6. CHEMICAL PROCESS SAFETY

6.1 Purpose of Review

The primary purpose of the review is to determine with reasonable assurance that the applicant has designed a facility that will provide adequate protection against chemical hazards related to the storage, handling, and processing of licensed materials as required by Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," of the *Code of Federal Regulations* (10 CFR Part 70). The facility design must adequately protect the health and safety of workers and the public during normal operations and credible accident conditions from the chemical risks in the facility. It must also protect against facility conditions that could affect the safety of licensed materials and thus present an increased chemical or radiation risk (e.g., a chemical that incapacitates operators and precludes their entry to an area of the facility where licensed materials are handled).

Chemical safety issues are initially evaluated as part of the applicant's integrated safety analysis (ISA) summary. The ISA summary must evaluate credible accident sequences at the facility, identify items relied on for safety (IROFS) to prevent the occurrence or to mitigate the consequences of accidents, and include the management measures that provide reasonable assurance of the availability and reliability of IROFS when needed. To begin the chemical safety review, the reviewer should review (1) the license application, (2) the facility and process description in Standard Review Plan (SRP) Section 1), and (3) the ISA summary (SRP Chapter 3), to gain familiarity with the following:

- process information and accident sequences leading to conditions that could pose chemical hazards
- IROFS and sole IROFS used to prevent or mitigate such chemical hazards
- proposed procedures to protect public health and safety and the environment (e.g., high-level programmatic description of how the licensee or applicant proposes to operate, maintain, or manage the facility)
- definition of "unlikely," "highly unlikely," and "credible" as used in the ISA evaluations
- quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or a chemical produced from licensed materials that are on site or expected to be on site
- recommended management measures for ensuring that the IROFS will be available and reliable when required

6.2 Responsibility for Review

Primary: Chemical Process Safety Reviewer (all sections of this chapter)

Supporting: Licensing Project Manager
Fuel Cycle Facility Inspection Staff (as needed)
Health Physicist (for uranium and transuranic toxicity issues)
Primary Reviewers of Chapters 1, 3, 8, 9, and 11 of this SRP

6.3 Areas of Review

An applicant is required by 10 CFR 70.62(a) to establish and maintain a safety program that will adequately protect worker and public health and safety and the environment from the chemical hazards from licensed material. The applicant is not necessarily required to establish a separate chemical process safety program, but the applicant must demonstrate that it has considered chemical hazards and accident sequences that affect licensed material. Hazards and accident sequences must be adequately prevented or mitigated in accordance with 10 CFR 70.61, "Performance Requirements." Applicants are required to conduct an ISA and provide an ISA summary that meets the requirements of 10 CFR 70.65, "Additional Content of Applications."

The staff's chemical process safety review should focus on the chemical safety-related accident sequences described in the ISA summary (SRP Chapter 3) and the corresponding management measures (SRP Chapter 11) to confirm that the applicant's equipment, facilities, and management measures are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material, and chemical risks of plant conditions that affect the safety of licensed material. The review must verify that any grading of IROFS or management measures proposed by the applicant in accordance with 10 CFR 70.62(a) is commensurate with the accident risk that the IROFS are designed to reduce.

The 1988 memorandum of understanding between the U.S. Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) directs the NRC to oversee chemical safety issues related to (1) radiation risks of licensed materials, (2) chemical risks of licensed materials, and (3) plant conditions that affect or may affect the safety of licensed materials or the availability or reliability of IROFS and thus increase radiation risk to workers, the public, and the environment. The NRC does not oversee plant conditions that do not affect or involve the safety of licensed materials.

The staff's review should cover the following specifications:

- chemical process description—narrative description of the site, facility, and processes with respect to chemical safety for normal operations. The chemical process description can include process chemistry, flow diagrams, major process steps, and major pieces of equipment. The ISA summary must include a reasonably simple description of each process (unit operations).

- chemical accident sequences—including unmitigated accident sequences involving hazardous chemicals and licensed materials and interpretation of the quantitative chemical risk levels, as described in the ISA summary.

- chemical accident consequences—identified in the ISA summary, including the applicant's interpretation of the qualitative chemical risk levels and the assumptions, bases, and methods the applicant used to forecast the consequences to workers and the public of accidents that involve hazardous chemicals and licensed materials.

- chemical process IROFS and sole IROFS—including a list of items relied on for chemical safety and a description of their safety function, as described in the ISA summary.

- chemical process management measures—including management measures to ensure the reliability and availability of IROFS (chemical process safety), as described in the ISA summary.

Review Interfaces

In addition to Chapter 6 of the application, the chemical reviewer should examine information in the following other areas to ensure that it is consistent with the information in Chapter 6 of the application:

- facility and process description applied to chemical safety as described in Chapter 1 of this SRP.
- safety program, ISA commitments, and ISA documentation applied to chemical safety under SRP Chapter 3.
- emergency plan applied to chemical safety under SRP Chapter 8.
- dispersion models used for consequence modeling under SRP Chapter 9.
- configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, and other quality assurance elements as described in Standard Review Plan (SRP) Chapter 11.

6.4 Acceptance Criteria

6.4.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant requirements of the following regulations:

- The general and additional contents of an application for chemical process safety are given in 10 CFR 70.22, "Contents of Applications," and 10 CFR 70.65, respectively. General information that must be included in the license application appears in 10 CFR 70.22. Information that must be included in the ISA summary appears in 10 CFR 70.65.
- The requirements for the approval of the application are in 10 CFR 70.23.
- The chemical process safety review should be conducted to provide reasonable assurance of compliance with the performance requirements in 10 CFR 70.61.
- Requirements to maintain and establish a safety program are found in 10 CFR 70.62, "Safety Program and Integrated Safety Analysis."
- Requirements for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72, "Facility Changes and Change Process," appear in 10 CFR Part 70.64.

6.4.2 Regulatory Guidance

The following regulatory guidance is relevant to chemical process safety:

- NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001.
- NUREG-1601, "Chemical Process Safety at Fuel Cycle Facilities," August 1997.
- NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998.
- NUREG/CR-6481, "Review of Models Used for Determining Consequences of UF_6 Release," November 1997.

6.4.3 Regulatory Acceptance Criteria

The reviewer should find the applicant's chemical process safety information acceptable if it provides reasonable assurance that the acceptance criteria presented below are adequately addressed and satisfied. The applicant may elect to incorporate some or all of the requested chemical process information in the facility and process description (SRP Section 1.1) or the ISA summary, rather than in this section. Either approach is acceptable, as long as the information is adequately cross-referenced.

6.4.3.1 Chemical Process Description

The regulation in 10 CFR 70.65(b)(3) requires a description of each process in the facility. This information must be included in the ISA summary. The applicant's descriptions of the chemical processes are acceptable if they meet the following conditions:

- Process descriptions are sufficiently detailed to allow an understanding of the chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow development of potential accident sequences .
- Process descriptions are sufficiently detailed to allow an understanding of the theory of operation.

6.4.3.2 Chemical Accident Sequences

The chemical accident sequences are acceptable in the following circumstances:

- The applicant provides a general description of the accident sequences identified in the ISA summary as involving hazardous chemicals produced from licensed material or chemical risks of plant conditions that affect the safety of licensed materials.
- The ISA summary describes the hazards identified in the ISA. Each accident sequence identified by the applicant in the ISA should include a chemical hazard evaluation of potential interactions of process chemicals with confinement vessels, process equipment, and facility personnel. The hazard evaluation should use appropriate accepted methods.

- The applicant provides reasonable assurance that measures to mitigate the consequences of accident sequences identified in the ISA summary are consistent with actions described in SRP Chapter 8. (Note that some facilities are not required to have an emergency plan.)

6.4.3.3 Chemical Accident Consequences

The chemical accident consequences are acceptable if the following apply:

- The applicant identifies and uses appropriate techniques and valid assumptions in estimating the concentrations for releases of hazardous chemicals produced from licensed material or by abnormal plant conditions that could affect the safety of licensed materials.

- The applicant provides evidence that the dispersion models used to determine whether a release of chemicals might affect worker or public health and safety are appropriate to the process. The applicant should demonstrate that the models used lead to a conservative estimate of potential consequences.[1]

- Consequence analyses conform to the guidance on atmospheric and consequence modeling in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," 1998.

- If the applicant does not use the methods in NUREG/CR-6410, the applicant may propose an alternative method accompanied by supporting documentation to justify the selection of such an alternative.

- The application describes the quantitative standards (chemical concentration limits) used to assess the unmitigated and mitigated consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials that are on site or expected to be on site.

- Acceptable exposure standards include, but are not limited to, the Emergency Response Planning Guidelines established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and the exposure limits established by OSHA. If the applicant does not use a published exposure standard or knows of no exposure standard for a chemical, the applicant may propose an alternative exposure standard accompanied by supporting documentation to justify the alternative.[2]

- Consequence categorization is in accordance with the performance requirements in 10 CFR 70.61(b) and 10 CFR 70.61(c).

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1 Source term and vapor dispersion models used to calculate the concentration of uranium hexafluoride (UF_6) and its reaction products conform to the guidance on the applicability of models in NUREG/CR-6481.

2 Note that 10 CFR 70.61 requirements are for "acute chemical exposures," and OSHA permissible exposure limits are typically time-weighted average values. Consequently, for ISA purposes, acute chemical release limits may not be adjusted by the time-weighted average calculation (which involves concentration and duration of exposure) unless the ISA summary provides a rational basis.

- The application includes definitions of “unlikely,” “highly unlikely,” and “credible” as used in the evaluations in the ISA.

6.4.3.4 Chemical Process IROFS and Sole IROFS

The license application should identify the design basis for chemical process safety for normal operation and demonstrate that the proposed equipment and facilities adequately protect public health and safety and the environment. Based on a comparison of the unmitigated chemical consequences determined in Section 6.4.3.3 with the performance criteria of 10 CFR 70.61, the applicant must provide (in the ISA summary) a list of chemical process safety controls (i.e., IROFS) suitable to prevent or mitigate potential accidents. This list must also briefly describe the IROFS, in sufficient detail to permit an understanding of their safety functions. The application should identify IROFS for those accident sequences containing a chemical system or process failure that may ultimately lead to radiological consequences that exceed the performance requirements. The applicant must demonstrate that the likelihood of each credible high-consequence event will be reduced after implementation of IROFS, so that the event will be highly unlikely or the consequence of the event will be low. For each credible intermediate consequence event, after the implementation of controls, the event should be unlikely or its consequences should be low.

If the applicant takes a graded approach to safety in accordance with 10 CFR 70.62(a), the reviewer should establish that the grading of IROFS is appropriate and sufficient to protect against chemical process risks. For example, the applicant should consider reliance on passive controls of active systems and defense-in-depth in accordance with 10 CFR 70.64(b). To reduce common mode failures, the applicant should favor design features that use independent sources of motive force for items such as control actuators, jet pumps, eductors, and ejectors. Fail-safe controls are preferred unless safety concerns preclude this approach.

6.4.3.5 Chemical Process Management Measures

The applicant must review management measures to ensure the availability and reliability of IROFS and sole IROFS when they are required to perform their safety functions. Management measures may be graded commensurate with risk.

The application must meet the following criteria:

- The application must describe the engineering approach, basis, or schemes employed for maintaining safety in normal operations.

- The ISA summary must identify the administrative and engineered controls to prevent or mitigate a chemical process risk, the hazard being mitigated, and the risk category. The applicant should also explain how any safety grading of IROFS and management measures has been made and how such grading is commensurate with the reduction in risk that the IROFS are designed to achieve.

- The application should demonstrate the management measures proposed to ensure that IROFS are available and reliable by briefly describing the following:

  – procedures to ensure the reliable operation of engineered controls (e.g., inspection and testing procedures and frequencies, calibration programs,

functional tests, corrective and preventive maintenance programs, criteria for acceptable test results)

– procedures to ensure that administrative controls will be correctly implemented, when required (e.g., employee training and qualification in operating procedures, refresher training, safe work practices, development of standard operating procedures, training program evaluation)

6.4.3.6 Requirements for New Facilities or New Processes at Existing Facilities

The application should address the baseline design criteria (BDC) for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72. The baseline criteria must be applied to the design of new processes but do not require retrofits to existing facilities or existing processes; however, all facilities and processes must comply with the performance requirements in 10 CFR 70.61. NUREG-1601, Section 2.4, contains a list of items that should be considered in an adequate facility design. For new facilities and processes in existing facilities, the design must provide for adequate protection against chemical risk from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material. With respect to chemical process safety, the application should be considered acceptable if it includes the information listed below (or references other sections of the application that include this information):

- The applicant briefly describes how the ISA was performed for the new process and how the ISA, satisfies the principles of the BDC and the performance requirements in 10 CFR 70.61. The applicant also explains how it applies defense-in-depth to higher risk accident sequences. Acceptable principles for defense-in-depth of the chemical process safety design are those that support a hierarchy of controls: prevention, mitigation, and operator intervention, in order of preference.

- The applicant describes proposed facility-specific or process-specific relaxations or additions to BDC, along with justifications for relaxations.

- The ISA summary describes how the chemical safety BDC were applied in establishing the design principles, features, and control systems of the new process.

6.5 Review Procedures

6.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should scan the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 6.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Obvious problems that can be addressed in a single request for additional information (RAI) should be accepted. However, major deficiencies that would require several RAI letters to resolve must be corrected before a detailed review is performed.

Reviewers should record whether each area of review is adequately addressed in the application, adequately addressed in a referenced document, not applicable to the application, or has a major deficiency.

6.5.2 Safety Evaluation

During the safety evaluation, the reviewer determines whether the application comprehensively describes the chemical safety of the licensed activity as identified in SRP Section 6.3. For deviations from the specific acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in Section 6.4.

During the license application and ISA summary review, the reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the engineered controls are implemented though procedures and operator training.

For an existing facility, the reviewer may consult NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewers may wish to consult with the facility design team to gain a better understanding of the process, its potential hazards, and safety approaches. These interactions should be coordinated through the licensing project manager.

The primary reviewer will prepare safety evaluation report (SER) input for the licensing project manager in support of the licensing action.

6.5.2.1 Chemical Process Description

The results of the ISA are the basis for the chemical process safety evaluation. The reviewer should establish that the applicant's facility design, operations, and IROFS for chemical safety provide reasonable assurance that they will function as intended and provide for the safe handling of licensed material at the facility. The reviewer must verify that the applicant's proposed equipment and facilities are adequate to protect public health and safety and the environment. The reviewer should examine the mechanisms that will allow the applicant to identify and correct potential problems.

6.5.2.2 Chemical Accident Sequences

The ISA shall contain the potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena. The reviewer should review the chemical risks identified in the ISA summary and ensure that the design and the operational plans for the facility reflect the level of safety. In return, to validate the criteria used by the applicant in reporting sequences in the ISA summary, the reviewer will make an independent judgment of the comparative risks assigned by the applicant to accident sequences identified in the ISA summary. The judgment is based on risk relative to other sequences (competing risks), the complexity of the sequence, facility operating history, and general industry performance. Whenever possible, a licensee's own experience should be used to supplement the identification of potential chemical hazards. The review may cover a selected number of lower risk, chemical safety-related accident sequences not identified in the ISA summary.

6.5.2.3 Chemical Accident Consequences

The reviewer must verify that the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure are appropriate. Events with high and intermediate consequences should be identified, and IROFS should be used to reduce the likelihood or the consequences of the event.

6.5.2.4 Chemical Process IROFS and Sole IROFS

The staff reviews the chemical process safety IROFS to ensure their adequacy in protecting against all unmitigated sequences identified in the ISA summary. The reviewer should establish that the applicant's controls (IROFS) for chemical safety provide reasonable assurance that they will function as intended and provide for the safe handling of licensed material at the facility.

6.5.2.5 Chemical Process Management Measures

There should be an overall chemical safety element describing the methods, activities, and implementation of the overall safety program. The technical reviewer should verify the applicant's commitment to retaining records for chemical process safety compliance and reporting commitments for chemical releases. In addition, the reviewer should verify the applicant's commitment to refer any unacceptable performance deficiency to the facility's corrective action function in accordance with Chapter 11 of this SRP.

If the applicant has applied a graded approach to safety, the reviewer should establish that the grading of IROFS or management measures is appropriate and sufficient to protect against chemical process risks (see Chapter 11 of this SRP).

6.5.2.6 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews the applicant's commitments to adhere to the BDC, according to 10 CFR 70.64(a), for the design of new facilities or new processes at an existing facility that require a license amendment under 10 CFR 70.72.

6.6 Evaluation Findings

The reviewer writes an SER input addressing each topic reviewed and explains why the NRC staff has reasonable assurance that the chemical safety portion of the application is acceptable. The reviewer may propose license conditions to impose requirements where the application is deficient. If unable to make a finding of reasonable assurance, the reviewer will prepare SER input explaining the deficiencies and the reasons for denying the proposed application. In cases where the SER is drafted in advance of resolving all outstanding chemical process safety issues, the reviewer documents the review as described below and includes a list of open issues that require resolution before the staff can make a finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer uses applicable sections of the acceptance criteria and the SER, and the reviewer notes areas that were not reviewed and the chemical process safety significance, if any. On completion of the review, the NRC staff may impose temporary license conditions to authorize short-duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

The SER should include a summary statement of what was evaluated and the basis for the reviewer's conclusions. The SER should include statements like the following:

> The staff has evaluated the application using the criteria listed previously. Based on the review of the license application, the NRC staff has concluded that the applicant has adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects. The applicant has constructed a hazard analysis that identified and evaluated those chemical process hazards and potential accidents and established safety controls to provide reasonable assurance of safe facility operation. To ensure that the performance requirements in 10 CFR Part 70 are met, the applicant has provided reasonable assurance that controls are maintained available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.
>
> The staff concludes that the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of 10 CFR Part 70 and provide reasonable assurance that the health and safety of the public will be protected.

6.7 References

Center for Chemical Process Safety, "Guidelines for the Technical Management of Chemical Process Safety," American Institute of Chemical Engineers, New York, 1989, Chapter 11, as revised.

Chemical Manufacturers Association, "Responsible Care®, Process Safety Code of Management Practices," Washington, DC, 1990.

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material," as revised.

U.S. Code of Federal Regulations, Title 29, "Labor," Section 1910.100, Chapter XVII-, "Occupational Safety and Health Administration: Subpart Z – Toxic and Hazardous Substances, Tables Z-1 and Z-2," as revised.

U.S. Nuclear Regulatory Commission, Manual Chapter 2603, "Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities," as revised.

U.S. Nuclear Regulatory Commission/Occupational Safety and Health Administration, "Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, 'Worker Protection at NRC-Licensed Facilities,'" *Federal Register* No.53, October 31, 1988.

U.S. Nuclear Regulatory Commission, "Chemical Process Safety at Fuel Cycle Facilities," NUREG-1601, August 1997.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

U.S Nuclear Regulatory Commission, “Review of Models Used for Determining Consequences of UF_6 Release,” NUREG/CR-6481, November 1997.

Emergency Response Planning Guidelines: Published periodically by the American Industrial Hygiene Association. The latest available list of approved ERPGs, dated January 1, 2008, is available on SCAPA’s home page (http://orise.orau.gov/emi/scapa/default.htm).

National Research Council; “Acute Exposure Guidelines Levels for Selected Airborne Chemicals”; National Academy of Sciences (ISBN: 978-0-309-12755-4), Washington DC, Volume 7 (2008).