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

June 25, 2003

MEMORANDUM TO: Special Projects
and Inspection Branch Staff
Fuel Manufacturing Section Staff
Region II Fuel Facilities Branch Staff

FROM: Kathy Halvey Gibson, Acting Chief
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

SUBJECT: INFORMATION TO CLARIFY THE APPLICATION OF 10 CFR PART 70 FOR REGULATION OF HAZARDOUS CHEMICALS AT NRC-LICENSED FUEL CYCLE FACILITIES

The purpose of this memorandum is to provide staff with information to clarify the application of 10 CFR Part 70 for regulation of hazardous chemicals at NRC-licensed fuel cycle facilities.

Two attachments are provided for your use. The first attachment is a March 10, 2003, memorandum from Robert C. Pierson, Director, Division of Fuel Cycle Safety and Safeguards, NMSS, through Martin J. Virgilio, Director, NMSS, to Carl J. Paperiello, Deputy Executive Director for Materials, Research and State Programs, titled "Regulatory Authority over Chemical Hazards at Fuel Cycle Facilities." The second attachment is an excerpt from the July 30, 1999, Federal Register Notice for the proposed Part 70 that explains implementation of Part 70.61 Performance requirements. The discussion in the third column of page 41341 explains in detail the responsibilities of NRC and the Occupational Safety and Health Act for the regulation of chemical hazards at nuclear facilities.

If you have any questions concerning this memorandum, please contact me at (301) 415-6850 or Don Stout at (301) 415-5269.

Attachments: 1. Regulatory Authority Over Chemical Hazards at
Fuel Cycle Facilities
2. Excerpt from Federal Register Notice July 30, 1999

cc: Martin J. Virgilio, NMSS
Robert C. Pierson, FCSS
Eric J. Leeds, FCSS
Susan Frant, FCSS
Robert L. O'Connell, IMNS
Douglas M. Collins, RGN II

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March 10, 2003

MEMORANDUM TO: Carl J. Paperiello, Deputy Executive Director
Materials, Research
and State Programs

THRU: Martin J. Virgilio, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Robert C. Pierson, Director /RA/
Division of Fuel Cycle Safety
and Safeguards

SUBJECT: REGULATORY AUTHORITY OVER CHEMICAL HAZARDS AT FUEL CYCLE FACILITIES

PURPOSE:

The purpose of this memorandum is to reiterate the Nuclear Regulatory Commission's (NRC's) role concerning safety regulation of hazardous chemicals at NRC-licensed fuel cycle facilities. After the events of September 11, 2001, NRC initiated actions at licensed fuel cycle facilities that may be causing a perception that NRC is changing its regulatory position regarding safety regulation of hazardous chemicals. This memorandum is to reaffirm the staff's application of 10 CFR Part 70 for regulation of hazardous chemicals at NRC-licensed fuel cycle facilities.

BACKGROUND:

During the 1980s, the Environmental Protection Agency (EPA) and OSHA developed programs to control chemical and other non-radiological hazards. In February 1992, OSHA issued requirements, in 29 CFR Part 1910.119, "Process Safety Management (PSM) of Highly Hazardous Chemicals." In June 1996, because of the *"Clean Air Act Amendments of 1990," Section 112(r)*, EPA promulgated Title 40 CFR Part 68, which details the "Risk Management Plan" (RMP) program for hazardous chemicals. These regulations apply to any plant or facility in the United States, including NRC-licensed fuel cycle facilities, that have hazardous chemical inventories that exceed the listed threshold quantities and concentration thresholds for chemicals listed by each agency. Presently, two low-enriched fuel fabrication facilities are required to follow EPA's-RMP and OSHA's-PSM because they store in excess of 10,000 pounds of anhydrous ammonia.

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Attachment 1

DISCUSSION:

Since October 2000, NRC has used 10 CFR Part 70, Subpart H, for evaluating and regulating risks associated with chemical accidents and their impact on licensed material. NRC regulation for chemical safety, as provided in 10 CFR 70.62(c), focuses on the following items: (1) radiological hazards related to the processing of licensed material; (2) chemical hazards of licensed material and hazardous chemicals produced from licensed material; and (3) facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk.

The phrase "hazardous chemicals produced from licensed material" used in 10 CFR Part 70, Subpart H, is defined at 10 CFR 70.4 as:

> Substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and 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, which is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to the process addition to licensed material or after the process separation from licensed material. (emphasis added)

To provide information on which chemicals NRC does regulate according to Subpart H, the following examples are provided. Item (1) above covers radiological aspects and is generally understood. An example corresponding to Item (2) above would be uranium hexafluoride which reacts with moisture in the air to produce uranyl fluoride and hydrofluoric acid. Another example of Item (2) would be the release of nitric acid that would result during a dissolution operation where an excess amount of nitric acid is added to uranium oxide. An example of Item (3) above would be a spill of aqueous ammonia due to overfilling of a mixing vessel containing both liquid ammonia and uranyl fluoride which would increase radiological risk. In the consequence analyses that licensees perform as part of their Integrated Safety Analyses, potential accident sequences involving chemicals listed above in Items (1) through (3) will need to be evaluated. NRC staff will review the accident sequences and consequences included in the licensees' safety analyses to verify that hazardous chemical consequences produced from licensed material meet regulatory requirements and that facility hazards that could affect licensed material and increase radiological risk have been addressed.

Examples of chemicals that NRC would not provide safety regulation for are, chlorine that is used for disinfecting cooling or drinking water, or anhydrous ammonia that is used to provide a source of hydrogen via thermal/catalytic cracking, unless within the scope of Item (1), (2), or (3), above. In such cases, these chemicals are regulated by OSHA and EPA. For chemicals that are not covered by PSM or RMP regulations, OSHA and EPA rely on the General Duty Clause.

The operating environment for every industry using hazardous materials changed after the events of September 11, 2001. To provide assurance that NRC licensees are implementing appropriate protective measures to address the current threat environment, NRC has issued Interim Compensatory Measure orders to high-enriched fuel cycle facilities, uranium enrichment

facilities, a uranium conversion fuel cycle facility, and low-enriched fuel cycle facilities. These orders were based, in part, on the potential threat NRC regulated chemicals present to licensed material and activities subject to NRC regulation and are consistent with the Part 70 regulatory approach discussed above.

CONCLUSION:

NRC has maintained its responsibility for the safety and security of licensed material and plant conditions that could affect licensed material and increase radiological risk. NRC has not changed its safety regulation of hazardous chemicals at licensed fuel cycle facilities as a result of the orders issued in the wake of terrorist acts committed on September 11, 2001.

separate building or outdoor area," the DP will continue to be the vehicle for regulatory approval of the licensee's practices for protection of health and safety during decommissioning. The ISA should provide valuable information with respect to developing the DP and the use of the ISA in this manner is encouraged.

Section 70.61 Performance Requirements

In the past, the regulation of licensees authorized to possess SNM, under 10 CFR Parts 20 and 70, has concentrated on radiation protection for persons involved in nuclear activities conducted under normal operations. The proposed amendments to Part 70 would explicitly address potential exposures to workers or members of the public and environmental releases as a result of accidents. Part 20 continues to be NRC's standard for protection of workers and public from radiation during normal operations, anticipated upsets (e.g., minor process upsets that are likely to occur one or more times during the life of the facility), and accidents. Although it is the Commission's intent that the regulations in Part 20 also be observed to the extent practicable during an emergency, it is not the Commission's intent that the Part 20 requirements apply as the design standard for all possible accidents at the facility, irrespective of the likelihood of those accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the Part 70 changes seek to assure adequate protection of workers, members of the public, and the environment by limiting the risk (combined likelihood and consequence) of such accidents.

There are three risk-informed performance requirements for the rule, each of which is set out in 10 CFR 70.61: (1) Section 70.61(b) states that high-consequence events must meet a likelihood standard of highly unlikely; (2) section 70.61(c) requires that intermediate-consequence events must meet a likelihood standard of unlikely; and (3) section 70.61(d) requires that risk of nuclear criticality be limited by assuring that all processes must remain subcritical under any normal or credible abnormal conditions. The term "performance requirements" thus considers together consequences and likelihood. For regulatory purposes, each performance requirement is considered an equivalent level of risk. For example, the acceptable likelihood of intermediate-consequence events is allowed to be greater than the acceptable likelihood for high-consequence events.

A risk-informed approach must consider not only the consequences of potential accidents, but also their likelihood of occurrence. As mentioned above, the performance requirements rely on the terms "unlikely" and "highly unlikely" to focus on the risk of accidents. However, the Commission has decided not to include quantitative definitions "unlikely" and "highly unlikely" in the proposed rule, because a single definition for each term, that would apply to all the facilities regulated by Part 70, may not be appropriate. Depending on the type of facility and its complexity, the number of potential accidents and their consequences could differ markedly. Therefore, to ensure that the overall facility risk from accidents is acceptable for different types of facilities, the rule requires applicants to develop, for NRC approval (see § 70.65), the meaning of "unlikely" and "highly unlikely" specific to their processes and facility. To accommodate this development, the Commission believes that the SRP is the appropriate document to include guidelines for licensees to use. A draft "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" has been developed. The draft SRP provides one acceptable approach for the meaning of "unlikely" and "highly unlikely" that can be applied to existing fuel cycle facilities.

The general approach for complying with the performance requirements is that, at the time of licensing, each hazard (e.g., fire, chemical, electrical, industrial) that can potentially affect radiological safety is identified and evaluated, in an ISA, by the licensee. The impact of accidents, both internal and external, associated with these hazards is compared with the three performance requirements. Any (and all) structures, systems, components, or human actions, for which credit is taken in the ISA for mitigating (reducing the consequence of) or preventing (reducing the likelihood of) the accident such that all three performance requirements are satisfied, must be identified as an "item relied on for safety." "Items relied on for safety" is a term that is defined in 10 CFR 70.4, and in this approach, the applicant has a great deal of flexibility in selecting and identifying the actual "items." For example, they can be defined at the systems-level, component-level, or sub-component-level. "Management measures" [see discussion in 10 CFR 70.62(d)] are applied to each item in a graded fashion to ensure that it will perform its safety function when needed. The combination of the set of "items relied on for safety" and the "management measures" applied to each item will determine the extent of the licensee's programmatic and design requirements, consistent with the facility risk, and will ensure that at any given time, the facility risk is maintained safe and protected from accidents (viz., satisfies the performance requirements).

The proposed performance requirements also address certain chemical hazards that result from the processing of licensed nuclear material. The question of the extent of NRC's authority to regulate chemical hazards at its fuel cycle facilities was raised after an accident in 1986 at a Part 40 licensed facility, in which a cylinder of uranium hexafluoride ruptured and resulted in a worker fatality. The cause of the worker's death was the inhalation of hydrogen fluoride gas, which was produced from the chemical reaction of uranium hexafluoride and water (humidity in air). Partly as a result of the coordinated Federal response and resulting Congressional investigation into that accident, NRC and the OSHA entered into an MOU, in 1988, that clarified the agencies' interpretations of their respective responsibilities for the regulation of chemical hazards at nuclear facilities. The MOU identified the following four areas of responsibility. Generally, NRC covers the first three areas, whereas OSHA covers the fourth area:

(1) Radiation risk produced by radioactive materials;

(2) Chemical risk produced by radioactive materials;

(3) Plant conditions that affect the safety of radioactive materials; and

(4) Plant conditions that result in an occupational risk, but do not affect the safety of licensed radioactive materials.

One goal of the performance requirements in § 70.61 is to be consistent with the NRC–OSHA MOU. Therefore, the performance requirements in § 70.61 include explicit standards for the MOU's first two areas of responsibility. In addition, the third MOU area of responsibility is specifically evaluated by licensees under the ISA requirements of § 70.62(c)(1)(iii). As an example of the third MOU area, if the failure of a chemical system adjacent to a nuclear system could affect the safety of the nuclear system such that the radiation dose (and associated likelihood of that accident) exceeded a performance requirement, the chemical system failure would be within the scope of the ISA and the means to prevent the chemical system failure from impacting

Attachment 2

the nuclear system would be within NRC's regulatory purview.

OSHA provided comments, by a letter dated February 1, 1999, on a draft of the rule that had been revised to be consistent with the MOU. In that letter, OSHA expressed concerns that the rule language would preempt OSHA from enforcing any of its standards, rules or other requirements with respect to chemical hazards at the facilities covered by the NRC draft rule. This concern is based on case law under the OSH Act. The pertinent provision in the OSH Act states:

"(b)(1) Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 2021 of title 42, exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." [29 U.S.C. 653(b)(1)]

NRC staff subsequently met with OSHA officials on February 25, 1999, and some clarifications and further information were provided at that meeting. As a result of the meeting discussions, some changes were made to the rule language to more clearly specify the scope of NRC involvement. However, these changes do not fully resolve the basic preemption issue. The problems identified with the rule are not unique, i.e., the preemption issue is generic and may already exist for any NRC-licensed facilities where there are requirements to analyze hazards. At the February 25 meeting, OSHA confirmed that the rule language is consistent with the October 21, 1988 MOU; indicated that they have no suggested changes to the MOU; and indicated that they are not opposed to the proposed rule. The Commission's view is that the proposed rule is consistent with NRC responsibilities and authority under the Atomic Energy Act, and consistent with the OSHA MOU. The only resolution of the preemption issue appears to be a legislative modification of the OSH Act. Public comments would be appreciated on any options that may have been overlooked.

Within each performance requirement, NRC recognizes that the proposed radiological standards are more restrictive, in terms of acute health effects to workers or the public, than the chemical standards for a given consequence (high or intermediate) and that this is consistent with current regulatory practice. The choice of each criterion is discussed below in a paragraph-by-paragraph discussion of § 70.61.

The use of any of the performance requirements is not intended to imply that the specified worker or public radiation dose or chemical exposure constitutes an acceptable criterion for an emergency dose to a worker or the public. Rather, these values have been proposed in this section as a reference value, to be used by licensees in the ISA (a forward-looking analysis) to establish controls (i.e., items relied on for safety and associated management measures) necessary to protect workers from potential accidents with low or exceedingly low probabilities of occurrence that are not expected to occur during the operating life of the facility.

Section 70.61(b). This section addresses performance requirements for high-consequence events.

The consequences identified in § 70.61(b) of the proposed rule are referred to as "high-consequence events" and include accidental exposure of a worker or an individual located outside of the controlled area to high levels of radiation or hazardous chemicals. These accidents, if they occurred, would represent radiation doses to a worker or an individual located outside of the controlled area at levels with clinically observable biological damage or concentrations of hazardous chemicals produced from licensed material at which death or life-threatening injury could occur. The goal is to ensure an acceptable level of risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, high-consequence events must be sufficiently mitigated to a lower consequence or prevented such that the event is highly unlikely (or lower). The application of "items relied on for safety" provides this prevention or mitigation function.

Section 70.61(b)(1). An acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE) is considered to be a high-consequence event. According to the National Council on Radiation Protection and Measurements (NCRP, 1971), life-saving actions—including the "* * * search for and removal of injured persons, or entry to prevent conditions that would probably injure numbers of people"—should be undertaken only when the "* * * planned dose to the whole body shall not exceed 100 rems." This is consistent with a later NCRP position (NCRP, 1987) on emergency occupational exposures, that states "* * * when the exposure may approach or exceed 1 Gy (100 rad) of low-LET [linear energy transfer] radiation (or an equivalent high-LET exposure) to a large portion of the body, in a short time, the worker needs to understand not only the potential for acute effects but he or she should also have an appreciation of the substantial increase in his or her lifetime risk of cancer."

Section 70.61(b)(2). The exposure of an individual located outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE is considered a high-consequence event. This is generally consistent with the criterion established in 10 CFR 100.11, "Determination of exclusion area, low population zone, and population center distance," and 10 CFR 50.34, "Contents of applications; technical information," where a whole-body dose of 0.25 Sv (25 rem) is used to determine the dimensions of the exclusion area and low-population zone required for siting nuclear power reactors.

Section 70.61(b)(3). The intake of 30 mg of soluble uranium by an individual located outside of the controlled area is considered a high-consequence event. This choice, which is based on a review of the available literature [Pacific Northwest Laboratories (PNL), 1994], is consistent with the selection of 30 mg of uranium as a criterion that was discussed during the Part 76 rulemaking, "Certification of Gaseous Diffusion Plants." In particular, the final rule that established Part 76 (59 FR 48944; September 23, 1994) stated that "The NRC will consider whether the potential consequences of a reasonable spectrum of postulated accident scenarios exceed * * * uranium intakes of 30 milligrams. * * *" The final rule also stated that "The Commission's intended use of chemical toxicity considerations in Part 76 is consistent with its practice elsewhere [e.g., 10 CFR 20.1201(e)], and prevents any potential regulatory gap in public protection against toxic effects of soluble uranium."

Section 70.61(b)(4). An acute chemical exposure to hazardous chemicals produced from licensed material at concentrations that either (1) could cause death or life-threatening injuries to a worker; or (2) could cause irreversible health effects to an individual located outside of the controlled area, is considered a high-consequence event. Chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures (i.e., a single exposure or multiple exposures occurring within a short time—24 hours or less) have been developed, or are under development, by a number of organizations. Of particular interest, the National Advisory Committee for Acute Guideline Levels for Hazardous Substances is developing Acute Exposure Guideline Limits (AEGLs) that