISA is a somewhat qualitative process that involves extensive review plant systems and the use of fault trees to determine vulnerabilities. However, NEI representatives questioned the nature of the problem that is attempting to be resolved through ISA. In particular, they questioned the cost-benefit of quantitative analysis and expressed objection to ISAs being treated with the level of rigor associated with PRAs.

- The NEI-sponsored assessment (task force) was established to evaluate whether the Tokaimura inadvertent criticality event could happen at U.S. fuel facilities. The assessment concluded that the Tokaimura event was caused, in part, by a safety culture that permitted the organization to adversely react under the stress of production or cost standards. An important observation was the concern/belief among U.S. fuel facility licensees that the Tokaimura event could happen here, despite administrative and engineered controls.

- For ISA, licensees are utilizing a three-region approach where subjective judgment is used to categorize risks into three quantitative ranges (low, medium, and high). The industry is concerned how the NRC will treat existing ISAs that licensees were using before issuance of the revised 10 CFR Part 70. In particular, the industry is concerned Standard Review Plan Chapter 3 will place too much importance on numerical evaluation of ISAs.

Industry Presentation

Mr. Ted Wyka of the Department of Energy (DOE) Safety Management Implementation Team provided a presentation to the Joint Subcommittee on the DOE Integrated Safety Management (ISM) program. Significant points made during the presentation include:

- ISM has been an evolutionary program at DOE beginning with the Price Anderson Act in 1989. Over the years, DOE Safety Orders have been issued and ISM Implementation Plans have been established at all DOE facilities.

- The objective of ISM is to integrate safety considerations into management and work practices at all levels to accomplish while protecting the public, worker, and environment. It involves a balance between DOE policy and mission (objectives, principles, and functions) and DOE contractor knowledge of work and hazards (mechanisms, responsibilities, and implementation).

- ISM requires formal feedback mechanisms. It requires an implementation strategy for integrating DOE Directives procedures and contracts. It also requires affirmation of effectiveness, verification, and formal reporting of continuous improvement.

SUBCOMMITTEE COMMENTS, CONCERNS, AND RECOMMENDATIONS

Subcommittee members raised the following significant points during its discussion with the staff and industry representatives:

- Dr. Garrick questioned the scope of PSA relative to nuclear power plant FSARs and PRAs. The staff stated that PSAs can be very large but noted that each is or will be plant-specific because of the uniqueness of each facility. The staff also noted that they are still negotiating the content of SRP Chapter 3 with licensees and stakeholders. The staff agreed that it should be a question of scope and not a contest of quantitative versus qualitative attributes.

- Dr. Kress questioned the rationale for having three categories and the criteria for those categories. The staff stated that NRC approach and expectation is that ISA Summaries will be mostly qualitative but will be quantitative in some areas. The staff noted that the proposed NEI approach is purely qualitative.

- Dr. Levenson questioned the infrastructure and resources needed to review licensee ISA Summaries. The staff stated that all reviews are expected to be conducted internally and that they have no plans for use of contractor support.

- Dr. Garrick expressed the view that it would be helpful if the staff better used the concepts and terminology in the Commission's White Paper (SECY-98-144) on risk-informed and performance-based regulation in order to establish a common risk language across the agency. He also suggested that it would be helpful to focus the ISA effort with the "risk triplet" definition of risk which questions: what can go wrong? What is the likelihood? and What are the consequences? Dr. Garrick stated that this would facilitate the merging of process hazards analysis (PHA) with reactor risk analysis. He also noted that there is a need to merge the approach for the high-level waste repository which is pursuing use of a pre-closure safety analysis (PCSA). The staff acknowledged these concerns but did not commit to a particular course of action.

- In discussing the issue of consequences, Drs. Garrick and Kress questioned how the ISA is designed to handle multiple hazards such as radiation and chemicals. They noted that, in some cases, chemicals dominate the risks. The staff stated that they plan to provide guidance through the use of examples. The staff presented three examples for consideration by the Joint Subcommittee. Dr. Garrick noted that one example was purely qualitative. Dr. Kress noted that the risk analysis for one example was similar to PRA except that fault trees were not presented in the analysis. Dr. Kress noted that another example was largely deterministic in its use of single-failure criterion.

- Dr. Levenson questioned whether the industry analysis of the Tokaimura event was limited to criticality safety. NEI representatives stated that they evaluated both facility safety and safety afforded through the regulatory process. They stated that their analysis noted that there was a strong pervasive belief within the fuel cycle component of the industry that "it can happen here." NEI representatives stated that there is a need for licensees to perform high quality ISAs that identify vulnerabilities but that they need not be quantitative. Dr. Garrick noted the experiences of the space shuttle "Challenger" incident and Exxon Valdez oil spill in terms of risk insights and acknowledged that different risk assessment tools are better suited for some applications than others. Dr. Garrick suggested that an important issue for the Joint Subcommittee to understand is whether ISA can do a better job of characterizing risk at fuel facilities than PRA.

- In response to a statement by Mr. Donald Goldbach of Westinghouse concerning additional regulatory burden of prescriptive work created through risk assessment, Dr. Garrick stated that it is important to create the proper framework for risk-informed regulatory decision making and suggested that it should preclude ISA Summaries and their review by the NRC from getting out of control. Dr. Garrick also suggested that there is great potential for the process to be simplified and associated regulatory burden be reduced through risk assessment.

- Dr. Levenson questioned the extent to which DOE delegates authority in implementing the ISM process. In particular, he questioned whether those assigned responsibility were given sufficient authority to address needs commensurate with their assigned responsibility. The DOE representative stated that responsibility is delegated at line management level of the organization. He stated that a major feature of the program is that ISM performance requirements and monitoring are specified in DOE contract requirements.

STAFF AND INDUSTRY COMMITMENTS

During this meeting, the staff made the following commitments in response to comments and questions raised by members of the Joint Subcommittee:

None.

SUBCOMMITTEE DECISIONS

At the conclusion of the meeting, the Joint Subcommittee decided to pursue the following courses of action:

- Review an actual ISA Summary, when available (e.g., MOX fuel or BWXT)
- Review the staff's reconciliation of NUREG-1520 SRP Chapter 3
- Review a risk-informed case study, when available
- Evaluate the issue of consistency in risk analysis including whether greater application of PRA methods is appropriate in NMSS licensed activities.

FOLLOW-UP ACTIONS

None.

BACKGROUND MATERIALS PROVIDED TO THE SUBCOMMITTEE PRIOR TO THIS MEETING

1. Subcommittee agenda.
2. Subcommittee status report.
3. Letter dated July 27, 2000, from John B. Garrick, Chairman, ACNW, to Richard A. Meserve, Chairman, NRC, Subject: Development of Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards.
4. Memorandum dated July 25, 2000, from Annette Vietti-Cook, Secretary, NRC, to William D. Travers, EDO, Subject: Staff Requirements on SECY-00-0111 - Final Rule to Amend 10 CFR Part 70, Domestic Licensing of Special Nuclear Material, and associated Commissioner vote sheets.
5. Memorandum dated November 27, 2000, from William D. Travers, EDO, to The Commissioners, Subject: Status of Nuclear Fuel Cycle Facility Oversight Program Revision.
6. Memorandum dated May 19, 2000, from William D. Travers, EDO, to The Commissioners, Subject: Staff Requirements on SECY-00-0111 - Final Rule to Amend 10 CFR Part 70, Domestic Licensing of Special Nuclear Material and associated NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.
7. NMSS Risk Task Group, Plan for Using Risk Information in the Materials and Waste Arenas, Case Studies, October 2000.
8. U.S. Nuclear Regulatory Commission, NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility."

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Note: Additional details of this meeting can be obtained from a transcript of this meeting available for downloading or viewing on the Internet at "http://www.nrc.gov/ACRSACNW" or can be purchased from Neal R. Gross and Co., Inc., (Court Reporters and Transcribers) 1323 Rhode Island Avenue, N.W., Washington, DC 20005 (202) 234-4433.

REVISED 1/17/01

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
ADVISORY COMMITTEE ON NUCLEAR WASTE
MEETING OF THE ACRS/ACNW JOINT SUBCOMMITTEE
ROOM T-2B3, 11545 ROCKVILLE PIKE, ROCKVILLE, MD
JANUARY 19, 2000

ACRS Contact: Michael T. Markley (301) 415-6885
E-mail: mtm@nrc.gov

- PROPOSED SCHEDULE -

	TOPIC	PRESENTER	TIME
1)	**Introduction**		
•	Review goals and objectives for this meeting	John Garrick, ACNW	8:30-8:35 am
•	Review discussion related to May 4, 2000 Joint Subcommittee meeting, concerning risk assessment methods associated with Integrated Safety Assessments (ISAs)		
•	Update on status of risk-informed regulatory activities in NMSS (SECY-99-100) including the NMSS Risk Task Group		
2)	**NRC Staff Presentation**		
•	Current licensing status	Tom Cox, NMSS	8:35-9:15 am
	– 10 CFR Part 70 requirements for submittals and approvals		
	– Staff initiatives to develop guidance; licensee submittals, to date; and staff review plans		
•	NRC/NMSS ISA Method	Dennis Damon, NMSS	9:15-10:15 am
	– Standard Review Plan Chapter 3 (Draft NUREG-1520)		
	– Expected ISA reviews and schedules		
	**** BREAK ****		10:15-10:30 am

3)	**NRC Staff Presentation - continued**		
•	NRC/NMSS ISA Method	Dennis Damon, NMSS	10:30-11:30 am
	– Standard Review Plan Chapter 3 (Draft NUREG-1520)		
	– Expected ISA reviews and schedules		
	**** LUNCH ****		11:30-12:30 pm
4)	**Industry Presentation**		
•	Comments on ISA methods, applications, etc.	Ralph Beedle, NEI Jack Bron~~y~~, NEI	12:30-~~1:30~~ 1:45 pm
5)	**Department of Energy Presentation**		
•	Discussion of DOE Integrated Safety Management (ISM) risk analysis methods and applications	Ted Wyka, DOE	~~1:30-2:00~~ 1:45-2:30 pm
	~~** BREAK **~~		~~2:00-2:15 pm~~
6)	**NRC Staff Presentation**		
•	Status of risk-informed regulatory activities in NMSS (SECY-99-100) and the NMSS Risk Task Group	Lawrence Kokajko, NMSS	~~2:15-3~~:15 2:30-2:45 pm
7)	**General Discussion and Adjournment**		
•	General discussion and comments by Members of the Subcommittee; items for future meetings	John Garrick, ACRS	~~3:15-3:30~~ 2:45-2:55 pm

Note: Presentation time should not exceed 50% of the total time allocated for a specific item. Number of copies of presentation materials to be provided to the ACRS/ ACNW - 35.

INTRODUCTORY STATEMENT BY THE CHAIRMAN OF THE
ACRS/ACNW JOINT SUBCOMMITTEE
11545 ROCKVILLE PIKE, ROOM T-2B3
ROCKVILLE, MARYLAND
JANUARY 19, 2001

The meeting will now come to order. This is a meeting of the Advisory Committee on Reactor Safeguards (ACRS) and Advisory Committee on Nuclear Waste (ACNW) Joint Subcommittee. I am Dr. John Garrick, Chairman of the Joint Subcommittee representing the ACNW. Dr. Thomas Kress is Co-Chairman representing the ACRS.

Joint Subcommittee Member in attendance is Dr. Milton Levenson of the ACNW.

The purpose of this meeting is to discuss risk assessment methods associated with Integrated Safety Analysis (ISA) and the status of risk-informed activities in the Office of Nuclear Material Safety and Safeguards (NMSS). The Joint Subcommittee will also discuss risk analysis methods and applications associated with the Department of Energy (DOE) Integrated Safety Management (ISM) program. The Joint Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee(s). Michael T. Markley is the Cognizant ACRS/ACNW Staff Engineer for this meeting.

The rules for participation in today's meeting have been announced as part of the notice of this meeting previously published in the *Federal Register* on December 28, 2000.

A transcript of the meeting is being kept and will be made available as stated in the Federal Register Notice. It is requested that speakers first identify themselves and speak with sufficient clarity and volume so that they can be readily heard.

We have received no written comments or requests for time to make oral statements from members of the public regarding today's meeting. However, Mr. Donald Goldbach of Westinghouse Electric Corporation has requested an opportunity to participate via telephone and we are accommodating that request.

(Chairman's Comments-if any)

The Joint Subcommittee last met on May 4, 2000. During that meeting, the Joint Subcommittee discussed the development of risk-informed regulation in NMSS, including proposed revision to 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and associated requirements for licensees to submit ISA Summaries. At the conclusion of the meeting, the Joint Subcommittee decided to schedule this meeting to discuss the technical aspects of ISA methods.

We will now proceed with the meeting and I call upon Mr. Thomas Cox of NMSS to begin.

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
&
ADVISORY COMMITTEE ON NUCLEAR WASTE

JOINT SUBCOMMITTEE MEETING

JANUARY 19, 2001
Today's Date

NRC STAFF SIGN IN FOR MEETING

PLEASE PRINT

NAME	BADGE #	NRC ORGANIZATION
THOMAS H. COX	A6420	NMSS/FCSS/FCLB
~~JACK BESS~~ JBB	~~Visitor~~ JBB	~~DEES/ LAS VEGAS~~ DEB
Dennis R. Damon	A 7327	NMSS / Risk Task Group
R Torti	B-9707	NMSS/DWM
T. McCartin	B6760	NMSS/DWM
Philip Ting	A-6771	NMSS/FCSS
ALBERT WONG	A-7523	NMSS / PMDA/RTG
Marissa Bailey	B-6142	NMSS/RTG
Jocelyn Mitchell	B-6685	RES
Barend Jagannath	B 6305	NMSS
Andrew Persinko	A7575	NMSS.
ROBERT K. JOHNSON	B-8771	NMSS / EAPB / PA
Robert Pierson	A-6589	NMSS / FCSS
Lawrence E. Kokajko	B-6378	NMSS/RTG
David Dancer	B-6528	NMSS/DWM
Rex Wescott	A-7528	NMSS/FCSS

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
&
ADVISORY COMMITTEE ON NUCLEAR WASTE

JOINT SUBCOMMITTEE MEETING

JANUARY 19, 2001
Today's Date

ATTENDEES - PLEASE SIGN BELOW

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NAME	AFFILIATION
Dealis Gwyn	DOE/YMP M&O
CARL R. YATES	BWXT, Inc
CRAIG D. SELLERS	ITSC
Jack BESS	DOE/YMP M&O
Stan Echols	Winston + Strawn
KEITH ZIELENSKI	BAH/DOE
FRED STETSON	PARALLAX, INC
Peter Hastings	DCS
JOHN C. BRONS	NEI
Felix M. Killar, Jr.	NEI
CLIFTON W. FARRELL	NEI
RALPH BEEDLE	NEI
~~Robert Pierson~~	~~USPAE~~
John Russell	CNWRA
BOB YOUNGBLOOD	ISL
Ted Wyka	DOE

Cox copy

Rules and Regulations

Federal Register
Vol. 65, No. 181
Monday, September 18, 2000

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

RIN 3150–AF22

Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the domestic licensing of special nuclear material (SNM) for licensees authorized to possess a critical mass of SNM, that are engaged in one of the following activities: enriched uranium processing; fabrication of uranium fuel or fuel assemblies; uranium enrichment (other than certified existing gaseous diffusion plants); enriched uranium hexafluoride conversion; plutonium processing; fabrication of mixed-oxide fuel or fuel assemblies; scrap recovery of SNM; or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. The amendments establish performance requirements, require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety necessary to prevent these potential accidents and/or mitigate their consequences; require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; require the safety bases to be maintained, and changes reported to NRC; allow for licensees to make certain changes to their safety program and facilities without prior NRC approval; require reporting of certain events; and require the NRC to perform a backfit analysis under specified circumstances.

EFFECTIVE DATE: The final rule, with the exception of § 70.76, is effective October 18, 2000. Section 70.76 will become effective after the issuance of staff guidance for the implementation of that provision. Once such guidance has been developed, the NRC will publish a **Federal Register** notice specifying the effective date of § 70.76.

FOR FURTHER INFORMATION CONTACT: Theodore S. Sherr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7218; e-mail *tss@nrc.gov*, Heather Astwood, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–5819; e-mail *hma@nrc.gov*, or Andrew Persinko, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6522; e-mail *axp1@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background
II. Public Comments on Proposed Rule
III. Changes from the Proposed Rule
IV. Section-by-Section Analysis of Part 70 Amendments
V. Finding of No Significant Environmental Impact: Availability
VI. Paperwork Reduction Act Statement
VII. Public Protection Notification
VIII. Regulatory Analysis
IX. Regulatory Flexibility Certification
X. Voluntary Consensus Standards
XI. Backfit Statement
XII. Small Business Regulatory Enforcement Fairness Act
XIII. List of Subjects

I. Background

On July 30, 1999 (64 FR 41338), the Commission published a proposed rule for public comment that would amend its regulations governing the domestic licensing of SNM for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a Petition for Rulemaking, (PRM)–70–7, submitted by the Nuclear Energy Institute (NEI), which was published on November 26, 1996 (61 FR 60057). The proposed rule was intended to grant the NEI PRM in part and would modify the petitioner's proposal. The majority of the proposed modifications to Part 70 were included in a proposed new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These modifications were proposed in order to increase confidence in the margin of safety at the facilities affected by the rule.

In developing the proposed rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach that included: (1) The identification of performance requirements for prevention of accidents or mitigation of their consequences; (2) the performance of an ISA to identify potential accidents at the facility and the items relied on for safety; (3) the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; (4) the maintenance of the safety bases, including the reporting of changes to the NRC; and (5) the allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The 75-day public comment period on the proposed rule ended on October 13, 1999. During and after the public comment period, the NRC staff posted on the NRC web site revised versions of the draft Standard Review Plan (SRP) that would implement the proposed requirements (*i.e.*, on August 4, 1999, a complete draft SRP was posted, and revised chapters, taking into account comments received, were posted during the period March 16–April 3, 2000). In addition, three stakeholder meetings were held to discuss the SRP (September 14–15, 1999, February 9, 2000, and April 18–19, 2000).

II. Public Comments on Proposed Rule

In preparing the final rule, the NRC staff carefully reviewed and considered more than 90 comments on the rule, included in 9 individual letters filed during the public comment period. In addition, 13 submittals containing more than 200 specific comments were received on the SRP. To simplify the analysis, the NRC staff grouped all written comments on the rule into the following major topic areas: Performance Requirements and Design Criteria; Content of Applications and ISA Summary; Safety Program; Change Process, License Renewal and Backfit; Definitions; and Miscellaneous. A more detailed analysis is also documented as

AVAILABLE AT: www.access.gpo.gov/su_docs/aces/aces140.html

an attachment to SECY–00–0111. A review of the comments and NRC staff's responses follow:

A. Performance Requirements and Design Criteria

Comment A.1: One commenter stated that the proposed rule should specify dose limits for anticipated occurrences similar to those in §§ 72.104 and 72.106. This part of the rule would then cover the range of likelihood (anticipated, likely, unlikely, and highly unlikely) of potential accidents that could occur at nuclear fuel cycle facilities. This could result in an increase in the number of structures, systems, and components (SSCs) relied on for safety and would impact the design, operation, and licensing of the mixed-oxide (MOX) facility.

Response: No change in the rule language has been made. The dose limits for normal operation are contained in 10 CFR Part 20 [viz., 0.05 Sv (5 rem) Total Effective Dose Equivalent (TEDE)/yr for a trained worker]. The NRC staff views "anticipated occurrences" to be conditions of normal operations, and believes that the measures currently used by Part 70 licensees to comply with Part 20 have been and will continue to be successful in protecting workers and the public during normal operations. Thus, there is insufficient justification to require identification of "items" to demonstrate compliance with Part 20 during normal operations.

Comment A.2: One commenter proposed that the NRC maintain consistency with past precedent (*i.e.*, the Commission's rationale in Part 60) and eliminate the specific worker dose limits in Part 70.

Response: No change in rule language has been made. The regulatory experience and industry events that initiated the effort to add a systematic accident analysis to Part 70 primarily involved health impacts to workers as opposed to the public. The NRC staff believes that the rule's focus on both the potential impacts on workers and the public is appropriate. Based on the discussions and correspondence with the industry and public during development of the proposed rule, and all other comments on the proposed rule, there appears to be general consensus on this approach.

Comment A.3: One commenter stated, in response to the **Federal Register** notice request for comments on the clarity and effectiveness of the language used (per June 1, 1998, Presidential Memorandum), that the language in § 70.61(b) and (c) could be substantially clearer; the commenter provided an alternative plain language version of this section.

Response: The language in the proposed rule was written in response to public comments to focus on risk (*i.e.*, likelihood times consequence) of accidents. The language has been changed, in response to the comment, to provide additional clarity. The proposed revisions provided by the commenter, however, are not merely editorial but represent substantive changes. They appear to have eliminated the concept of limiting risk, and instead, focused on the likelihood of accidents. The revised language in the rule attempts to retain the emphasis on controlling accident risks within appropriate performance requirements.

Comment A.4: Three commenters expressed concerns about how the worker dose limits in § 70.61(f) would be applied to "co-located workers." One commenter suggested that the performance requirements in § 70.61 consider the individuals working in the nearby facilities as public when performing an accident analysis to determine the consequences of the accidents that may occur at the facility. The commenter concluded that this would result in a more stringent application of safety requirements for the protection of workers (*e.g.*, additional items relied on for safety) at the MOX Fuel Fabrication Facility, Pit Disassembly, Conversion Facility, Immobilization Facility, and any other nearby DOE facilities, and would also have a substantial impact on the cost of the MOX facility. A second commenter agreed with this assessment, noting that a worker (as defined in § 70.4) who leaves the controlled area to perform a work-related function would have to be treated as a member of the public when performing an ISA and would be subject to the more stringent public radiation exposure limits. Outside of the controlled area the TEDE limit of 1 mSv (0.1 rem) for members of the public would apply [cf. 10 CFR 20.1301(a)(1)] rather than the annual TEDE occupational dose limit of 50 mSv (5 rems) (10 CFR 20.1201). According to this commenter, this problem has already arisen at the Hanford Tank Waste Remediation System where co-located workers are governed by the appreciably lower public dose limits. A third commenter agreed with the above positions and also stated that the NRC intends to consider individuals outside of the controlled boundary as workers if they are subject to Part 20 requirements. The commenter noted, as did the first commenter, that DOE requirements in 10 CFR Part 835 provide an equivalent level of protection, such that co-located workers—who are subject to the requirements of either Part 20 or 10 CFR Part 835—should be considered "workers," provided the licensee can demonstrate the ability to provide management measures (*e.g.*, notification, evacuation, etc.) in the event of an emergency.

Response: NRC regulations do not specifically address personnel designated as "co-located" workers. In response to the comments, the first sentence in § 70.61(f) was changed to read as follows: "Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area." The licensee can set the controlled area at any location around its facility as long as it maintains control of that area as specified in Part 20 and retains the authority to exclude or remove personnel and property from the area. If the controlled area included the nearby Department of Energy (DOE) facilities, then NRC would consider the personnel working at those facilities to be "workers" for the purposes of the performance requirements of § 70.61, provided the conditions of § 70.61(f)(2) are met. The DOE and its contractors could satisfy these conditions by documenting their compliance with the requirements of 10 CFR 19.12(a)(1)–(5). To emphasize that the § 70.61(f)(2) requirements, regarding 10 CFR Part 19 training, can be satisfied in combination with existing training, rather than separate training solely devoted to 10 CFR Part 19, 10 CFR 70(f)(2) has been changed to read: "Provides training that satisfies 10 CFR 19.12(a)(1)–(5)". To emphasize that the training provided to satisfy § 70.61(f)(2) requirements includes making individuals aware of the risks associated with accidents involving the licensed activities as determined by the ISA, the word "to" was changed to "and," so that it now reads "to these individuals and ensures that they are aware of the risks associated with accidents".

Regarding the concern about the worker who leaves the controlled area, the risk levels of § 70.61 for the public pertain to *any* individual, including workers, outside the controlled area. On the other hand, with respect to the applicability of the Part 20 occupational dose limit of 0.05 Sv (5 rem)/yr TEDE, a worker can receive an occupational dose and be subject to the Part 20 occupational limit, regardless of his location—including activities outside the controlled area. The "assigned duties performed in the course of employment" is the distinguishing factor for radiation workers consistent

plan will depend on the quality of the plan submitted by the licensee. In addition, current industry development of an ISA Summary guidance document should facilitate the licensing review process.

Comment C.6: One commenter stated that the plan required in § 70.62(c) which should be submitted within 6 months of the effective date of the rule, should pertain only if a licensee has not already completed the actions outlined in § 70.62(c)(3)(ii).

Response: The implementation plan and the ISA must satisfy the requirements in the final rule. If the actions outlined in § 70.62(c)(3)(ii) have been completed, then all that would be required to satisfy § 70.62(c)(3)(i) is submission of a description of any additional work that must be performed to meet the requirements in Subpart H of the rule, or a confirmation that the work submitted meets the requirements in Subpart H of the rule.

Comment C.7: Four commenters disagreed with the requirement in § 70.62(a)(3) to establish and maintain a log of failures of items relied on for safety. One commenter stated that the requirement should be rewritten to be performance-based rather than prescriptive. The commenter noted that most licensees have an incident reporting and corrective action system, which is used for all activities at the facility. As long as these systems meet the performance objective, it seems unnecessary for the rule language to be prescriptive in how it is met. Another commenter agreed, stating that it is inappropriate to impose this extra record-keeping burden on the licensee, because the licensee already has to generate records of this nature to manage its business and another different log is unnecessary work. Another commenter noted that because of the reporting requirements of § 70.62(a)(2) and § 70.74(a)(1), the NRC will already possess all of the information sought in the "log" of § 70.62(a)(3).

Response: The NRC generally agrees with the comment that maintenance of the failure log would be unnecessarily prescriptive. Regarding the concern about prescriptiveness, the rule has been revised to eliminate the requirement for licensees to establish and maintain a specific log of information developed and maintained elsewhere. However, the final rule requires that data be readily retrievable and available. This information is necessary to evaluate the reliability and availability of items relied on for safety, the likelihood of failure of the items, and the effectiveness of management measures implemented by the licensee. The NRC also anticipates this information will be reviewed during periodic inspections by NRC as part of the revised oversight process that is being developed. Regarding the redundancy of reporting, the rule currently requires the licensee to report only any loss or degradation of items relied on for safety that results in failure to meet the performance requirements of § 70.61. The requirements of § 70.62(a)(3) include a much broader set of items, including all items relied on for safety or management measures that have failed to perform their function.

D. Change Process, License Renewal, and Backfit

Comment D.1: Five commenters were concerned about the requirement in § 70.72(d)(1) to submit changes to the ISA Summary every 90 days. Two commenters stated that an annual update [similar to the annual Final Safety Analysis Report updates for reactors per 10 CFR 50.71(e)] should suffice, considering that the potential consequences of reactor accidents are significantly greater than those at fuel cycle facilities. One commenter stated that an annual update to the ISA Summary would be consistent with the reporting requirements (for changes to records) of § 70.72(d)(3). Another commenter stated that the 90-day reporting of changes is entirely too frequent, which would mean that the facility and the NRC would always have change reporting in progress. According to the commenter, there is no need for NRC to have this "real-time" knowledge; rather, it is only important that the licensee have "real-time" knowledge. The commenter noted that the NRC only needs reasonably current knowledge, because the current ISA is available and accessible at the site. The commenter believes that a 12-month to 24-month update for reporting, as used in other places, is satisfactory and more efficient, noting that this seems clearly justified based on the fact that all the information is available at the site and accessible to the NRC at any time.

Response: The NRC agrees with the comment that submitting updates to the ISA Summary to the NRC can be less frequent than required in the proposed rule. The final rule requires only annual reporting within 30 days after the end of the calender year during which the changes occurred.

Comment D.2: One commenter noted that, under § 70.72, the NRC should define "periodically" in the context of reporting of changes made to SSCs *etc.*

Response: The NRC determined that no change to the reporting requirements is necessary in response to the comment. The comment referenced language in the "Statement of Considerations" not the rule. The specific reporting requirements were defined in the proposed rule and are included, as revised, in the final rule.

Comment D.3: Two commenters were concerned about the footnote in § 70.72(c) that attempts to explain new types of accident sequences. Both commenters stated that the language in the footnote would require nearly all process changes to be approved by NRC through a license amendment, which would be in conflict with the overall objectives for the proposed rule. Both commenters recommended that the footnote be deleted.

Response: The NRC agrees that the footnote did not successfully clarify the definition of "new types of accident sequences." Thus, the footnote has been deleted from the final rule. The NRC staff will develop a guidance document, with input from stakeholders, to describe an acceptable change process that meets the requirements of the final rule in more detail. The degree of detail provided in the ISA Summary, together with the other information available, must be sufficient for the NRC staff to make the determination specified in § 70.66. In addition, the NRC staff had added a discussion to Chapter 3 of the SRP to describe an acceptable level of detail in the identification of the types of accident sequences.

Comment D.4: Three commenters were concerned about the requirements, in § 70.72, regarding configuration management and the overly broad process for making changes at licensed facilities. One commenter stated that the requirements, as written, apply to all site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, regardless of safety significance. The commenter noted that compliance with these requirements would appear to require configuration management and change control applied to everything on the site of the licensed facility; that could include the wastewater treatment facility, a laser facility, the administration building, maintenance of the shrubbery, *etc.* Every change would require an evaluation and a summary submitted to the NRC, even though inclusion in the change control process would make no contribution to the safety of licensed operations and would impose an undue burden on the licensee. To remedy this, the commenter recommended that the configuration and change process be limited to any "changes to the site, processes or items relied on for safety as described in the

ISA Summary." Another commenter agreed, stating that the requirement is too broad and all-encompassing and would require configuration management evaluation of changes having no or absolutely minimal effect on health and safety (*e.g.*, office remodeling, planting of shrubbery, changing paint colors). The commenter suggested that rather than control every change by means of configuration management, the licensee should first rely on internal procedures to screen any proposed changes initially for their potential safety significance.

Response: No change in the rule language has been made. The emphasis of this requirement is clearly on licensed operations and the associated safety controls. If a licensee has established a configuration management system in accordance with § 70.72(a), it is important the licensee use the system to evaluate every change made at a facility that could affect safety (*i.e.*, generally not shrubbery, paint color) to ensure that any impacts from those changes on the safety of operations is identified, considered, documented, before implementing the change. In some cases, the analysis would be trivial because no known hazards would be involved in the change (*e.g.*, certain changes in the administration building, or changes to shrubbery). Often it is clear that there are no safety implications associated with the proposed change. However, there may be special cases in which apparently minor changes could adversely affect safety, such as installation of a drinking water fountain in a radiological control area. In addition, every change which is assessed in the configuration management system does not need to be submitted to the NRC. Section 70.72(d)(2) states that only those changes to records required by § 70.62(a)(2) need to be submitted. These would include changes to the process safety information, ISA, and management measures. In addition, with respect to the use of an "initial screening" mechanism, the NRC staff considers an initial screening to assess the safety impact of a change to be part of an evaluation, as called for in § 70.72(a). In some cases, this screening will be sufficient.

Comment D.5: One commenter stated that §§ 70.72(c)(1)(i), (c)(2), and (c)(3) are wrong to use the ISA Summary as the decision-making document. The commenter noted that the ISA, the detailed licensee-generated information and evaluations that the licensee uses to manage its program, comprises the information base for decisions. Summaries only provide a general level of information about the more important elements of the safety system for operations as determined under the licensed program.

Response: No change in the rule language has been made. The ISA Summary is prepared based on the ISA, and contains key information that is directly related to facility safety, such as a list of items relied on for safety, a description of hazards identified in the ISA, and a general description of the types of accident sequences. The contents of the ISA Summary are described in § 70.65(b). The NRC staff could review the adequacy of changes using the ISA instead of the ISA Summary, but this approach would require submission of a greater amount of information to NRC and would pose an unnecessary burden on the licensee. (Also, see response to Comment B.3.)

Comment D.6: Two commenters are concerned about the annual requirement in § 70.72(d)(3) to submit a brief summary of all changes to the records required by § 70.62(a)(2). According to one commenter, the submittal would cover process safety information [§ 70.62(b)] including procedures, drawings, and detailed equipment lists. The commenter does not believe the NRC requires a summary of changes to this type information. A second commenter agreed, stating that the wording of this section will inadvertently and significantly expand the information that would have to be reported. In particular, the view was expressed that § 70.72(d) would require the licensees to submit voluminous information that could include the update to process safety information, including drawings, flow process diagrams, and piping and instrumentation diagrams. The commenter suggested that this section should be reworded to read: "a brief summary of all changes to the *integrated safety analysis and ISA summary,* that are made without prior Commission approval, must be submitted to the NRC every 12 months * * *."

Response: No change in the rule language has been made. The regulation currently requires submission of "* * * a brief summary of all the changes to the records required by § 70.62(a)(2) * * *" This does not require the submittal of actual charts and drawings but a written summary of the changes made. For the reasons cited in the response to comment D.1, it is important that the NRC be knowledgeable of changes made to this information.

Comment D.7: One commenter noted that, unlike § 50.59, the requirements of § 70.72 do not call for the submittal of a brief description and summary safety evaluation for each change. The commenter believes that the NRC would benefit from a description of changes made to the ISA Summary. Accordingly, § 70.72 should require brief descriptions and summary safety evaluations of each change made pursuant to § 70.72 and require that an updated ISA Summary be provided on a biennial basis.

Response: No change in the rule language has been made. The brief summaries of changes submitted under the requirements of § 70.72(d)(2) would be expected to include an explanation of each change, the reasons why the change was made, and why it did not require pre-approval. This information will be included in a guidance document to be developed. The NRC staff views this as sufficient and does not anticipate the need for licensees to submit a summary safety evaluation for each change, as long as each change has been made in accordance with the final rule and the approved process.

Comment D.8: Two commenters questioned the current timeframe (10 years) or the need for renewal of licenses, suggesting that the new rule, in effect, resulted in a "living license." One commenter stated that if a "living license" is truly the outcome as described in the **SUPPLEMENTARY INFORMATION**, renewal periods as long as 20 years would be appropriate. The other commenter noted that with updates required every 12 months there is no real need for the NRC to renew the license—it only becomes a maintenance chore to confirm periodically that the licensing basis remains intact. The commenter believes that the living license concept provides advantages for the NRC and the licensee.

Response: Although the NRC generally agrees with those comments, no change in the rule language has been made. A specific time period for renewals is not specified in Part 70 and to establish one in the rule would require consideration of many factors, such as compliance with the National Environmental Policy Act and the impact of the loss of commitments linked to license renewal, that were not addressed in the current rulemaking (*e.g.*, financial assurance for decommissioning). Establishment of a new term for licenses (*e.g.*, 20 years) in 10 CFR 70 would require an analysis of these factors and an opportunity for public comment. The NRC staff will evaluate whether a longer term for fuel cycle licenses is appropriate in light of the new requirements in Subpart H. In any case, even if NRC ultimately declines to extend the term of the fuel cycle licenses (nominally 10 years), the burden of license renewal should be

significantly reduced because the licensee will be required to maintain current the ISA Summary, items relied on for safety, and management measures.

Comment D.9: Five commenters recommended that a backfit provision similar to that in 10 CFR 50.109 or 10 CFR 76.76 should be included in the final rule. One commenter stated that the backfit provision should apply to current proposed changes at existing facilities. Another commenter stated that the backfit provision should be immediately effective for those processes or parts of an existing facility for which an ISA has been completed. A third commenter favored an immediately effective backfit provision. However, as an alternative, the commenter would make the provision effective for facilities or systems for which the ISA has been completed and the ISA Summary submitted to the NRC. A fourth commenter stated that deferring consideration of a backfit provision would be evading an extremely important issue, expressing the view that it is vital that a formal, systematic, and disciplined review of new, changed, or differing positions that could backfit existing facilities be applied to increase regulatory certainty. According to the commenter, no change to the backfit language in 10 CFR 50.109, which has been used successfully to control backfits at power reactors in the past, is needed to allow for qualitative analysis. 10 CFR 50.109, which the commenter endorses, is viewed as neither a quantitative nor a qualitative backfit provision. In contrast to the statement made in the Statement of Considerations of the proposed rule, the commenter does not believe that a comprehensive risk baseline is necessary before reasoned judgments can be made on the benefits and risks of a proposed backfit.

Response: The Commission agrees that regulatory stability and certainty can be improved by establishing a backfit provision for fuel cycle facilities covered by Subpart H of the final rule. Consequently, NRC has included a backfit provision in the rule in § 70.76. The wording of § 70.76 is similar to the current language in § 76.76. For requirements other than Subpart H, this provision will apply immediately after NRC publication of backfit guidance. For Subpart H requirements, this provision shall apply for a licensee as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. The NRC will publish guidance that will address the qualitative versus quantitative analysis issue and consideration of chemical risks. The NRC staff anticipates completing this guidance within six months of the publication of the final rule. Under the § 70.76 backfit provision, a backfit analysis is not required for modifications necessary to bring the facility into compliance with the rule, including the performance requirements in Subpart H. The subject of backfit is discussed in more detail in an attachment to SECY–00–0111.

E. Definitions

Comment E.1: One commenter recommended a change (from 4 percent to 5 percent enrichment) in the definition of a critical mass of SNM to reflect the higher enrichments that are currently in use.

Response: The definition of critical mass of SNM in Part 70 is used solely to determine when Subpart H applies. To emphasize this point, the definition was changed to include the phrase, "for purposes of subpart H." The definition, including the 4 percent figure, is identical to that used in § 70.24, which requires criticality accident alarms and other related measures.

Comment E.2: Regarding the issue of "reasonable assurance," two commenters stated that, in the definition of available and reliable to perform their function when needed, the use of the term "ensure" implies a level of certainty that is unrealistically high. Both commenters recommended replacing the term "ensure" with the term "provide reasonable assurance." One commenter also recommended removing the word "continuous" from the definition, which would now read "* * * means that * * * items relied on for safety will perform their intended safety function when needed and management measures will be implemented to *provide reasonable assurance of* compliance with the performance requirements of § 70.61."

Response: The definition was revised to remove the word "continuous," but no change was made regarding "ensure." With respect to "ensure," the proposed rule language does not indicate a level of certainty that is unrealistic. The term "ensure" is used extensively throughout NRC's regulations in the context of a licensee's obligations to connote "make sure" or "make certain." Specifically, elsewhere in Part 70 alone, the term is used in this context eight times: §§ 70.24(a)(3), 70.32(j), 70.38(g)(4)(iii), 70.51(a)(10), 70.52(c), 70.57(b)(3), 70.57(b)(4), and 70.57(b)(6). Whereas, the term "reasonable assurance" is used just once in Part 70, in § 70.23(b), to describe the level of assurance that the Commission must find in order to approve construction. The use of "ensure" in the definition of "available and reliable to perform their function when needed"' in § 70.4 is appropriate. In short, licensees "ensure" and the Commission determines "with reasonable assurance." Regarding the issue of "continuous compliance," the definition of "available and reliable" in § 70.4 has been modified to delete the word "continuous." This change recognizes the concept that a failure of an item relied on for safety does not automatically infer a failure to meet the performance requirements of § 70.61. In addition, the NRC recognizes that items relied on for safety may temporarily not be available (*i.e.*, not continuous) when taken out of service for maintenance or functional testing; however, the performance requirements must still be met. A discussion has been added to Chapter 3 in the SRP to address the relationship of failures of items relied on for safety to meeting the performance requirements.

Comment E.3: One commenter stated that there is a "disconnect" regarding the definition of the term items relied on for safety and recommends that the term be replaced by the term Measures relied on for safety.

Response: The reason for the comment is not clear, but perhaps the commenter objects to the use of the term "item" to refer to a personnel action. Part 70 does, in fact, allow human actions to be items relied on for safety and permits flexibility in determining how the items and measures are defined. Consequently, the Commission has retained the original text in the final rule. (See related Comments B.2. and E.4.)

Comment E.4: One commenter was concerned that the term items relied on for safety includes "activities of personnel," and proposed changing the definition in 70.4 to limit items relied on for safety to "structures, systems, equipment, and components." According to the commenter, it is reasonably straightforward to classify physical items as being relied upon for safety, and to apply graded quality assurance controls, including management measures, to design, construction, operation, and maintenance, *etc.*, of those physical items, based on their respective safety functions. The commenter stated that it can be confusing to try and classify and grade items when they include "personnel activities," since an activity has little importance absent the context of its influence on a physical item's safety function. Removing "personnel activities" from the definition of items relied on for safety would not limit their

importance but rather, would put activities in context with the structures, systems, equipment, or components to which they are related, without necessitating a change in the balance of the proposed rule. The commenter stated that removing personnel activities from the definition of items relied on for safety will also help address the concern raised (in comment B.2) regarding the treatment of procedures as items relied on for safety.

Response: No change was made to the rule language. Human actions that are relied on to prevent an accident (*i.e.*, administrative controls) are as important as the "physical items" needed to prevent an accident. Just as there are measures (*e.g.*, maintenance, configuration management) needed to ensure the availability and reliability of physical controls, there are analogous measures (*e.g.*, training, procedures) needed to ensure the availability and reliability of human actions. Graded approaches that can be applied to the maintenance of a physical control depending on the risk significance of the control could also be applied to the training of workers who perform safety functions, depending on the risk significance of the human's actions. Although the reliability of engineered controls may be higher than administrative controls, the final rule allows licensees the flexibility to employ both engineered as well as administrative controls.

Comment E.5: One commenter stated that the NRC should define the terms likely, unlikely, highly unlikely, and credible in the rule so that there will be one set of definitions applied to all nuclear fuel facilities. The commenter stated that this will minimize the interpretation and application of these terms in the ISA.

Response: No change in the rule language has been made. Part 70 applies to different types of fuel cycle facilities, some of which are more complex and have more accident sequences than others. Accordingly, since the application of the terms in the rule will be necessarily specific to the individual context in which they are applied, the development of a definition for these terms in the rule language is impracticable. The Commission, however, will provide general guidance on the application of the terms unlikely and highly unlikely in the SRP to aid licensees in implementing the provisions of the rule.

Comment E.6: One commenter recommended a change in the definition of worker. In particular, the language "* * * exposure to radiation and /or radioactive material from licensed and unlicensed sources of radiation" would be replaced with "* * * exposure to radiation and /or radioactive material from licensed sources of radiation, and radiation from man-made non-regulated sources (*e.g.*, an individual)." As originally defined, persons who are subject to occupational doses from natural sources of radiation, (*e.g.*, airline pilots and astronauts subject to high cosmic background might be included, whereas workers involved with the possession or use of unlicensed radioactive materials might not be). The commenter stated that the proposed change removes this source of confusion.

Response: The NRC staff agrees in principle with the comment. However, the commenter's proposed change does not eliminate the confusion (*e.g.*, some man-made unlicensed sources of radiation are part of background or otherwise not included in occupational doses as defined in NRC's radiation protection standards in 10 CFR 20). Instead, in response to the comment, the definition in § 70.4 was changed to: Worker, as used in Subpart H, means an individual who receives an occupational dose as defined in 10 CFR 20.1003.

F. Miscellaneous

Comment F.1: One commenter recommended that the criticality requirements of § 70.24 be revised to permit alternate criticality control provisions to be accepted for DOE facilities without requiring an exemption.

Response: Comments on § 70.24 are outside the scope of the rulemaking.

Comment F.2: Two commenters recommended changes in the decommissioning requirements of §§ 70.22(a)(9) and 70.38. In particular, one commenter recommended that the timeliness and schedule provisions in the decommissioning requirements of § 70.38 be revised to include separate requirements for DOE facilities.

Response: Comments on §§ 70.22(a)(9) and 70.38 are outside the scope of the rulemaking.

Comment F.3: One commenter expressed concern with the language in § 70.23(b), which states that the Commission will approve construction of a plutonium processing and fuel fabrication facility only after determining that the design bases of SSCs, and the attendant quality assurance program are adequate to protect against natural phenomena and the consequences of potential accidents. In particular, the commenter stated that this provision, as written, seems contrary to other changes being proposed under the draft rule, because it addresses *consequences* of potential accidents, as opposed to the *risk* associated with *credible* accidents.

Response: Section 70.23(b) has not been modified in this rulemaking. The reference to "consequences" in the rule language does not preclude a risk-informed approach in satisfying this requirement. The NRC will need to consider the risk, and thus the likelihood of consequences of potential accidents occurring, in order to determine whether there is reasonable assurance of protection against such consequences. This consideration of risk will be important in determining the need for (and the ability of) the applicant to reduce the likelihood of accidents and to mitigate their consequences.

Comment F.4: One commenter recommended that § 70.11 be revised to reflect the applicability of NRC authority over a MOX fuel fabrication facility owned by the DOE, pursuant to changes in law last year.

Response: The NRC agrees with the comment, but believes a separate rulemaking is required. Since October 17, 1998, when the amendment to Section 202 of the Energy Reorganization Act of 1974 was enacted, § 70.11, as well as several other subsections of the regulations, need to be updated to reflect this legislative change. However, to address this subsection and all the other instances, and to avoid the necessity for potential future revisions of this type, the NRC intends to institute an administrative-type rule amendment to conform all of the references to Section 202 in the regulations, including § 70.11, to merely cite Section 202, rather than repeat the text of that section. Because this rule change affects various parts of the regulations, it will be conducted independently of the current Part 70 amendments.

Comment F.5: One commenter stated that as additional DOE facilities are licensed by the NRC under Part 70, the NRC should ensure that the requirements address the full range of fissionable and fissile materials at these facilities.

Response: This issue is beyond the scope of the rulemaking. It will be addressed, if necessary, in the future.

Comment F.6: One commenter agreed that the proposed rule is entirely consistent with the U.S. Environmental Protection Agency's Risk Management Program regulations and the general duty clause of the Clean Air Act, and contains appropriate complementary safety measures for facilities possessing a critical mass of SNM.

Response: No response necessary.

Comment F.7: One commenter strongly recommended that the NRC adopt, by reference, the 1998 edition of National Fire Protection Association (NFPA) 801, "Facilities Handling Radioactive Materials." NFPA 801 would apply to § 70.62, "Safety program and integrated safety analysis," that addresses protection from all relevant hazards, including radiological, criticality, fire, and chemical. The NFPA standard would also apply to § 70.64, "Requirements for new facilities or new processes at existing facilities," that addresses fire protection. The reference to NFPA 801 is in keeping with the requirements of Public Law 104–113, "National Technology Transfer and Advancement Act," that requires Federal agencies to use private sector-developed national consensus technical standards in carrying out public policy, wherever appropriate.

Response: The suggested change would be an unnecessarily prescriptive rule requirement. Instead, the NRC identifies the standards in NFPA 801 and 600 as an acceptable approach for demonstrating compliance with 10 CFR Part 70 in the SRP.

Comment F.8: One commenter noted that the proposed rule incorporates the current terms of the MOU between the NRC and OSHA. This should avoid misunderstanding and result in more effective implementation for all concerned parties.

Response: Although the rule is consistent with the NRC–OSHA MOU, the rule itself does not incorporate the terms of the MOU. Nevertheless, the NRC agrees with the spirit of the comment.

Comment F.9: Two commenters expressed concern over those portions of §§ 70.22 and 70.23 of the existing rule that address the regulation of plutonium processing and fuel fabrication facilities. One commenter asked if § 70.22 (f) should be coordinated with § 70.65. The commenter noted that it is not clear if the requirements are collateral, complementary, or redundant. The same commenter stated that § 70.23(b) should be examined to clarify the need for this requirement in light of similar information being submitted pursuant to § 70.65. The second commenter agreed, stating that § 70.22(f) requires plutonium-related applicants to provide information on the facility site and design basis of principal SSCs, *etc.*, as part of the license application. The commenter believed that this information is also required in other sections of the revised rule, and thus is redundant.

Response: No change in the rule language has been made. The requirements are not viewed as redundant, considering: the timeframe for submittal of information required by the two sections could be different; and § 70.23(b) contains a requirement for NRC construction approval before the start of construction.

Comment F.10: Two commenters were concerned about the construction authorization provisions in §§ 70.23(b) and 70.23(a)(7). According to one commenter, irrespective of § 70.65, the construction authorization provision in § 70.23(b) appears to be an unnecessary step and should be considered for deletion by the NRC. If the NRC chooses to retain § 70.23(b), the NRC should clarify how the authorization process would be conducted, given that the procedural step has never been exercised. Furthermore, the NRC should identify how the "design basis" authorization is defined, why it is necessary, and how it relates to the ISA. The second commenter noted that § 70.23(a)(7), which applies to other Part 70 licensees, allows construction to commence based on a conclusion by the Director, NRC Office of Nuclear Material Safety and Safeguards, that environmental impacts have been appropriately addressed. The commenter stated that this discretion afforded the NRC under § 70.23(a)(7)—*i.e.*, NRC's authority over construction associated with "any * * * activity which the Commission determines will significantly affect the quality of the environment" is adequate to ensure the sufficiency of information provided to the NRC to authorize or disallow construction. The commenter proposes that § 70.23(a)(7) be clarified for applicability to plutonium facilities, and that §§ 70.22(f), 70.23(a)(7),and 70.23(b) be eliminated. Doing so would avoid the preconception that, irrespective of design features and material composition, plutonium is "more special" than other SNM.

Response: No change in the rule language has been made. The Atomic Energy Commission specifically established these requirements (see 36 FR 9786; May 28, 1971 and 36 FR 17573; September 2, 1971).for plutonium facilities in recognition of the potential exposures and ground-contamination levels that may result if only a small fraction of the dispersible plutonium in process were released (see SECY–R 188, March 17, 1971). The current revisions to Part 70 do not impact this section and therefore, the suggested change is outside the scope of the rulemaking. Regarding the authorization process, the NRC staff has clarified this process in a letter to Duke, Cogema, Stone & Webster, dated September 10, 1999. The design basis was also identified in this letter. NRC provided additional guidance on this process in the draft Standard Review Plan for a Mixed Oxide Fuel Fabrication Facility. In addition, the NRC staff is currently assessing the opportunities for hearings associated with the review of a license application for a plutonium processing facility and may offer additional guidance on this topic later in 2000.

Comment F.11: One commenter noted that, under § 70.23(a)(8), the NRC will approve a plutonium facility's license application only after construction of principal SSCs has been completed in accordance with the application. Certainly this is not a requirement unique to plutonium facilities. The NRC already has the authority to grant licenses conditional on successful completion of certain actions (such as successful start-up testing, training, *etc.*). Completion of construction in accordance with the license application seems such an obvious condition that this specific provision seems redundant and therefore unnecessary.

Response: The NRC established § 70.23(a)(8) specifically for plutonium processing facilities. Because the current revisions to Part 70 do not impact this section, comments regarding this section are outside the scope of the rulemaking. See response to Comment F.10.

Comment F.12: One commenter noted that the terminology in Appendix A (b)(1) clearly ties the failure to the performance requirements. The phrase, "and which results in failure to meet the performance requirements of § 70.61" is very clear. This phrase should be consistently included in Appendix A (b)(2)–(5) using the exact same wording.

Response: No change in the rule language has been made. The linkage to the failure to meet the performance requirements is already included in Appendix A (b)(2) and (b)(3). For the events described in Appendix A (b)(4) and (5), the NRC staff desires to be informed when such events occur, regardless of the licensee's determination with respect to the performance requirements. In these cases, the NRC staff will independently confirm the licensee's assessment of whether the performance requirements were met, on the basis of the information reported.

Comment F.13: One commenter stated that the reporting requirements of § 70.50 continue to misrepresent the principles of the 1988 NRC-OSHA MOU. Section 70.50(c)(1)(iii)(A)

requires the reporting of chemical hazards and § 70.50(c)(1)(iii)(B) requires the reporting of personnel exposures to chemicals. According to the commenter, although the MOU principles have been correctly incorporated into other proposed revisions to Part 70 (*e.g.*, §§ 70.4, 70.61(b), 70.62(c), 70.64(a), 70.74, and Appendix A), they were incorrectly referenced in § 70.50. MOU principle (2) limits NRC jurisdiction to regulation of chemical hazards of licensed material and hazardous chemicals *produced from licensed material*. The two aforementioned sections of § 70.50 should be corrected to properly incorporate the MOU principles.

Response: The rule was revised in response to the comment to reflect more precisely the language in the NRC-OSHA MOU.

Comment F.14: One commenter noted that applicants for licenses to operate new facilities or new processes at existing facilities would be expected ("Statements of Consideration," 64 FR 41346) to update their ISAs, based on as-built conditions, and submit the results to the NRC before operation. The process for uranium enrichment facilities that must comply with § 70.23a would differ from this description. Uranium enrichment facilities would submit a complete license application, including an ISA Summary, for construction and operation. This application would be the basis for NRC review, and culminate in issuance of a license for construction and operation. After issuance of the license, the licensee would institute change control under § 70.72. The licensee would then be required to submit summaries of changes and ISA Summary updates as required by § 70.72. An inspection would verify that the facility has been constructed in accordance with the license, before operation, as required by § 70.32(k). No pre-operational submittal and review of an updated ISA Summary are anticipated for uranium enrichment facilities because their configuration would be controlled after issuance of the construction and operation license.

Response: As recognized by the commenter, no changes to the rule are necessary. The differences in the licensing process for enrichment facilities other than the gaseous diffusion plants (regulated under 10 CFR Part 76) reflect the process mandated in Section 193 of the Atomic Energy Act of 1954, *et. seq.*

III. Changes from the Proposed Rule

Subpart A—General Provisions

Authority

This section has been changed to reflect the redesignations of §§ 70.61 and 70.62 as §§ 70.81 and 70.82, respectively.

Section 70.4 Definitions

The definition of "available and reliable to perform their function when needed" has been modified to eliminate the need to maintain "continuous" compliance with the performance requirements of § 70.61. The definition of "configuration management" has been modified to clarify its role as a "management measure." The definition of "critical mass of special nuclear material" has been modified to emphasize that the definition is only for the purposes of Subpart H. The definition of "double contingency" has been changed to provide minor clarification. The definition for "worker" has been clarified and has been revised to emphasize that the definition is only for purposes of Subpart H. The definitions of "ISA" and "ISA Summary" have been changed to indicate that the ISA can be performed on a process by process basis and the ISA Summary can be submitted in multiple documents that cover all the portions of the facility.

Subpart G—Special Nuclear Material Control Records, Reports, and Inspections

Section 70.50 Reporting Requirements

The reporting requirements for hazardous chemicals have been revised to be consistent with the language of the 1988 NRC-OSHA MOU (53 FR 43950; November 22, 1988).

Subpart H—Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material

Section 70.60 Applicability

The applicability of the Subpart H requirements has been revised to clarify when the requirements will take effect.

Section 70.61 Performance Requirements

The performance requirements in §§ 70.61(b) and (c) have been revised to provide clarification. The requirement to establish a controlled area in § 70.61(f) has been revised to clarify the conditions for establishing the controlled area, and to clarify the applicability of the performance requirements to individuals within the controlled area. The requirement in § 70.61(f)(2) to provide training "in accordance with" 10 CFR 19.12(a)(1)–(5) has been revised to clarify that equivalent training is acceptable. The new language specifies that this training must "satisfy" 10 CFR 19.12(a)(1)–(5).

Section 70.62 Safety program and integrated safety analysis

The requirement to establish and maintain a safety program in § 70.62(a)(1) has been revised to clarify that the safety program referred to in this section is focused on the safety program for satisfying the new Subpart H requirements, and that the application of management measures may be graded according to risk. Section 70.62(a)(3) has been modified to make it performance-based by eliminating the prescriptive requirement to maintain a log of failures for items relied on for safety. Section 70.62(c)(3) has been revised to clarify the schedule for planning and performing an ISA, correcting all performance deficiencies, and submitting the ISA Summary to the NRC for approval. The ISA Summary can be submitted as a single document, or as a sequence of documents (*e.g.*, on a process basis). The approval process for the ISA Summary will require the issuance of a license amendment; however, a license condition will be established that allows the licensee to make changes in accordance with § 70.72, including certain changes that do not require prior NRC approval. In addition, a provision has been added to the schedule for complying with the requirements in subpart H for factors beyond control of the licensee. This would allow additional time for correcting a performance deficiency if the NRC approves. Also § 70.62(d) has been modified to reflect that management measures may be graded commensurate with the reduction in risk.

Section 70.64 Requirements for New Facilities or New Processes at Existing Facilities

Section 70.64(a) has been revised to provide the correct reference, § 70.62(c), to the performance of an ISA. Section 70.64(a)(6)(ii) has been modified to specify that the required emergency capability is concerned with the evacuation of only on-site personnel.

Section 70.65 Additional Content of Applications

Section 70.65(a) has been revised to clarify that the ISA Summary is not part of the safety program description required for inclusion in the license application. Rather, the ISA Summary, that contains a description of

management measures, is submitted *with* the license application.

Section 70.66 Additional Requirements for Approval of License Application

Section 70.66(b) has been added to clarify, for existing licensees, the basis for Commission approval of the ISA plan, submitted under § 70.62(c)(3)(i), and the ISA Summary, submitted under § 70.62(c)(3)(ii).

Section 70.72 Facility Changes and Change Process

Section 70.72(c)(1) has been revised to eliminate the footnote, which did not adequately clarify the meaning of "new types of accident sequences." The revised section 70.72(d)(3) replaces proposed rule section 70.72(d)(1) to reflect a modified schedule for submission of revised ISA Summary pages.

Section 70.76 Backfitting

Section 70.76 was added to include requirements for performing a backfit analysis. The wording in § 70.76 is similar to the current language in § 76.76 for gaseous diffusion plants with one exception, 70.76(a)(4)(i). The exception in § 70.76(a)(4)(i) relates to the backfit requirements being inapplicable to changes associated with bringing the facility in compliance with the requirements of the new subpart H. The backfit section includes a provision stating that it shall apply for subpart H requirements as soon as NRC approves that licensee's ISA Summary (contents of ISA Summary described in § 70.65(b)) pursuant to § 70.66 and, for requirements other than Subpart H, it shall apply immediately after NRC publication of backfit guidance.

Section 70.92 Criminal Penalties

This section has been changed to reflect the redesignations of §§ 70.13a, 70.14, 70.61, 70.62, 70.71, and 70.72 as §§ 70.14, 70.17, 70.81, 70.82, 70.91, and 70.92, respectively, and the addition of §§ 70.66, 70.73, and 70.76.

IV. Section-by-Section Analysis of Part 70 Amendments

Authority

This section has been changed to reflect the redesignations of §§ 70.61 and 70.62 as §§ 70.81 and 70.82, respectively.

Subpart A—General Provisions

Section 70.4 Definitions

Definitions of the following 12 terms have been added to this section to clarify the meaning of certain terms and phrases used in the new Subpart H: "Acute," "Available and reliable to perform their function when needed," "Configuration management," "Critical mass of SNM," "Double contingency principle," "Hazardous chemicals produced from licensed materials," "Integrated safety analysis," "Integrated safety analysis summary," "Items relied on for safety," "Management measures," "Unacceptable performance deficiencies," and "Worker."

Section 70.14 Foreign Military Aircraft

This section reflects an administrative change to redesignate this section, formerly § 70.13a.

Section 70.17 Specific Exemptions

This section reflects an administrative change to redesignate this section, formerly § 70.14.

Subpart G—Special Nuclear Material Control Records, Reports, and Inspections

Section 70.50 Reporting Requirements

Paragraph (c) has been reworded to include information to be transmitted when making verbal or written reports to the NRC. The new information derives from the specifics of the new Subpart H, such as sequence of events and whether the event was evaluated in the ISA. To the extent the new information is also applicable to licensees not subject to Subpart H, the information was added with no differentiation noted. The new information that would only apply to Subpart H licensees is noted.

Subpart H—Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material

Section 70.60 Applicability

This section lists the types of NRC licensees or applicants that are subject to the new Part 70, Subpart H, and describes when the new requirements will be effective.

Section 70.61 Performance Requirements

This section identifies the performance requirements that licensees subject to Part 70, Subpart H must satisfy. These performance requirements explicitly address the risks to workers or members of the public and the environmental releases caused by accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the Part 70 changes seek to ensure adequate protection of workers, members of the public, and the environment by limiting the risk (product of likelihood and consequence) of such accidents. If, without the implementation of controls, a high consequence event under § 70.61(b) is highly unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule. Similarly, if, without the implementation of controls an intermediate consequence event under § 70.61(c) is unlikely, then it is not necessary for the licensee to apply the engineered or administrative controls mentioned in the rule.

Section 70.62 Safety Program and Integrated Safety Analysis

This section describes requirements for establishing and maintaining a safety program that demonstrates compliance with the performance requirements of § 70.61. The elements of this safety program include the compilation of process safety information, the performance of an ISA, and the application of management measures to ensure the availability and reliability of items relied on for safety.

Section 70.64 Requirements for New Facilities or New Processes at Existing Facilities

This section describes baseline design criteria for new facilities or new processes at existing facilities. The application of these criteria, which are similar to the general design criteria in Part 50, Appendix A; Part 72, Subpart F; and 10 CFR 60.131, are consistent with good engineering practice, which dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear process or facility. The baseline design criteria do not provide relief from compliance with the performance requirements of § 70.61.

Section 70.65 Additional Content of Applications

In addition to the information that currently must be submitted to the NRC under § 70.22, for a license application, this section requires additional information to be submitted to demonstrate compliance with the new subpart H requirements. In particular, this additional information includes a description of the applicant's safety program established under § 70.62. This information will be incorporated in the license, as appropriate. The ISA Summary must be submitted with the license application or in accordance with 70.62(c)(3)(ii), but will not be incorporated in the license.

(1) Does not:

(i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of § 70.61 and that have not previously been described in the integrated safety analysis summary; or

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary;

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 70.61; and

(4) Is not otherwise prohibited by this section, license condition, or order.

(d)(1) For changes that require pre-approval under § 70.72, the licensee shall submit an amendment request to the NRC in accordance with § 70.34 and § 70.65 of this chapter.

(2) For changes that do not require pre-approval under § 70.72, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, a brief summary of all changes to the records required by § 70.62(a)(2) of this subpart.

(3) For all changes that affect the integrated safety analysis summary, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised integrated safety analysis summary pages.

(e) If a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.

(f) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

§ 70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65 of this chapter. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

§ 70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center. (1) Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in § 70.50(c)(1).

(4) Follow-up information to the reports must be provided until all information required to be reported in § 70.50(c)(1) of this subpart is complete.

(5) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) Written reports. Each licensee that makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report must contain the information as described in § 70.50(c)(2).

§ 70.76 Backfitting.

(a) For each licensee, this provision shall apply to Subpart H requirements as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. For requirements other than Subpart H, this provision applies regardless of the status of the approval of a licensee's ISA Summary.

(1) Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a facility into compliance with Subpart H of this part;

(ii) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee;

(iii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iv) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that the regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediate effective regulatory action is required, then the documented evaluation may follow, rather than precede, the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written license commitments, or there are two or more ways to reach an adequate level of protection, then ordinarily the licensee is free to choose the way that best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory

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Revised Part 70 and Current Licensing Status

Presentation to ACRS/ACNW Joint Subcommittee

January 19, 2001

Tom Cox, NMSS/FCSS

Revised Part 70 and Current Licensing Status

The Rule

Primary Requirements of the Rule

Submittals Required

Effectivity of Rule

Licensing Status

The Rule

Applicable To:

Applicants or Licensees with greater than a “critical mass of special nuclear material” (SNM)

Designed To:

Achieve a risk-informed, performance based regulatory approach

Primary Requirements of the Rule

1. Licensee perform an Integrated Safety Analysis (ISA) -70.62(c)

2. Licensee comply with performance requirements (70.61)

3. Licensee identify items relied on for safety - 70.62(c)

Primary Requirements of the Rule

4. Licensee provide management measures - 70.62(d).

5. Licensee maintain safety bases, report changes -70.72(d), (e), (f).

6. Licensee can make certain changes without NRC approval -70.72(c).

Primary Requirements of the Rule

7. Licensee must report certain events (70.50, 70.74, Appendix A).

8. NRC must perform backfit analyses under specified circumstances (70.76).

Submittals Required

1. April 18, 2001 - Licensees submit, for NRC approval, a plan describing:

   - the ISA approach

   - the processes to be analyzed

   - the schedule for completing the analyses for each process

Submittals Required

2. October 18, 2004 - In accordance with the Plan (item 1), licensees:

   - complete an ISA

   - correct all unacceptable performance deficiencies

   - submit an ISA Summary for NRC approval, in accordance with 70.65.

Effectivity of Rule

1. Rule is generally effective as of October 18, 2000.

2. Backfit section 70.76 applies to non-subpart H requirements as of October 18, 2000. Applies to subpart H requirements after ISA Summary is approved by NRC.

3. Reporting requirements 70.74 (and Appendix A) generally apply after the licensee submits an ISA Summary for approval. Certain events are to be reported after October 18, 2000.

Licensing Status

1. Chapter 3 (ISA), Standard Review Plan.
2. Standard Review Plan, NUREG 1520.
3. NEI's proposed "Industry Guidance Document on Preparation of an ISA Summary."
4. Review of previously submitted ISA material.
5. ISA Plan guidance (70.62(c)(3) requirement).

Licensing Status

6. Staff guidance on the change process (70.72), reporting requirements (70.74), and backfitting (70.76).

7. ISA Plan reviews.

8. NRC's ISA Guidance Document, NUREG 1513.

9. ISA Summary reviews.

10. Interaction with CRGR.

11. Interaction with ACRS/ACNW Subcommittee.

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Integrated Safety Analysis Required by Revised 10 CFR 70

PRESENTATION TO THE ACRS/ACNW SUBCOMMITTEE
January 19, 2001

Part 70 SRP ISA Method

OBJECTIVES

Objectives of this presentation:

1) To explain the ISA methods of the Part 70 SRP.

2) To show typical results of applying the method.

Part 70 SRP ISA Method

SCOPE OF PRESENTATION

Scope:

1) Discusses the SRP guidance on methods for ISA tasks. What is an ISA?

2) Explains the likelihood evaluation method of SRP Chap. 3 Appendix A

3) Shows example results of analysis of fuel cycle processes using this likelihood evaluation method.

SCOPE OF PRESENTATION

Not focussed on details of acceptance criteria.

No discussion of status of industry ISA's because:

1) Part 70 was revised Sept 18, 2000

2) Part 70 requires submittal of plans and schedules by April 18, 2001

§70.62 Mandates ISA Tasks

..shall perform an ISA that..

- Identifies radiological and chemical hazards
- Identifies accident sequences
- Identifies consequence and likelihood
- Identifies Items Relied on for Safety
- Evaluates compliance with performance requirements of section 70.61

§70.61 - performance requirements

- ‘High Consequence’ Events:
  - Worker: 100 rem or more, chemical-caused fatality
  - Person offsite: >25 rem, or >30 mg Uranium intake, or irreversible chemical injury
- ...must be ‘highly unlikely’.
- ‘Intermediate Consequence’ Events:
  - worker: more than 25 rem but less than 100 rem, or irreversible chemical injury
  - Person offsite: >5 rem (but <25 rem), or chemically-induced transient illnesses, or contamination 5000 times environmental effluent standard
- ...must be ‘unlikely’.

§70.61 performance requirements

- continued -

- Chemical standards are only for
  - licensed material e.g., UO_2F_2
  - chemicals produced from licensed material (defined term) e.g., HF from UF_6
  - Defer to OSHA - general worker chemical safety issues
  - Defer to EPA - general public chemical safety issues

- Part 70 ISA term, 'item relied on for safety':
  - Structures, systems, equipment, components and <u>activities of personnel</u> that are relied on to prevent or mitigate potential accidents that could exceed the performance requirements

NRC review of ISA Summary

Acceptance Criteria for Compliance with 70.61

- Criteria for applicant's evaluation of potential accidents against performance requirements
  - Completeness ..of accident identification
  - Correctness .. of consequence evaluations
  - Adequacy .. of likelihood evaluations
- SRP Chapter 3 provides ISA review guidance
- Appendix A of Chap. 3 describes an example ISA analysis method

What does an ISA look like?

ISA TASKS

- 1. Identify hazards
- 2. Identify accidents
- 3. Estimate consequences
- 4. Identify items relied on for safety (IROFS)
- 5. Specify accident sequences
- 6. Evaluate likelihoods of accident sequences
- 7. Define ‘highly unlikely’ and ‘unlikely’
- 8. Compare accident likelihoods to definitions

Hazard and Accident Identification

NUREG-1513, ISA Guidance Document

- NUREG-1513: How to do an ISA
- Describes several hazard and accident identification methods
- Flow chart for selection of method appropriate to complexity of process
- Methods: fault trees, event trees, HAZOP, What If-Checklist

Consequence Estimation

- ‘High Consequences’ is defined quantitatively
- So ISA must estimate consequences quantitatively
- SRP guidance for calculations: NUREG/CR-6410
- Purpose of consequence evaluation is to determine gross level of prevention or mitigation required, not to assess risk.

Accident Sequence Specification

- SRP ISA Chap. 3 Appendix A gives one example of a method for displaying accident sequences
- App. A method lists each accident sequence as a row in a table
- Other methods are acceptable
- Other good methods: fault trees or event trees

App. A Likelihood Evaluation Method

Appendix A gives an example of one acceptable method for likelihood evaluation.

Other methods may be acceptable.

App. A Likelihood Evaluation Method

- Based on the equation for the frequency of the accident sequence as a function of event rates, probabilities, outage or mission times
- Uses integer indices representing logarithms of event rates, probabilities, and times
- Example tables relating control qualities to indices
- Intent was that applicants develop such tables of qualities relatable to failure rates

Likelihood Evaluation

- Double Contingency - ANSI/ANS 8.1 standard: a qualitative criterion
- Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

App. A Likelihood Evaluation Method

Based on equation for accident frequency

Examples of different accident sequence equations:

1. system of 2 active redundant contols:

accident frequency $f = \lambda_2 u_1 + \lambda_1 u_2$

Where: λ_2 is failure rate of control 2

u_2 is unavailability of control 2

App. A Likelihood Evaluation Method

freq. of sequence 1: $f_1 = \lambda_1 u_2 \approx \lambda_1 \lambda_2 T_2$

Where: λ's are failure rates

T_2 is down-time for control 2

That is, T_2 is the duration that the system is vulnerable to failure of the other control.

App. A Likelihood Evaluation Method

freq. of sequence 1: $f_1 = \lambda_1 u_2 \approx \lambda_1 \lambda_2 T_2$

$$\log(f_1) \approx \log(\lambda_1) + \log(\lambda_2) + \log(T_2)$$

App. A Likelihood Evaluation Method

For example, if:

$\lambda_1 = 10^{-1}$ $\quad$ $\mathrm{Log}(\lambda_1) = -1$

$\lambda_2 = 10^{-2}$ $\quad$ $\mathrm{Log}(\lambda_2) = -2$

$T_2 = 10^{-3}$ $\quad$ $\mathrm{Log}(T_2) = -3$

Then: $\mathrm{Log}(f_1) = -1-2-3 = -6$

App. A Likelihood Evaluation Method

Based on equation for accident frequency

2. operator performs task subject to a safety procedure to avoid a failure limit.

f_a = frequency of accident

λ_1 = frequency of task (e.g. 365 times per year)

p_1 = probability operator exceeds failure limit per task

$f_a = \lambda_1 p_1$

App. A Likelihood Evaluation Method

Basing likelihood evaluation method on underlying frequency equation helps assure that failure rates and down-times of all relevant items relied on for safety are:

1) considered in the evaluation, and

2) subject to management measures

App. A Likelihood Evaluation Method

In the Appendix A method, assignments of index values to failure rates and times are to be based on pre-defined tabulated qualitative or quantitative criteria. (See tables A-3,4,5)

The bases underlying these criteria should be explained in the documentation of the applicant's ISA methodology. Over-arching goals are objectivity, validity, and consistency.

Example 1:
Double toxic chemical line

The system is a line for adding an aqueous toxic chemical to a U process. The accident is a leak with potential for exposure of workers to the chemical. Protection against leaks in the line is provided by an outer containment pipe. Presence of chemical in the space between the two lines is checked by weekly surveillance of a sight glass. Outer line leak tightness is tested every 2 years.

Example 1: Double Chemical Line

Failure rate of inner line: $\lambda_1 = 10^{-2}$ per year

$\mathrm{Log}(\lambda_1) = \mathrm{frq1} = -2$

Average outage time of line 1 is ½ week

$T_1 = ½ \text{ week} = 10^{-2}$ year

$\mathrm{Log}(T_1) = \mathrm{dur1} = -2$

Example 1: Double Chemical Line

Failure rate of outer line: $\lambda_1 = 10^{-2}$ per year

$\mathrm{Log}(\lambda_2) = \mathrm{frq2} = -2$

Average outage time of outer line is 1 year

$T_2 = 1$ year $= 10^0$

$\mathrm{Log}(T_2) = \mathrm{dur2} = 0$

Example 1: Double Chemical Line

f_1 = frequency of accident sequence 1

$f_1 \approx \lambda_1 \lambda_2 T_2$

$\log(f_1) \approx \log(\lambda_1) + \log(\lambda_2) + \log(T_2)$

See Example Table A-1

Summary of Appendix A Method

- A table of accident sequences, one event per column
- A set of parameters taken from the equation for the frequency of the accident sequence
- Integer indices assigned to parameters and summed as a likelihood (frequency) index
- Assignments of index values based on pre-defined tables of criteria

HF Line Example, Table A-1: Tabular Summary of Accident Sequences

Process: Uranium Recovery
Unit Process: Dissolution Node: transfer of chemicals (HF) to dissolver tray

Accident Sequence	Initiating Event (a)	Preventive Control 1 (b)	Likelihood Index T (e)	Consequence Category (g)
HF line leaks, inner line first	inner line leaks first frq1= -2	outer line leaks before inner is corrected dur1=-2 frq2=-2	-2-2-2 = -6	2
HF line leaks, outer line first	outer line leaks first frq2=-2	inner line leaks before outer is corrected dur2= 0 frq1=-2	-2+0-1= -4	2

Table A-3: Failure Frequency Index Numbers

Frequency Index Number	Based on Evidence	Based on Type of Control**	Comments
-6	External event with freq. < 10^{-6} /yr		If initiating event, no controls needed
-4	No failures in 30 yrs for hundreds of similar controls in industry	Failure of an exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 independent AEC, PEC, or enhanced admin. controls	Rarely can be justified by evidence, since few systems are found in such large numbers. Further, most types of single control have been observed to fail.
-3	No failures in 30 years for tens of similar controls in industry	Failure of a single control with redundant parts, each a PEC or AEC	
-2	No failure of this type in this plant in 30 years	Failure of a single PEC	
-1	A few failures may occur during plant lifetime	Failure of a single AEC, an enhanced administrative control, an admin. control with large margin, or a redundant admin. control	
0	Failures occur every 1 - 3 years	Failure of a single administrative control	
1	Several occurrences per year	A normal event	Not for controls, just initiating events
2	Occurs every week or more often	Frequent event	Not for controls, just initiating events

** The index value assigned to a control of a given type in column 3 may be one value higher or lower than the value given in column 1. Criteria justifying assignment of the lower (more negative) value should be given in the narrative describing ISA methods. Exceptions require individual justification.

Table A-4: Failure Probability Index Numbers

Probability Index Number	Probability of Failure on Demand	Based on Type of Control	Comments
-6	10^{-6}		If initiating event, no controls needed
-4 or -5	10^{-4} - 10^{-5}	Exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 redundant controls better than simple admin controls (AEC, PEC, or enhanced admin)	Rarely can be justified by evidence, since few systems are found in such large numbers . Further, most types of single control have been observed to fail.
-3 or -4	10^{-3} - 10^{-4}	A single passive engineered ctrl. (PEC) or an active engineered control (AEC) with high availability	
-2 or -3	10^{-2} - 10^{-3}	A single active engineered control, or an enhanced admin control, or an admin control for routine planned operations	
-1 or -2	10^{-1} - 10^{-2}	An admin control that must be performed in response to a rare unplanned demand	

Table A-5: Failure Duration Index Numbers

Duration Index Number	Avg. Failure Duration	Duration in Years	Comments
1	More than 3 years	10	
0	1 year	1	
-1	1 month	0.1	Formal monitoring to justify indices less than "-1"
-2	A few days	0.01	
-3	8 hours	0.001	
-4	1 hour	10^{-4}	
-5	5 minutes	10^{-5}	

Markley
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Example 2: Overloading a Transfer Cart

The system is a mobile cart used to transfer uranium compounds between processes. The accident consists of overloading the cart to the point where a nuclear criticality occurs. The protection against this consists of two administrative controls and one passive engineered control. Cart is used less than 100 times a year.

Example 2: Overloading a Transfer Cart

CONTROLS

- Admin control: procedure requires loading of cans by independent operator and measurement to assure moderator content of storage cans is within limits
- Admin control: procedure and sign on cart limits number of storage cans on cart
- Passive Engineered Control: Cart has only a limited size and space to hold storage cans

Example 2: Overloading a Transfer Cart

EQUATION FOR ACCIDENT FREQUENCY:

Frq1 = frequency of uses of cart = 2 (100 /year)
See Table A-4:
Pr2 = prob. that moderator limit on cans is violated = -3
Pr3 = prob. that operator loads too many cans = -3
Pr4 = prob.that overload is sufficient to cause criticality
=-4 (passive structure limits overload)

Example 2: Overloading a Transfer Cart

Likelihood index = frq1+pr2+pr3+pr4

= 2 -3 -3 -4

= -8

Guideline: index < -5 should be acceptable

Example 3: Criticality due to excess U mass

System is a liquid chemistry process involving addition of U compound. Protection consists of an admin control with a passive engineered control. The administrative control limits total U-235 mass, implemented by documented weight measurement with mass limit of 350 grams U-235 in single batch sized containers. The passive control is the geometry of the process vessel, which is such that criticality would require 70 Kg U-235 of the most reactive compound available before criticality is possible.

Example 3: Criticality due to excess U mass

Accident is a criticality caused by failure to observe the mass limit by an amount exceeding 70 Kg U-235.

Example 3: Criticality due to excess U mass

Three "events" in accident sequence:

Loading process with U: frq1 = 2 (100 times/yr)

Not observing 350 gm limit: pr2 = -3

Loading 70 kg, given mass limit not observed:

Why unlikely? Very large safety factor:

70 Kg/.35Kg = 200 batches

Pr3 = -4 ?

Likelihood index = 2 -3 -4 = -5 ?

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Integrated Safety Management

Briefing to the

ACRS/ACNW Joint Subcommittee

Ted Wyka

Director,

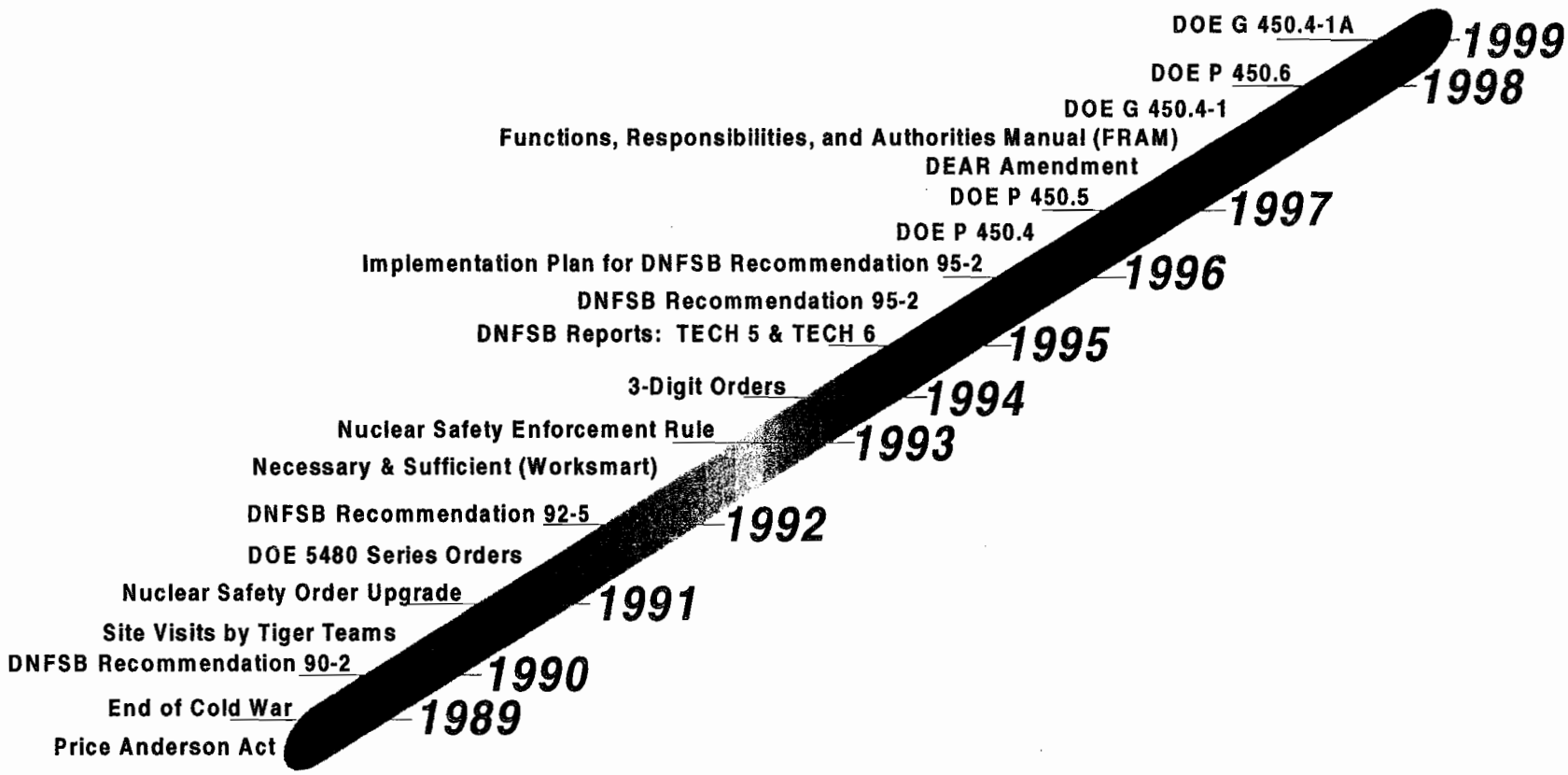
DOE Safety Management Implementation Team

Office of the Deputy Secretary

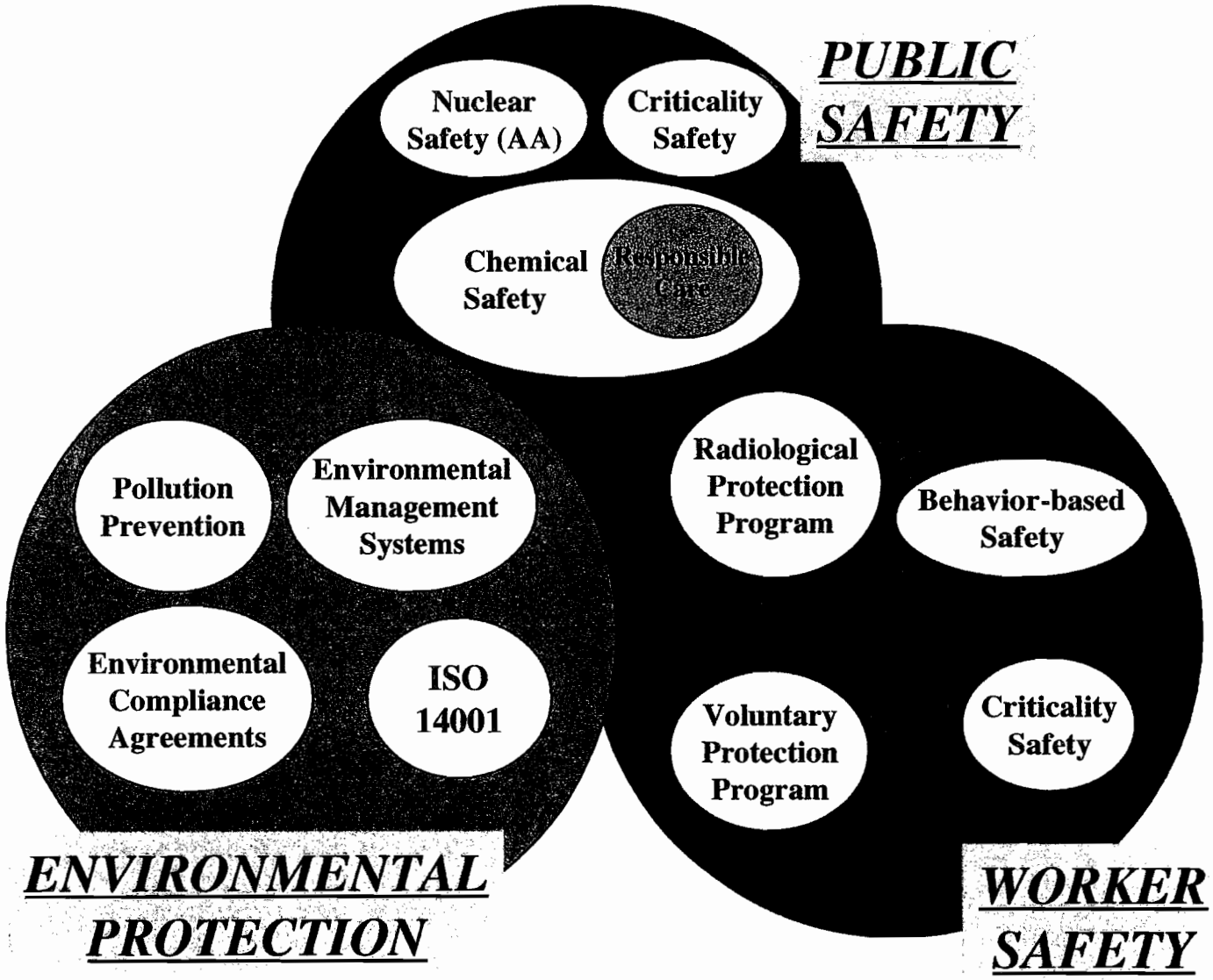
Washington, DC

January 19, 2001

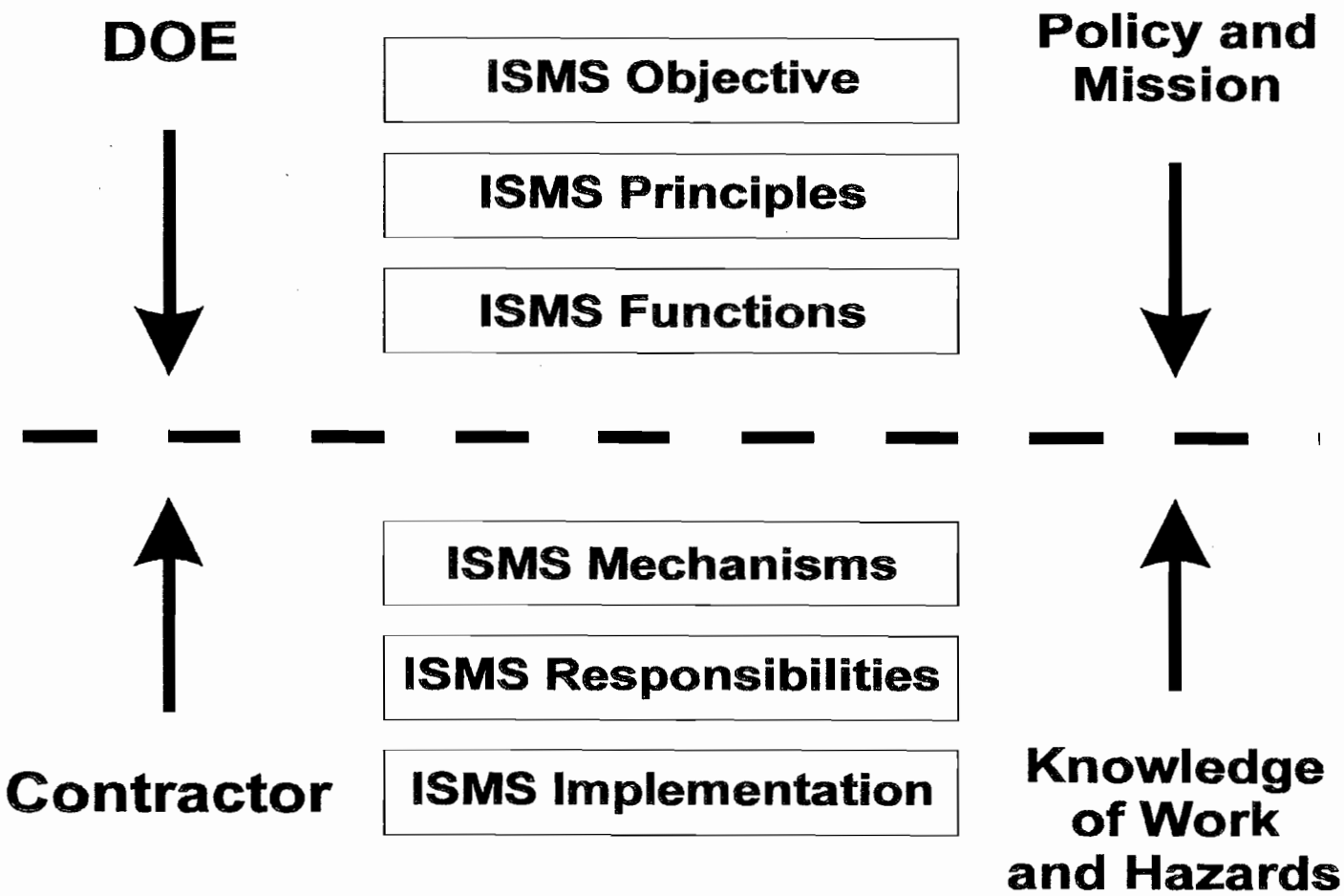
Evolution (not Revolution) of ISM



Integrated Safety Management

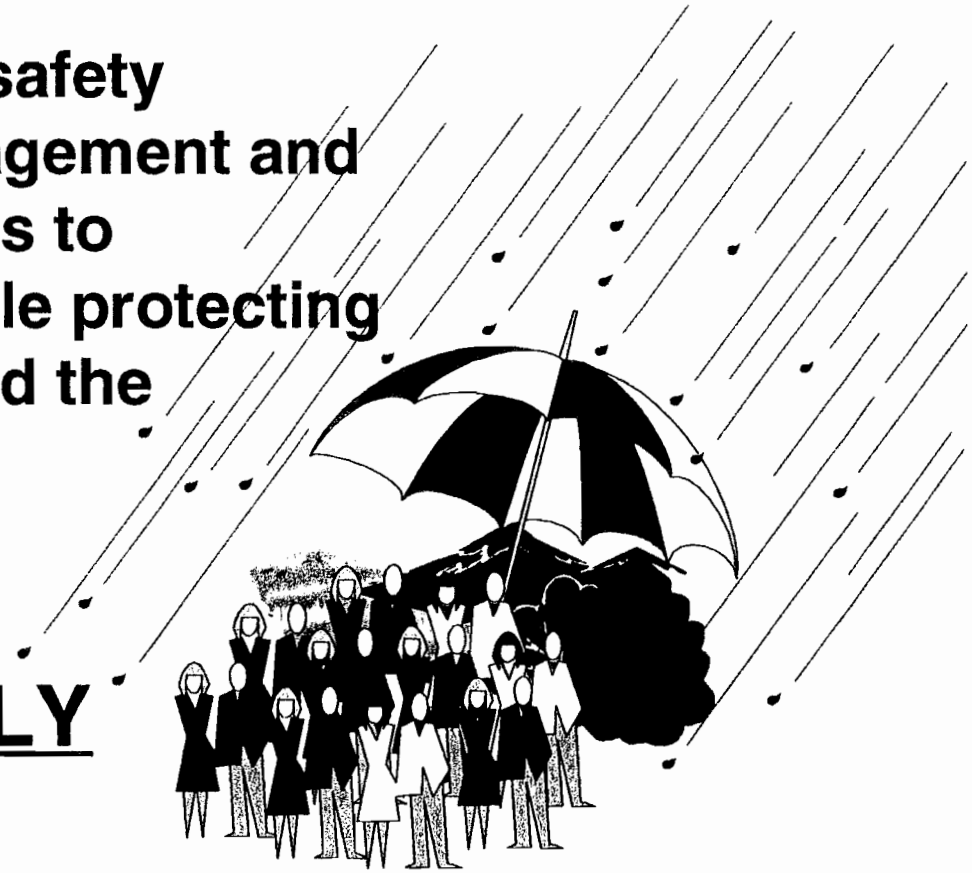


An Integrated Safety Management System (ISMS) -- in a Nutshell



ISMS Objective

Systematically integrate safety considerations into management and work practices at all levels to accomplish missions while protecting the public, the worker, and the environment



Stated simply,

DO WORK -- SAFELY

ISM Principles

- Line management responsible for safety
- Clear and unambiguous lines of authority
- Competence commensurate with responsibilities
- Balanced priorities
- Identification of safety standards and requirements
- Hazard controls tailored to work being performed
- Operations authorization

DOE P 450.4

ISM Functions

- Define the scope of work
- Analyze the hazards
- Develop and implement hazard controls
- Perform work within those controls
- Provide feedback and continuous improvement

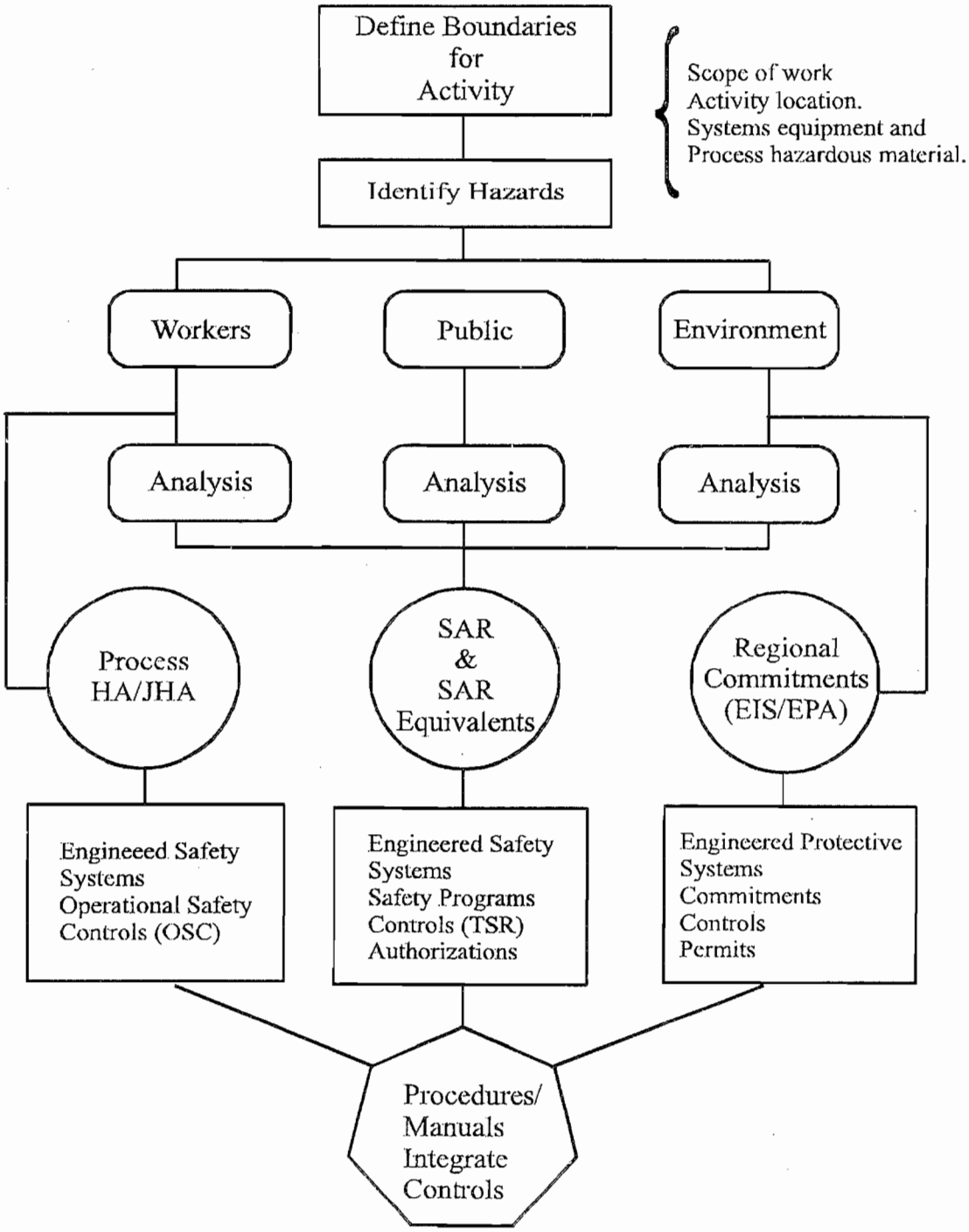
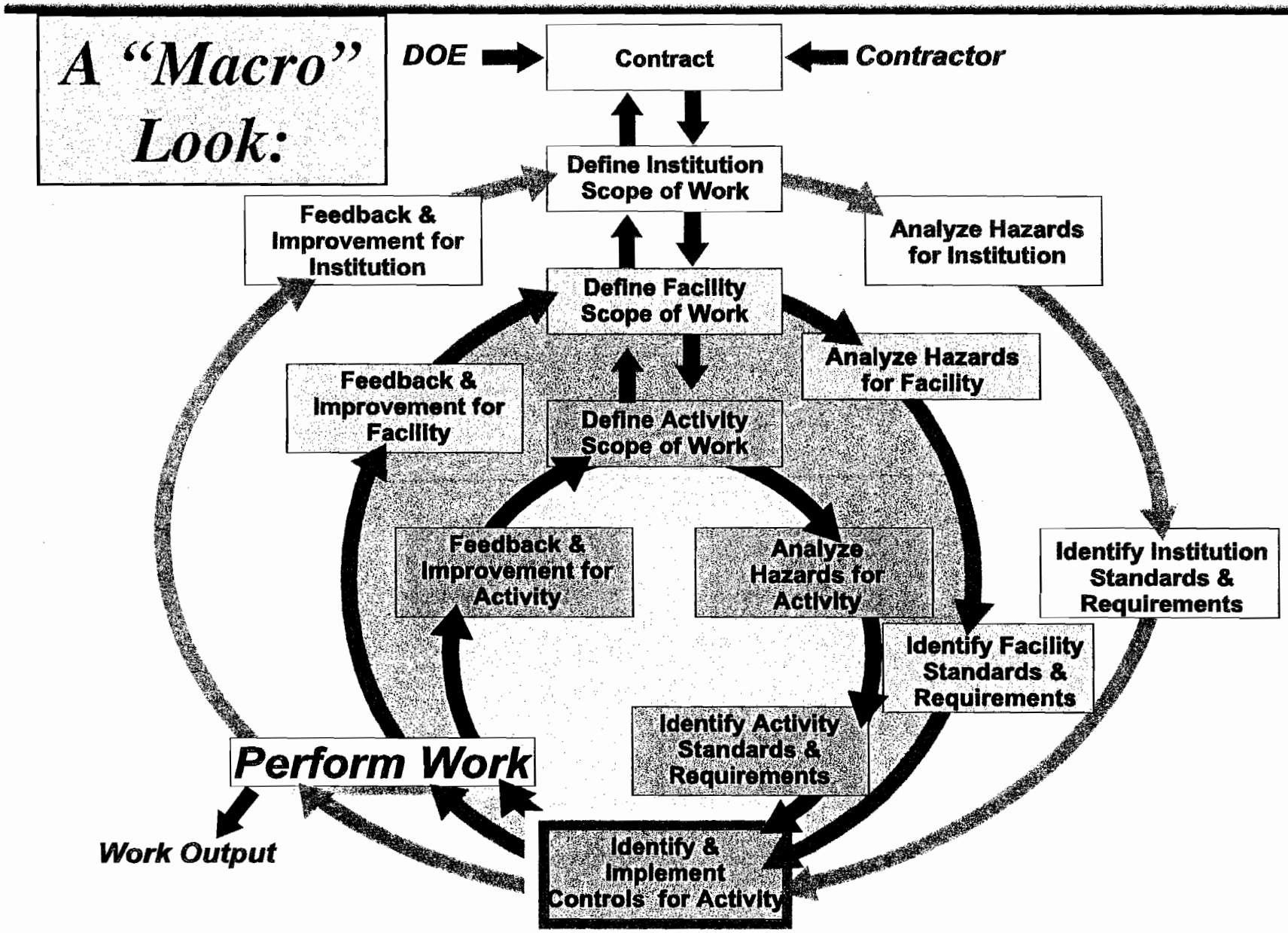


Figure 4a. An illustration derived from DNFSB Tech 16 of the development and integration of ES&H controls at the activity level.

ISM Mechanisms

- DOE mechanisms:
  - DEAR Clauses
  - Contracts
  - Authorization protocols
- Contractor mechanisms:
  - Contracts and Subcontracts
  - ISMS descriptions
  - Safety analyses, manuals, and programs
  - Health and Safety Plans
  - Specifications, training, plans, procedures, etc.

Functions - Institution, Facility, & Activity



ISM Implementation Strategy

- ✓ Incorporate ISM into DOE Directives and DEAR Clauses
- ✓ Incorporate DEAR Clauses into Contracts
- ✓ DOE/Contractor agree on SMS Descriptions, List B Safety Requirements, and Authorization Agreements
- ✓ DOE/Contractor initial implementation of SMS -- *Most completed*
- ✓ Workshops and Information Sharing -- *Ongoing*
- ✓ Verifications -- Phase I and Phase II -- *Most completed*

<u>ALL LED TOWARD</u>...

- ✓ Confirmation of Initial ISM Implementation by September 2000

ISM Verification Protocol

Verification Team Leader

- Selected by the Head Contracting Authority (HCA) (i.e., the Field Manager)
- Team Leader receives verification work scope from the HCA (which Facilities, Departments, Divisions, etc.)
- Team Leader selects Team personnel, using both local and complex-wide assets
- Team Leader responsible for developing relevant Criteria and Approach Documents (CRADs)

Phase I Verification: Assessment of the Safety Management System Description document and a Recommendation for Approval or Re-Work

Phase II Verification: Assessment of compliance with the Safety Management System Description document and a Recommendation for acceptance or non-acceptance of implementation

DOE Offices: Declaration Status

NNSA/DP	[redacted]
AL NNSA	[redacted]
NV NNSA	[redacted]
Y-12 NNSA	[redacted]
SC	[redacted]
CH	[redacted]
OR	[redacted]
OAK	[redacted]
EE	[redacted]

[redacted]	**EM**
[redacted]	ID
[redacted]	ORP
[redacted]	OH
[redacted]	RL
[redacted]	RF
[redacted]	SR
[redacted]	**FE**
[redacted]	**RW**

Seven ISM Implementation Criteria

- DOE and contractor organizations have established and are maintaining agreed-upon sets of applicable requirements and standards.
- DOE has approved applicable Safety Management System (SMS) descriptions.
- DOE has verified implementation of applicable Safety Management Systems.
- DOE Functions, Responsibilities and Authorities (FRA) documents are implemented.
- DOE has verified that feedback and improvement programs are in place and effective.
- DOE line oversight programs are in place and effective.
- DOE has established a documented process to maintain applicable Safety Management Systems.

ISM Verification Results: Opportunities for Improvement

- Flowdown of ISM to the appropriate subcontracts
- Flowdown to the actual work
- Worker involvement
- Feedback and improvement
- Lessons Learned sharing
- Clear roles and responsibilities
- High quality safety basis documentation
- Contractor self-assessments and line oversight
- Involvement by DOE Facility Representatives

Post-September 2000 Implementation

- **S-2's "ISM--Next Steps" Memo of 9/28/00:**

  "Realizing the Benefits of Integrated Safety Management"

- **Concurred in by all PSOs**

  - ✓**Sustain and Improve ISM Systems:**
    - **Conduct effective line oversight**
    - **Make annual ISM updates meaningful**
    - **Strengthen activity-level work planning**
    - **Independent oversight of ISM implementation**
  - ✓**Integrate Key DOE Processes with ISM:**
    - **Integrate ISM throughout the facility life-cycle**
    - **Strengthen integration of ISM with the budget process**
    - **Improve feedback and improvement mechanisms**

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U.S. Department of Energy
Washington, D.C.

POLICY

DOE P 450.4

10-15-96

SUBJECT : SAFETY MANAGEMENT SYSTEM POLICY

PURPOSE AND SCOPE

Safety Management Systems provide a formal, organized process whereby people plan, perform, assess, and improve the safe conduct of work. The Safety Management System is institutionalized through Department of Energy (DOE) directives and contracts to establish the Department-wide safety management objective, guiding principles, and functions.

The system encompasses all levels of activities and documentation related to safety management throughout the DOE complex. The objective of this policy is achieved by other means for Naval Reactors (Naval Nuclear Propulsion Program).

Throughout this policy statement, the term safety is used synonymously with environment, safety and health (ES&H) to encompass protection of the public, the workers, and the environment.

POLICY

The Department is committed to conducting work efficiently and in a manner that ensures protection of workers, the public and the environment. It is Department policy that safety management systems described herein shall be used to systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment. Direct involvement of workers during the development and implementation of safety management systems is essential for their success.

The DOE safety management system establishes a hierarchy of components (see figure 1) to facilitate the orderly development and implementation of safety management throughout the DOE complex. The safety management system consists of six components: 1) the objective, 2) guiding principles, 3) core functions, 4) mechanisms, 5) responsibilities, and 6) implementation. The objective, guiding principles, and core functions of safety management identified below shall be used consistently in implementing safety management throughout the DOE complex. The mechanisms, responsibilities, and implementation components are established for all work and will vary based on the nature and hazard of the work being performed.

DISTRIBUTION:
All Departmental Elements

INITIATED BY:
The Office of Environment, Safety and Health

COMPONENT 1 ***Objective of Integrated Safety Management***

The Department and Contractors must systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment. This is to be accomplished through effective integration of safety management into all facets of work planning and execution. In other words, the overall management of safety functions and activities becomes an integral part of mission accomplishment.

COMPONENT 2 ***Guiding Principles for Integrated Safety Management***

The guiding principles are the fundamental policies that guide Department and contractor actions, from development of safety directives to performance of work.

Line Management Responsibility for Safety. Line management is directly responsible for the protection of the public, the workers, and the environment. As a complement to line management, the Department's Office of Environment, Safety and Health provides safety policy, enforcement, and independent oversight functions.

Clear Roles and Responsibilities. Clear and unambiguous lines of authority and responsibility for ensuring safety shall be established and maintained at all organizational levels within the Department and its contractors.

Competence Commensurate with Responsibilities. Personnel shall possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.

Balanced Priorities. Resources shall be effectively allocated to address safety, programmatic, and operational considerations. Protecting the public, the workers, and the environment shall be a priority whenever activities are planned and performed.

Identification of Safety Standards and Requirements. Before work is performed, the associated hazards shall be evaluated and an agreed-upon set of safety standards and requirements shall be established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences.

Hazard Controls Tailored to Work Being Performed. Administrative and engineering controls to prevent and mitigate hazards shall be tailored to the work being performed and associated hazards.

Operations Authorization. The conditions and requirements to be satisfied for operations to be initiated and conducted shall be clearly established and agreed-upon.

COMPONENT 3 - ***Core Functions for Integrated Safety Management***

These five core safety management functions provide the necessary structure for any work activity that could potentially affect the public, the workers, and the environment. The functions are applied as a continuous cycle with the degree of rigor appropriate to address the type of work activity and the hazards involved.

Define the Scope of Work. Missions are translated into work, expectations are set, tasks are identified and prioritized, and resources are allocated.

Analyze the Hazards. *Hazards associated with the work are identified, analyzed and categorized.*

Develop and Implement Hazard Controls. *Applicable standards and requirements are identified and agreed-upon, controls to prevent/mitigate hazards are identified, the safety envelope is established, and controls are implemented.*

Perform Work within Controls. *Readiness is confirmed and work is performed safely.*

Provide Feedback and Continuous Improvement. *Feedback information on the adequacy of controls is gathered, opportunities for improving the definition and planning of work are identified and implemented, line and independent oversight is conducted, and, if necessary, regulatory enforcement actions occur.*

COMPONENT 4 ***Integrated Safety Management - Mechanisms***

Safety Mechanisms define how the core safety management functions are performed. The mechanisms may vary from facility to facility and from activity to activity based on the hazards and the work being performed and may include:

Departmental expectations expressed through directives (policy, rules, orders, notices, standards, and guidance) and contract clauses.

Directives on identifying and analyzing hazards and performing safety analyses.

Directives which establish processes to be used in setting safety standards.

Contractor policies, procedures and documents (e.g., Health and Safety Plans, Safety Analysis Reports, Chemical Hygiene Plans, Process Hazard Analyses) established to implement safety management and fulfill commitments made to the Department.

COMPONENT 5 ***Responsibilities for Integrated Safety Management***

Responsibilities must be clearly defined in documents appropriate to the activity. DOE responsibilities are defined in Department directives. Contractor responsibilities are detailed in contracts, regulations and contractor-specific procedures. For each management mechanism employed to satisfy a safety management principle or function, the associated approval authority needs to be established. The review and approval levels may vary commensurate with the type of work and the hazards involved.

COMPONENT 6 ***Implementation of Integrated Safety Management***

Implementation involves specific instances of work definition and planning, hazards identifications and analysis, definition and implementation of hazard controls, performance of work, developing and implementing operating procedures, and monitoring and assessing performance for improvement .

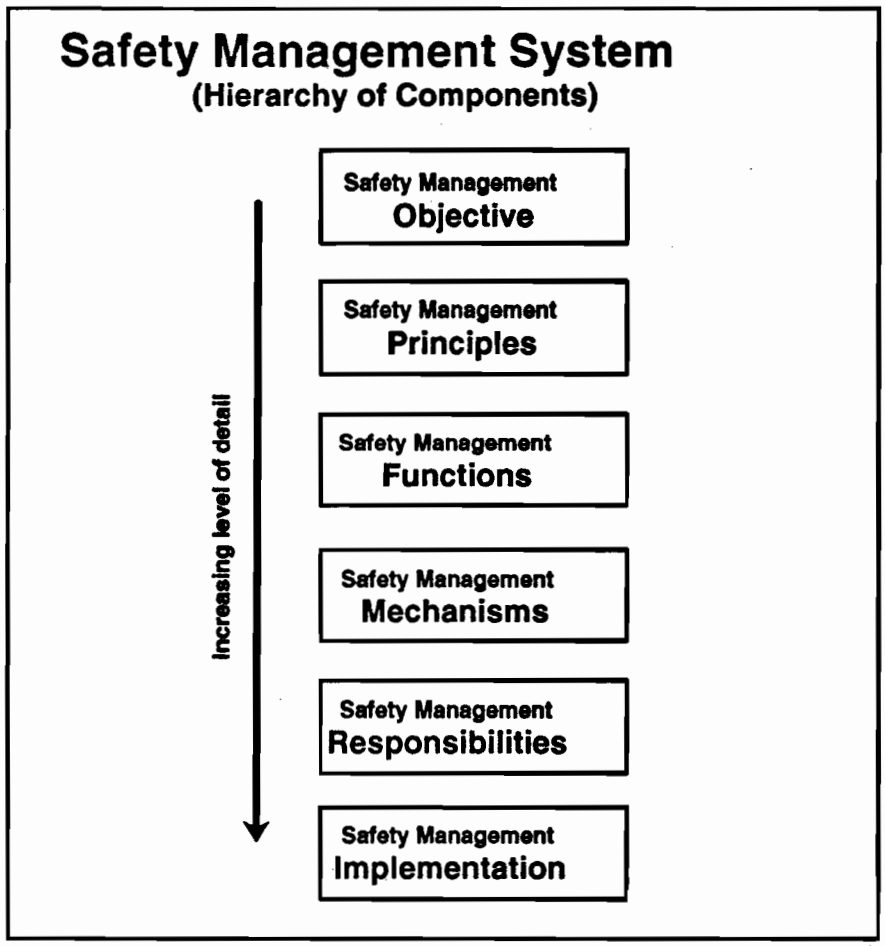

Figure 1

HAZEL R. O'LEARY
Secretary of Energy

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NMSS Risk Task Group

Who We Are and Why We're Here

SECY 99-100

- Staff proposed a framework for risk-informed regulation in material and waste arenas
- SRM on SECY 99-100, the Commission approved staff's proposal and directed staff to:
  - Develop appropriate material and waste safety goals
  - Use an enhanced participatory process

SECY 99-100
The Five-Step Implementation Process

- Identify
  - Candidate regulatory applications
  - Responsible organizations
- Decide how to modify current regulatory approaches
- Change regulatory approaches
- Implement risk-informed approaches
- Develop or adapt risk-informed tools

RTG Operating Plan Linked to Strategic Plan

Performance Goal: Make NRC activities and decisions more *effective, efficient*, and *realistic*.

- Develop and conduct case studies in material and waste arenas to test screening criteria and develop draft safety goals
- Develop and conduct training in NMSS application of risk analysis
- Provide assistance and continuity for implementing NMSS risk-informed regulatory actions

Case Study Approach

- As a first step toward developing framework, the staff established a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk information

⇨ *CASE STUDY APPROACH*

- Other activities (e.g., RES, ICRP, NCRP, NAS, EPA) may supplement development of risk-informed framework

Case Studies

- Purposes of the Case Studies are:
  - To illustrate what has been done and what could be done in material and waste arenas to alter the regulatory approach in a risk-informed manner
  - To establish a framework for using a risked-informed approach in material and waste by testing the draft screening criteria

Case Studies (continued)

- Purposes of the Case Studies are:
  - To illustrate what has been done and what could be done in material and waste arenas to alter the regulatory approach in a risk-informed manner
  - To establish a framework for using a risked-informed approach in material and waste by testing the draft screening criteria

Case Study Areas

- Gas Chromatographs
- Fixed Gauges
- Site Decommissioning
- Uranium Recovery
- Radioactive Material Transportation
- Part 76
- Spent Fuel Interim Storage
- Static Eliminators

Case Study Schedule

- Case study plan was presented to stakeholders at a public meeting on September 21, 2000.
- Based on stakeholder comments, plan was revised and issued on October 27, 2000.
- Work on case studies will be conducted throughout FY 2001.
- When completed, staff will present results to Commission.

Screening Criteria

1. Resolve a question with respect to maintaining or improving the activity's safety?
2. Improve the efficiency or the effectiveness of the NRC regulatory approach?
3. Reduce unnecessary regulatory burden?
4. Help to effectively communicate a regulatory decision or situation?

⇨ *If YES to <u>any</u> of the above, proceed to additional criteria; if NO to <u>all</u>, the activity is screened out.*

Screening Criteria (continued)

5. Do information (data) and analytical models exist that are of sufficient quality or could they be developed to support risk-informing a regulatory activity?

⇨ *If the answer to criterion 5 is YES, proceed to additional criteria; if NO, the activity is screened out.*

Screening Criteria (continued)

6. Can start-up and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit?

⇨ *If the answer to criterion 6 is YES, proceed to additional criteria; if NO, the activity is screened out.*

Screening Criteria (continued)

7. Do other factors exist (e.g., legislative, judicial, adverse stakeholder reaction) which would preclude changing the regulatory approach in an area and, therefore, limit the utility of implementing a risk-informed approach?

⇨ *If the answer to criterion 7 is NO, a risk-informed approach may be implemented; if the answer is YES, the activity may be given additional consideration or be screened out.*

Training

- RTG is working with TTC to develop classes to train staff on risk activities in the materials and waste arenas.
- Pilot program held in September, 2000
- Final version implemented in December, 2000

Assistance in Implementing NMSS Risk-Informed Regulatory Actions

- Review and comment on Yucca Mountain Review Plan
- Assist IMNS in responding to PRM-36-1
- Use of NUREG-6642 to assist in review of Mallinckrodt Lessons Learned and for potential revisions to inspection guidance
- Participate in team review of Mallinckrodt Lessons Learned
- Assist FCSS in review of BWXT ISA Summary

Assistance in Implementing NMSS Risk-Informed Regulatory Actions (continued)

- Monitor Part 72 rulemaking to allow use of PSHA methodology in ISFSI designs
- Monitor SFPO/RES dry cask storage PRA study
- Monitor FCSS oversight program development
- Review FCSS process change for threat assessment of DBT and adversary characteristics
- Monitor CNWRA study of potential hazards from Uranium Recovery in situ leaching
- Will continue to monitor and assist NMSS Divisions in risk-related activities