UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 14, 1999

Mr. James Makris, Director
Chemical Emergency Preparedness
and Prevention Office
U.S. Environmental Protection Agency
401 M. Street S. W. (Mail Code 5101)
Washington, D.C. 20460

SUBJECT: PENDING U.S. NUCLEAR REGULATORY COMMISSION REGULATIONS FOR DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

Dear Mr. Makris:

The U.S. Nuclear Regulatory Commission (NRC) is currently in the process of developing revisions to its regulations (10 CFR Part 70) for domestic licensing of special nuclear material. The amendments will require certain NRC-licensed facilities to develop and implement a safety program based on the performance of an integrated hazard analysis. Generally, the facilities that will be affected by these amendments are nuclear reactor fuel fabrication facilities and some uranium enrichment facilities. In addition to special nuclear material, these facilities may also possess quantities of hazardous chemicals that subject them to the U.S. Environmental Protection Agency's (EPA's) chemical accident prevention provisions (i.e., 40 CFR Part 68) and to the Occupational Safety and Health Administration's (OSHA's) process safety management regulation (i.e., 29 CFR 1910.119).

The regulatory revisions are intended to be consistent with the October 31, 1988, NRC-OSHA Memorandum of Understanding (Enclosure 1). That is, NRC regulatory purview would include radiological risk, chemical risk produced by radioactive materials, and facility hazards (e.g., chemical, fire, electrical and mechanical) which could affect the safety of NRC-licensed materials and thus present an increased radiological risk; however, NRC would not have regulatory responsibility for facility hazards that may result in occupational risks but do not affect the safety of NRC-licensed materials. Similarly, the regulatory revisions would not place the impacts of hazardous chemicals on members of the public under NRC's regulatory purview, unless those chemicals were licensed radioactive material themselves or were produced from licensed radioactive material.

Upon its review of a previous version of the rule, the Commission directed the NRC staff to revisit the issues related to chemical safety and further discuss them with the affected agencies, to understand the respective authorities and the degree to which those authorities are implemented. In addition, the Commission directed the staff to discuss the relevant documents with stakeholders and the public and submit a proposed rulemaking package in May 1999. (Stakeholders and the public will also have an opportunity for formal comment

99-011

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ORG EPA

X MHB 5-3-2-4

once the Commission approves a rule for publication as a proposed rule.) Since September 1998, we have held two public meetings and have established a World Wide Web site (http://techconf.llnl.gov/cgi-bin/messages?dom_lic) that contains discussion threads and a library of documents related to this rulemaking. As a result of discussions at those meetings and written comments received, two sections of the rule text were developed (Enclosure 2). These two sections are intended to implement the NRC areas of responsibility and be consistent with the respective statutory authorities of NRC, EPA, and OSHA. Accordingly, we would greatly appreciate your views on these two sections.

To facilitate submission of a proposed rule package to the Commission in May 1999, we would like to resolve in January any major issues with the draft rule language itself, particularly for the attached two rule sections. Again, your views on the attached draft rule text would be appreciated. It would be desirable if your views could be provided by January 29, 1999. Should you like to arrange a meeting or have any questions, please contact Mr. Theodore Sherr on (301) 415-7218 or Mr. Andrew Persinko on (301) 415-6522.

Sincerely,

(Original signed by)

Carl. J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. NRC-OSHA Memorandum of Understanding
2. Draft changes to 10 CFR §§70.60 and §70.62

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10-31-88
Vol. 53 No. 210
Pages 43843-43998

Federal Register

Monday
October 31, 1988

Briefing on How To Use the Federal Register—
For information on a briefing in Washington, DC, see announcement on the inside cover of this issue.

[Docket No. 88-49]

Summer Grove Pharmacy, Shreveport, LA; Hearing

Notice is hereby given that on April 12, 1988, the Drug Enforcement Administration, Department of Justice, issued to Summer Grove Pharmacy an Order to Show Cause as to why the Drug Enforcement Administration should not revoke your DEA Certificate of Registration AS5413755 and deny any pending applications.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Thursday, November 17, 1988, commencing at 10:00 a.m., at the United States Custom House, 423 Canal Street, courtroom, 211, New Orleans, Louisiana.

Dated: October 24, 1988.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 88-25097 Filed 10-28-88; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 88-54]

Michael C. Vizcarra, Hesperia CA; Notice of Hearing

Notice is hereby given that on April 22, 1988, the Drug Enforcement Administration, Department of Justice, issued to Michael C. Vizcarra, M.D., an Order to Show Cause as to why the Drug Enforcement Administration should not deny your application for a DEA Certificate of Registration.

Thirty days having elapsed since the said Order to Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held on Tuesday, November 15, 1988, commencing at 10:00 a.m., at the Alhambra Municipal Court, 150 West Common Wealth Avenue, Division One Courtroom, Second Floor, Alhambra, California.

Dated: October 25, 1988.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 88-25096 Filed 10-28-88; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

NUCLEAR REGULATORY COMMISSION

Memorandum of Understanding Between The Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-licensed Facilities

The Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) have entered into a Memorandum of Understanding (MOU) to provide general guidelines for interface activities between the two agencies. The MOU is designed to ensure that there will be no gaps in the protection of workers at NRC-licensed facilities where the OSHA also has health and safety jurisdiction. At the same time, the MOU is designed to avoid duplication of effort on the part of the two agencies in those cases where it is not always practical to sharply identify boundaries between the NRC's responsibilities for nuclear safety and the OSHA's responsibilities for industrial safety.

The MOU, which replaces an existing procedure for interagency activities, defines the general areas of responsibilities of both agencies, describes generally the efforts of each to achieve worker protection at NRC-licensed facilities, and provides general procedures for the coordination of interface activities and exchange of information between the NRC and OSHA. The text of the MOU is set out below.

Purpose and Background

1. The purpose of this Memorandum of Understanding between the U.S. Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) is to delineate the general areas of responsibility of each agency; to describe generally the efforts of the agencies to achieve worker protection at facilities licensed by the NRC; and to provide guidelines for coordination of interface activities between the two agencies. If NRC licensees observe OSHA's standards and regulations, this will help minimize workplace hazards.

2. Both NRC and OSHA have jurisdiction over occupational safety and health at NRC-licensed facilities. Because it is not always practical to sharply identify boundaries between the nuclear and radiological safety NRC regulates and the industrial safety OSHA regulates, a coordinated interagency effort can ensure against gaps in the protection of workers and, at the same time, avoid duplication of effort. This memorandum replaces an existing procedure for interagency activities, "General Guidelines for Interface Activities between the NRC Regional Offices and the OSHA."

Hazards Associated With Nuclear Facilities

3. There are four kinds of hazards that may be associated with NRC-licensed nuclear facilities:

a. Radiation risk produced by radioactive materials;

b. Chemical risk produced by radioactive materials;

c. Plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers. For example, these might produce a fire or an explosion, and thereby cause a release of radioactive materials or an unsafe reactor condition; and,

d. Plant conditions which result in an occupational risk, but do not affect the safety of licensed radioactive materials. For example, there might be exposure to toxic nonradioactive materials and other industrial hazards in the workplace.

Generally, NRC covers the first three hazards listed in paragraph 3 (a, b, and c), and OSHA covers the fourth hazard described in paragraph 3 (d). NRC and OSHA responsibilities and actions are described more fully in paragraphs 4 and 5 below.

NRC Responsibilities

4. NRC is responsible for licensing and regulating nuclear facilities and materials and for conducting research in support of the licensing and regulatory process, as mandated by the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and the Nuclear Nonproliferation Act of 1978; and in accordance with the National Environmental Policy Act of 1969, as amended, and other applicable statutes. These NRC responsibilities cover the first three nuclear facility hazards identified in paragraph 3 (a, b, c). NRC does not have statutory authority for the fourth hazard described in paragraph 3 (d).

NRC responsibilities include protecting public health and safety; protecting the environment; protecting and safeguarding materials and plants in the interest of national security; and assuring conformity with antitrust laws for certain types of facilities, e.g., nuclear power reactors. Agency functions are performed through: Standards-setting and rulemaking;

technical reviews and studies; conduct of public hearings; issuance of authorizations, permits and licenses; inspection, investigation and enforcement; evaluation of operating experience, and confirmatory research.

OSHA Responsibilities

5. OSHA is responsible for administering the requirements established under the Occupational Safety and Health Act (OSHA Act) (29 U.S.C. 651 *et seq.*), which was enacted in 1970. OSHA's authority to engage in the kinds of activities described below does not apply to those workplace safety and health conditions for which other Federal agencies exercise statutory authority to prescribe and enforce standards, rules or regulations.

Under the OSH Act, every employer has a general duty to furnish each employee with a place of employment that is free from recognized hazards that can cause death or serious physical harm and to comply with all OSHA standards, rules, and regulations.

OSHA standards contain requirements designed to protect employees against workplace hazards. In general, safety standards are intended to protect against traumatic injury, while health standards are designed to address potential overexposure to toxic substances and harmful physical agents, and protect against illnesses which do not manifest themselves for many years after initial exposure.

OSHA standards cover employee exposures from all radiation sources not regulated by NRC. Examples include x-ray equipment, accelerators, accelerator-produced materials, electron microscopes and betatrons, and naturally occurring radioactive materials such as radium.

It is estimated that the Act covers nearly 6 million workplaces employing more than 80 million workers. Federal OSHA covers approximately three-fifths, or four million, of these workplaces. States which operate OSHA-approved job safety and health programs, or "Plans," cover the remainder.

OSHA State Plan States are encouraged, but not required, to delineate their authority for occupational safety and health at NRC-licensed facilities in the same manner as Federal OSHA.

The OSHA areas of responsibility described in this memorandum are subject to all applicable requirements and authorities of the OSH Act. However, the industrial safety record at NRC-licensed nuclear power plants is such that OSHA inspections at these facilities are conducted normally as a result of accidents, fatalities, referrals, or worker complaints.

Interface Procedures

6. In recognition of the agencies' authorities and responsibilities enumerated above, the following procedures will be followed:

Although NRC does not conduct inspections of industrial safety, in the course of inspections of radiological and nuclear safety, NRC personnel may identify safety concerns within the area of OSHA responsibility or may receive complaints from an employee about OSHA-covered working conditions. In such instances, NRC will bring the matter to the attention of licensee management. NRC inspectors are not to perform the role of OSHA inspectors; however, they are to elevate OSHA safety issues to the attention of NRC Regional management when appropriate. If significant safety concerns are identified or if the licensee demonstrates a pattern of unresponsiveness to identified concerns, the NRC Regional Office will inform the appropriate OSHA Regional Office. In the case of complaints, NRC will withhold, from the licensee, the identity of the employee. In addition, when known to NRC, NRC will encourage licensees to report to OSHA accidents resulting in a fatality or multiple hospitalizations.

When such instances occur within OSHA State Plan States' jurisdiction, the OSHA Regional Office will refer the matter to the State for appropriate action.

7. OSHA Regional Offices will inform the appropriate NRC Regional Office of matters which are in the purview of NRC, when these come to their attention during Federal or State safety and health inspections or through complaints. The following are examples of matters that would be reported to the NRC:

a. Lax security control or work practices that would affect nuclear or radiological health and safety.

b. Improper posting of radiation areas.

c. Licensee employee allegations of NRC license or regulation violations.

8. The NRC and OSHA need not normally conduct joint inspections at NRC-licensed facilities. However, under certain conditions, such as investigations or inspections following accidents or resulting from reported activities as discussed in items 6 and 7 above, it may be mutually agreed on a case-by-case basis that joint investigations are in the public interest.

9. The chemical processing of nuclear materials at some NRC-licensed fuel and materials facilities presents chemical and nuclear operational safety hazards which can best be evaluated by joint NRC–OSHA team assessments. Each agency will make its best efforts to support such assessments at about 20 facilities once every five years. Of these facilities, about one-third are in the OSHA Plan States. OSHA will also assist in promoting such participation by State personnel in OSHA Plan States.

10. Based upon reports of injury or complaints at nuclear power plant sites, OSHA will provide NRC with information on those sites where increased management attention to worker safety is needed. The NRC will bring such information indicating significant breakdown in worker safety to the attention of licensee management and monitor corrective actions. This will not interfere with OSHA authority and responsibility to investigate industrial accidents and worker complaints.

11. Power reactor sites are inspected by NRC Region-based and Resident Inspectors. Personnel from NRC Regional Offices routinely conduct inspections at most fuel and materials licensed facilities. In order to enhance the ability of NRC personnel to identify safety matters under OSHA purview during nuclear and radiological safety inspections, OSHA will provide NRC Regional personnel with basic chemical and industrial safety training and indoctrination in OSHA safety standards, consistent with ongoing OSHA training programs. To enhance the ability of OSHA and State Plan personnel to effectively participate in the Operational Safety Team Assessments, NRC will provide training in basic radiation safety requirements, consistent with ongoing NRC training programs. Details of such training will be as mutually agreed by the NRC Technical Training Center and the OSHA National Training Institute.

12. Resolution of policy issues concerning agency jurisdiction and operational relations will be coordinated by the NRC Deputy Executive Director for Operations, and by the OSHA Director of Policy. Appropriate Headquarters points of contact will be established.

13. Resolution of issues concerning inspection and enforcement activities involving both NRC and OSHA jurisdiction at NRC-licensed facilities will be handled between NRC's Office of Enforcement and OSHA's Directorate of Compliance Programs. Each NRC and OSHA Regional Office will designate points of contact for carrying out interface activities.

For the Nuclear Regulatory Commission.
Victor Stello, Jr.,
Executive Director for Operations.

October 21, 1988.

For the Occupational Safety and Health Administration.
John A. Pendergrass,
Assistant Secretary.

[FR Doc. 88-25065 Filed 10-28-88; 8:45 am]
BILLING CODE 7590-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 88-92]

NASA Advisory Council; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council (NAC), Informal Executive Subcommittee.

DATE AND TIME: November 18, 1988, 9 a.m. to 5 p.m.

ADDRESS: National Aeronautics and Space Administration, Room 7002, Federal Office Building 6, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Nathaniel B. Cohen, Code ADI-1, National Aeronautics and Space Administration, Washington, DC 20546, 202/453-8766.

SUPPLEMENTARY INFORMATION: The NAC Informal Executive Subcommittee was established under the NAC to assist the Chair in planning the activities, establishing meeting agendas, and otherwise guiding the activities of the Council. The Council is chaired by Dr. John L. McLucas, and includes eight other members, seven of whom chair standing committees of the Council.

The meeting will be closed to the public. The sole agenda item will be planning for the coming year of the activities of the Council, the committees, and their task forces, with emphasis throughout on prospective future membership of each of these groups and their interactions with NASA and outside parties. Throughout the sessions, the qualifications of these individuals will be candidly discussed and appraised with respect to the tasks to be accomplished. Because the meeting will be concerned throughout with matters listed in 5 U.S.C. 552b(c)(6), it has been determined that this meeting should be closed to the public. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the participants.

TYPE OF MEETING: Closed.

October 25, 1988.

Philip D. Waller,
Director, General Management Division.

[FR Doc. 88-25044 Filed 10-28-88; 8:45 am]
BILLING CODE 7510-01-M

NATIONAL SCIENCE FOUNDATION

National Science Board; Nominations for Membership November 1, 1988

The National Science Board (NSB) is the policymaking body of the National Science Foundation (NSF). The Board consists of 24 members appointed by the President, with the advice and consent of the Senate, for six-year terms, in addition to the NSF Director *Ex officio*, as follows:

Terms Expire May 10, 1990

Dr. Perry L. Adkisson, Chancellor, The Texas A&M University System, System Administration Building, Executive Offices, Room 219, College Station, Texas.

Dr. Annelise G. Anderson, Senior Research Fellow, The Hoover Institution, Room 301-M, Stanford University, Stanford, California.

Dr. Craig C. Black, Director, Los Angeles County Museum of Natural History, 900 exposition Boulevard, Los Angeles, California.

Dr. Rita R. Colwell, Director, Maryland Biotechnology Institute and Professor of Microbiology, Microbiology Building, University of Maryland, College Park, Maryland.

Dr. Thomas B. Day (Vice Chairman), President, San Diego State University, 5300 Campanile Drive, San Diego, California.

Dr. James J. Duderstadt, President, The University of Michigan, 2074 Fleming Administration Building, Ann Arbor, Michigan.

Dr. K. June Lindstedt-Siva, Manager, Environmental Sciences, Atlanuc Richfield Company, 515 South Flower Street, Los Angeles, California.

Dr. Kenneth L. Nordtvedt, Jr., Professor of Physics, Department of Physics, Montana State University, Bozeman, Montana.

Terms Expire May 10, 1992

Dr. Frederick P. Brooks, Jr., Kenan Professor of Computer Science, Department of Computer Science, University of North Carolina, Chapel Hill, North Carolina.

Dr. F. Albert Cotton, W.T. Doherty-Welch Foundation Distinguished Professor of Chemistry and Director, Laboratory for Molecular Structure and Bonding, Texas A&M University, College Station, Texas.

Dr. Mary L. Good (Chairman), Senior Vice President, Technology, Allied-Signal, Inc., P.O. Box 1021R, Morristown, New Jersey.

Dr. John C. Hancock, 4550 Warwick Boulevard, Suite 901, Kansas City, Missouri.

Dr. James B. Holderman, President, University of South Carolina, Columbia, South Carolina.

Dr. James L. Powell, President, Reed College, 3203 Southeast Woodstock Boulevard, Portland, Oregon.

Dr. Frank H. T. Rhodes, President, Cornell University, 300 Day Hall, Ithaca, New York.

Dr. Howard A. Schneiderman, Senior Vice President, Research and Development and Chief Scientist, Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri.

Terms Expire May 10, 1994

Dr. Warren J. Baker, President, California Polytechnic State University, San Luis Obispo, California.

Dr. Arden L. Bement, Jr., Vice President, Technical Resources, TRW, Inc., 1900 Richmond Road, Cleveland, Ohio.[1]

Dr. D. Allan Bromley, Director, Wright Nuclear Structure Laboratory, P.O. Box 6666, 272 Whitney Avenue, Yale University, New Haven, Connecticut.

Dr. Daniel C. Drucker, Graduate Research Professor, Department of Aerospace Engineering, Mechanics and Engineering Science, University of Florida, 231 Aerospace Building, Gainesville, Florida.

Dr. Charles L. Hosler, Senior Vice President for Research and Dean of Graduate School, 114 Kern Building, The Pennsylvania State University, University Park, Pennsylvania.

Dr. Miguel Rios, Jr., President, ORION International Technology, 300 San Mateo, N.E., Suite #200, Albuquerque, New Mexico.[1]

Dr. Roland W. Schmitt, President, Rensselaer Polytechnic Institute, Pittsburgh Building, Troy, New York.

(One Vacancy)

Member Ex Officio

Mr. Erich Bloch (Chairman, NSB Executive Committee), Director, National Science Foundation, Washington, DC.

Section 4(c) of the National Science Foundation Act of 1950 as amended.

[1] NSB Nominee.

For the website, December 17, 1998

The views expressed in this document do not necessarily represent the views of the U.S. Nuclear Regulatory Commission (NRC). The information in this document represents NRC staff-developed draft language for possible inclusion in a package to be provided for Commission approval for publication as a proposed rule. In accordance with Commission direction, NRC staff is providing this information at this time for preliminary public comment and discussion. The public will have an opportunity also for formal comment once the Commission approves a rule for publication as a proposed rule.

Contents:

1. Release notes

A. We have attempted to provide annotations [in redlined-brackets] that identify parallels to the SECY 98-185 version of the rule or call attention to certain clarifying information or other changes. These annotations will be put on the website but removed in the proposed rule package language. (Appropriate parts of this information would reappear in the rule package's statement of considerations.) The following redrafts are revisions-in-total of sections §70.60 and §70.62 of the SECY 98-185 version of the rule. The SECY 98-185 version of the rule may be viewed or downloaded from this page by clicking on the highlighted link or by setting your browser to
http://techconf.llnl.gov/cgi-bin/library?source=*&library=dom_lic_lib&file=042-0035.wp
and clicking on either the WordPerfect (wp) or html version of 042-0002.

B. The purpose of the following redrafts of §70.60, §70.62, and related definitions was to clarify the apparent confusion regarding the rule being "consequence-driven" as opposed to "risk-informed." This confusion was a major topic of discussion at the December 3-4, 1998, public meeting on the draft rule. Another purpose was to clarify the responsibilities under NRC's 1988 memorandum of understanding (MOU) with the Occupational Safety and Health Administration (OSHA) [see note D, below], and to incorporate, in part, the comments provided by the Nuclear Energy Institute (NEI), in a letter dated November 4, 1998, on NRC regulation of chemical hazards. To accomplish these purposes, we combined the consequence and likelihood sections, to reflect risk, and separated the performance requirements from the descriptive requirements for integrated safety analyses (ISAs) and safety programs.

C. The fact that a topic does not appear in the following draft rule language does not indicate that the topic will not be reinserted into the draft language that the staff will submit for Commission approval for publication as a proposed rule. For example, in the draft rule language below, the annotation after section §70.62(c)(5) mentions that the staff is currently evaluating the appropriate contents and location for the requirements for preliminary integrated safety analysis. Thus, preliminary integrated safety analysis language was not included in this

web posting even though it was in the parallel section in SECY 98-185. However, language regarding this subject will be included in the draft rule language. As another example, the draft rule below (see 70.60(b)(5) and (c)(4)) does not reference the quantitative Emergency Response Planning Guidelines (ERPG) and Acute Exposure Guideline Limits (AEGL) chemical consequence standards, but adopts equivalent, qualitative language. We are still considering the merits of this approach.

D. As mentioned above, we believe the redrafts of these two rule sections provide clearer treatment of the 1988 NRC-OSHA MOU on responsibilities for hazards at NRC licensed facilities. Specifically, item (c) of the NRC-OSHA MOU states that NRC has the general purview for regulating "plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers." As an example, NRC's regulatory purview would include the impacts of chemical system failures or fires that cause failure of a nuclear safety system, and NRC's purview would include impacts of plant conditions on the ability of operators to perform an activity (administrative control) that is relied on for nuclear safety. The draft rule addresses these responsibilities in two ways/cases, the performance requirements (70.60) and the ISA requirements (70.62(c)(1)(iii)). Language very similar to item (c) of the NRC-OSHA MOU now appears in the ISA requirements in §70.62(c)(1)(iii). Also, through §70.60, if the failure of a "non-nuclear" system could disable a nuclear system and cause an unacceptable risk [such as the frequency of a worker dose exceeding 25 rem being greater than "unlikely"-- per 70.60(c)(1)]; then 70.60(d) would require that the non-nuclear system be designated as an "item relied on for safety" and controlled by the safety program (viz., it would be under NRC's regulatory purview). In addition, 70.60(b) and (c) specify risk-based standards for "hazardous chemicals produced from licensed material," such as HF gas accidentally released from a reaction of UF_6 with water. Sections 70.62(c)(1)(i) and (ii) also contain statements that correspond to MOU items (a) and (b). Inclusion of this language assures that each MOU item for which NRC has general regulatory purview will be explicitly addressed by licensees in the ISA.

E. We have added two paragraphs, §70.62(c)(2) and §70.62(c)(3), that deal with integrated safety analysis (ISA) team qualifications and ISA revalidation, respectively. These sections are very similar to requirements of the OSHA process safety management rule (specifically, 29 CFR 1910.119(e)(4) and (e)(6)). We believe that inclusion of these sections may be appropriate, not only for consistency with OSHA, but also in consideration of the further development of requirements on the submittal and contents of the ISA summary, what is "on the docket" and/or "in the license," and the process (e.g., NRC pre-approval or not) for making changes to the plant and items relied on for safety. Revalidating the ISA will also permit an opportunity for consideration and incorporation of recent industry and facility accidents into the ISA, and possibly an opportunity to incorporate different experiences (e.g., if staff changed) into the updated ISA.

2. Clarifying modifications to 70.60

70.60 Performance Requirements for Certain Licensees Authorized to Possess Special Nuclear Material in Quantities Sufficient to Form a Critical Mass.

(a) Each applicant or licensee required to establish and maintain a safety program pursuant to §70.62 of this part shall demonstrate, in the integrated safety analysis, compliance with the

performance requirements in paragraphs (b) and (c) of this section. [annotation: most requirements of previous 70.60(a) and 70.60(d), dealing with the safety program and ISA contents have been moved into 70.62 (below) for clarity]

(b) The risk of each credible high-consequence event must be limited, unless the event is highly unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or (except for nuclear criticality) its consequence. Application of further controls is not required for those high-consequence events demonstrated to be highly unlikely. High-consequence events are those internally or externally initiated events that result in:

(1) a nuclear criticality;
(2) an acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;
(3) an acute dose outside the controlled site boundary of 0.25 Sv (25 rem) or greater total effective dose equivalent;
(4) an intake outside the controlled site boundary of 30 mg or greater of uranium in soluble form; or
(5) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could endanger the life of a worker, or (ii) outside the controlled site boundary, could lead to irreversible or other serious, long-lasting health effects. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the application information submitted pursuant to Section §70.65 of this Part.

[annotation: The ERPG and AEGL would be identified as acceptable standards in the SRP. Items (b)(5) and (c)(4) cover, for example, "HF;" and rely on a new §70.4 definition, *hazardous chemicals produced from licensed material*]

[annotation: "acute" is defined in section 70.4 (see below)]

(c) The risk of each credible intermediate-consequence event must be limited, unless the event is unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of further controls is not required for those intermediate-consequence events demonstrated to be unlikely. Intermediate-consequence events are those internally or externally initiated events, that are not high-consequence events, that result in:

(1) an acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;
(2) an acute dose outside the controlled site boundary of 0.05 Sv (5 rem) or greater total effective dose equivalent;
(3) a 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part 20; or
(4) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could lead to irreversible or other serious, long-lasting health effects to a worker, or (ii) outside the controlled site boundary, could cause mild transient health effects. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as

part of the application information submitted pursuant to Section §70.65 of this Part.

(d) Each engineered or administrative control necessary to comply with subsection (b) or (c) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to §70.62 of this part, shall ensure that each item relied on for safety will perform its intended function when needed and in the context of the performance requirements of this section.

3. Clarifying modifications to 70.62

70.62 Safety Program, Integrated Safety Analysis, and Filing of Integrated Safety Analysis Summary

(a) *safety program.* (1) Each licensee engaged in enriched uranium processing, uranium fuel fabrication, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, mixed-oxide fuel fabrication, scrap recovery, or any other activity that the Commission determines could significantly affect public health and safety, shall establish and maintain a safety program that ensures that actions taken will provide adequate protection from licensed materials, for worker and public health and safety and of the environment. The safety program may be graded such that management measures applied are commensurate with that item's reduction of the risk. Requirements for the safety program, including process safety information, integrated safety analysis, and management measures, are described in subsections (b) through (d) of this section.

[annotation: note "may be..." - grading of safety program is permitted but not required].

[annotation: by "management measures" we mean measures that assure that items used for safety will be available and perform their functions reliably when needed.]

(2) Each licensee shall establish records that demonstrate that the requirements of this section have been met. Each licensee shall maintain these records until license termination. [annotation: (a)(1) and (a)(2) parallels 70.60(a) and 70.60(d)(6), respectively, in SECY 98-185; note change to "license termination" instead of "lifetime of the plant"]

(3) If the decommissioning of a facility involves potentially hazardous activities such as chemical treatment of wastes, each licensee shall perform an ISA of the decommissioning process, demonstrate compliance with the performance requirements of section §70.60 of this part, and submit the results to NRC for approval before beginning such decommissioning activities. [annotation: parallels 70.62(b) in SECY 98-185]

(b) *process safety information.* Each licensee or applicant shall compile and maintain a set of process safety information to enable the performance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process. [annotation: parallels 70.60(d)(1) in SECY 98-185]

(c) *integrated safety analysis.* (1) Each licensee or applicant shall conduct an integrated safety analysis, that is of appropriate detail for the complexity of the process, that:

(i) identifies radiological hazards resulting from possessing or processing licensed material at its facility;

(ii) identifies chemical hazards of licensed material or hazardous chemicals produced from licensed material resulting from possessing or processing licensed material at its facility;

(iii) identifies facility hazards (e.g., chemical, fire, electrical and mechanical) which could affect the safety of licensed materials and thus present an increased radiological risk;
[annotation: (i)-(iii) modified slightly from draft rule to explicitly address OSHA MOU]

(iv) identifies and provides the basis for potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;

(v) identifies and provides the basis for the consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (b)(1)(iv) of this section; and

(vi) identifies and provides the basis for each item relied on for safety identified pursuant to section §70.60(d) of this Part, and the characteristics of its preventive, mitigative, or other safety function.

(2) *integrated safety analysis team qualifications.* [annotation: this paragraph added to match 29 CFR 1910.119(e)(4)] In order to assure the adequacy of the integrated safety analysis, the integrated safety analysis shall be performed by a team with expertise in engineering and process operations, and the team shall include at least one employee who has experience and knowledge specific to each process being evaluated, and employees who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. Also, one member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) *integrated safety analysis revalidation.* The integrated safety analysis shall be periodically revalidated by a team meeting the requirements of paragraph (c)(2) of this section, to ensure that the integrated safety analysis is consistent with the current facility. The minimum period for such revalidation shall be at each filing of an application for renewal of a license pursuant to section §70.33 of this part [annotation: this paragraph added to match 29 CFR 1910.119(e)(6). The wording permits a more frequent period between revalidations, e.g., every 5 years as specified in 29 CFR 1910.119(e)(6) for the process hazards analysis].

(4) *integrated safety analysis summary.* Each applicant or licensee shall submit an integrated safety analysis summary to NRC for approval, as appropriate: (i) in accordance with the requirements and schedule in paragraph (c)(5) of this section, if applicable; or (ii) as part of the license application contents, amendment application contents, or renewal

application contents identified in §§70.21, §70.22, §70.33, §70.34, and §70.65.
[annotation: this paragraph requires the submitted ISA-summary (which used to be called 'results of the ISA.' This paragraph (c)(4) parallels 70.62(a)(1)-(3) that were in SECY 98-185). The contents of applications section (70.65, under development) and the definitions (70.4) will identify the contents of the ISA summary and what is to be "in the license," "on the docket," etc. We plan to move the SECY 98-185 sentence "The process description in the integrated safety analysis summary must include information that demonstrates the licensee's compliance with the design requirements for criticality monitoring and alarms in §70.24." to §70.65 (contents of applications) since it addresses the contents of the ISA summary and license application. Note also that the correction of 'unacceptable vulnerabilities' identified by the ISA, that was in the parallel section of SECY 98-185, is now handled by 70.60(a)]

(5) *filing by existing licensees.* Individuals holding an NRC license on <the effective date of this rule> shall, with regard to existing licensed activities:

(i) within 6 months of <the effective date of this rule>, submit, for NRC approval, a compliance plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. Pending the correction of unacceptable vulnerabilities identified by the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(ii) within 4 years of <the effective date of this rule>, unless otherwise specified by the conditions of a license held on <the effective date of this rule>, complete an integrated safety analysis, correct all unacceptable vulnerabilities, and submit an integrated safety analysis summary in accordance with paragraph (c)(4) of this section or the approved compliance plan submitted under paragraph (c)(5)(i) of this section.

[annotation: (c)(4) and (5) parallel 70.62(a)(1)-(3) that were in SECY 98-185. We are currently reevaluating: (1) if preliminary ISA requirements should appear here (as they did in the SECY 98-185 version), or another section (e.g., §70.64); and (2) the nature and contents of the preliminary ISA requirements. After this reevaluation, we may reinsert language here that parallels the old 70.62(a)(3)]
[annotation: unacceptable vulnerabilities is defined in Section 70.4 (see below)]

(d) *management measures.* [annotation: except as noted, this section parallels 70.60(d)(3) in SECY 98-185] To ensure that each item relied on for safety will perform its intended function when needed, the integrated safety analysis shall be used by licensees to establish safety program management measures. The safety program management measures shall ensure that:

(1) Engineered controls that are identified as relied on for safety pursuant to section §70.60(d) of this part are designed, constructed, inspected, calibrated, tested, and maintained, as necessary, to ensure the ability to perform their intended functions when needed. Items subject to this requirement include but are not limited to: principal structures of the plant; passive barriers relied on for safety (e.g., piping, glove boxes, containers, tanks, columns, vessels); active systems, equipment, and components relied

on for safety; sampling and measurement systems used to convey information about the safety of plant operations; instrumentation and control systems used to monitor and control the behavior of systems relied on for safety; and utility service systems relied on for safety.

(2) Personnel are trained, tested, and retested, as necessary, to ensure that they understand, recognize the importance of, and are qualified to perform their duties that are identified as relied on for safety pursuant to section §70.60(d) of this part;

(3) Procedures that are identified as relied on for safety pursuant to section §70.60(d) of this part are developed, reviewed, approved, and distributed to ensure that personnel are able to perform the duties relied on for safety.

(4) Human-system interfaces are designed and implemented to ensure that personnel relied on for safety are able to perform their duties that are identified as relied on for safety pursuant to section §70.60(d) of this part;

(5) Configuration changes to site, structures, process, systems, equipment, components, computer programs, personnel, procedures, and documentation are managed so that such modifications are reviewed, documented, communicated, and implemented in a systematic, controlled manner.

(6) Quality assurance that is commensurate with the item's reduction of risk is applied to each item relied on for safety identified pursuant to section §70.60(d) of this part.

(7) Periodic audits and assessments of the safety program are performed to ensure that an adequate level of protection is maintained at the facility. [annotation: parallels 70.60(d)(4) in SECY 98-185]

(8) Abnormal events are investigated and corrective actions taken to minimize the recurrence of these events. [annotation: parallels 70.60(d)(5) in SECY 98-185]

4. Related Definitions from §70.4

Acute as used in section §70.60 of this part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less). [Annotation: slightly modified]

Acute exposure guideline levels (AEGL) [Annotation: this term is not used in the rule anymore]

Controlled site boundary means the physical barrier surrounding the facility that is used by the licensee to control access. It may or may not coincide with the property boundary.

Critical mass of SNM means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-

235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

Emergency response planning guidelines (ERPG) [Annotation: this term is not used in the rule anymore]

Hazardous chemicals [Annotation: this term is not used in the rule anymore]

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material. [Annotation: modified version of the NEI-proposed definition. The terms, process addition and process separation are used to indicate an intentional activity (as opposed to an accidental separation)]

Integrated safety analysis (ISA) means a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the site, structures, systems, equipment, components, and activities of personnel that are relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical.

Items relied on for safety means structures, systems, equipment, components, and activities of personnel that are relied on to prevent or to mitigate potential accidents at a facility.

Results of the ISA [Annotation: this term is not used anymore - it was replaced by integrated safety analysis summary].

Integrated safety analysis summary means the portion of the license application, license amendment application, or license renewal application that has the purpose of informing the Commission of the nature of the facility, the plans for its use, and the evaluations that have been performed to evaluate if the facility has been constructed and will be operated in accordance with NRC requirements and will provide adequate protection from licensed materials, for worker and public health and safety and of the environment. [Annotation: new definition].

Unacceptable vulnerabilities mean deficiencies in the items relied on for safety or the measures used to assure their availability and reliability of such items when needed, that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.60(b) or (c). [annotation: this term is now only used in one place - §70.62(c)(5) dealing with filing of the ISA summary by existing licensees].

Worker means an individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation (i.e., an individual who is subject to an occupational dose as in 20 CFR 20.1003).

once the Commission approves a rule for publication as a proposed rule.) Since September 1998, we have held two public meetings and have established a World Wide Web site (http://techconf.llnl.gov/cgi-bin/messages?dom_lic) that contains discussion threads and a library of documents related to this rulemaking. As a result of discussions at those meetings and written comments received, two sections of the rule text were developed (Enclosure 2). These two sections are intended to implement the NRC areas of responsibility and be consistent with the respective statutory authorities of NRC, EPA, and OSHA. Accordingly, we would greatly appreciate your views on these two sections.

To facilitate submission of a proposed rule package to the Commission in May 1999, we would like to resolve in January any major issues with the draft rule language itself, particularly for the attached two rule sections. Again, your views on the attached draft rule text would be appreciated. It would be desirable if your views could be provided by January 29, 1999. Should you like to arrange a meeting or have any questions, please contact Mr. Theodore Sherr on (301) 415-7218 or Mr. Andrew Persinko on (301) 415-6522.

Sincerely,

(Original signed by)

Carl. J. Paperiello, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. NRC-OSHA Memorandum of Understanding
2. Draft changes to 10 CFR §§70.60 and §70.62

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