ENCLOSURE 2

Appendix A

Establishing the Regulatory Framework to License Fuel Recycling Facilities

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I. Introduction

The Nuclear Energy Institute (NEI)[1] has developed a licensing framework for a recycling facility for used fuel and considerations of various regulations in Chapter I that are needed to implement this framework. This framework was developed by an NEI task force directed toward closing the fuel cycle. The Task Force is chaired by Mr. Jack Bailey, Vice President, Nuclear Generation Development, at the Tennessee Valley Authority. Working with Mr. Bailey are representatives from Exelon, Constellation Energy, Entergy, Duke Energy, AREVA, EnergySolutions, GE, and General Atomics. In addition, the Task Force is being supported by B&W Technical Services, Talisman International, CH2M Hill, and NEI staff. This extensive list demonstrates that the key cognizant organizations are participating in the process and that they represent a cross section of the industry.

The term "used fuel" as well as "spent fuel" and the term "recycling" as well as "reprocessing" are used in this paper to reflect the fact that recycling is utilizing the unspent energy left in fuel that comes out of a reactor. It is recognized that the current regulations use the terms of "spent fuel" and "reprocessing."

Recycling used fuel presents an opportunity to utilize the remaining energy in used fuel that will save resources and contribute to energy independence. Companies within the nuclear industry are giving serious consideration to building and operating fuel recycling facilities. Although these facilities would be consistent with the GNEP program, they can also be separate and distinct from those associated with the GNEP initiative. An important aspect of this consideration is the regulatory process that will be used to license these facilities as it is recognized that the current requirements in the NRC regulations do not provide a clear licensing path for a recycling facility.

It is recognized that the NRC is initiating effort to develop a regulatory framework. As expressed in the "NRC Report to the U.S. Department of Energy on Activities Covered Under Interagency Agreement DE-AI01-07NE24496 on the Global Nuclear Energy Partnership" (April 18, 2008), the NRC anticipated a rulemaking completion date for a closed fuel cycle of June 2014. From the perspective of the nuclear industry, June 2014 is inconsistent with its goals to license, construct, and operate recycling facilities in the next decade. In the interest of accelerating that schedule, so that the industry will be prepared to initiate applications sooner, NEI is proposing that the framework be completed two years earlier. To assist in achieving that goal, NEI is submitting this paper to the Commission to establish a regulatory framework for licensing a recycling facility under a new part, which has been labeled Part 7x. As discussed below, the framework is modeled under the risk-informed and performance-based approach of Part 70 supplemented with provisions from Part 50. Separate, but important to the success of a

[1] NEI is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

regulatory framework for regulations, will be the need to develop regulatory guidance similar to NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," and NUREG 1718- "Standard Review Plan for the Review of a License Application for a Mixed Oxide (MOX) Fuel Fabrication Facility."

II. Overview of the Framework and Safety Philosophy

The facility that would be licensed under the framework based on this paper is defined as a fuel recycling facility. It would be a facility for recycling and its associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel to the extent such associated activities are included in the application and/or license for the fuel recycling facility. The framework proposed is technology neutral. It should be sufficient to address the licensing of the various potential designs for recycling facilities that are contemplated by the industry.

The framework adopts the philosophy of 10 CFR Part 70 that utilizes a risk-informed and performance-based regulatory approach that includes: (1) the identification of performance requirements for prevention of accidents or mitigation of their consequences as well as specific design basis criteria: (2) the performance of an Integrated Safety Analysis (ISA) to identify potential accidents at the facility and the items relied on for safety (IROFS); (3) the implementation of measures to ensure that the IROFS are available and reliable to perform their function when needed; (4) the maintenance of the safety bases, including the reporting of changes to the NRC; and (5) the allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The underlying safety standard for the proposed framework is that the facility must meet the performance requirements of 10 CFR 7x.32 which are identical to the performance requirements in 10 CFR 70.61. This will assure that the design and operation of the facility will be protective of the public health and safety.

The proposed framework addresses the need of industry to have a process that will allow the option for a combined license similar to Part 52 so that, before construction begins, a determination can be made that the facility will be authorized to operate if constructed in accordance with the license. It also addresses the need to have the choice to either separately license, under existing requirements, individual aspects of the process, such as spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel, or to combine them under one license.

In developing this regulatory framework it is recognized that a fuel recycling facility is a production facility under the Atomic Energy Act of 1954, as amended (AEA). The licensing procedures in 10 CFR Part 50 were developed to implement the AEA requirements applicable to utilization and production facilities. Consequently, the framework, though based on the Part 70 licensing approach, adopts many of the licensing procedures of 10 CFR Part 50.

The proposed framework is divided into two sections. Section V, below, contains the conceptional language for a new Part 7x which is the substance of the licensing framework. Section VI, below, identifies the changes to the various regulations in Chapter I that are needed to implement this framework. Section IV does not address other regulations that may also require revision to ultimately enable the operation of a recycling facility (i.e., Parts 73, 74, 75, 140, 170, and 171). In addition to the Price Anderson issues under Part 140, insurance issues similar to 10 CFR 50.54 (w) have not yet been addressed. The industry did not consider Parts 170 and 171. The industry is continuing to review and develop its views on the remaining parts of the regulations. Apart from NRC requirements, consideration needs to be given to a revision of 40 CFR 190.10(b) which relates to the total quantity of radioactive materials entering the general environment from the entire uranium fuel cycle.

Set out below are some of the key considerations and aspects of the proposed framework. Following that discussion, each section of the framework is addressed.

III. Key Considerations

A. Need for a New Part 7x

A commercial recycling facility is a "production facility" under the AEA. It would be licensed under section 103 of the AEA which is the same provision used to license light water reactors (LWR). Section 189 of the AEA provides for a two part licensing process for production facilities. A construction permit is needed before construction is permitted and then an operating license is needed to authorize operation. In addition, under section 189 a mandatory hearing is required before the NRC can authorize construction. A hearing opportunity is also provided before an operating license is issued. In the case of a combined construction permit and operating license application, a single hearing would be conducted. Section 185 of the AEA provides for combined licenses for production facilities.

The basic licensing provisions for a production facility are currently found in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.” While a number of provisions in Part 50 are applicable to both production and utilization facilities, there are relatively few requirements specifically applicable to reprocessing facilities in Part 50 other than in § 50.36 “Technical specifications,” Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” and “Appendix F, “Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities.” The specific references to “fuel reprocessing” in Part 50 are addressed below in section IV.B. The combined license approach of Part 52 does not apply to production facilities.

A reprocessing facility’s operational characteristics would differ significantly from a light water reactor (LWR) licensed under Part 50. NRC has stated in SECY-06-0066, Regulatory and Resource Implications of a DOE Spent Nuclear Fuel Recycling Program (March 22, 2006), that:

> Part 50 is focused on LWR design and technology and would have limited applicability to commercial reprocessing facility design and technology. That is, the design and operational safety issues associated with a commercial

> reprocessing facility would be very different from design and operational safety issues associated with an LWR. The current Part 50 regulations would not necessarily address all commercial reprocessing facility safety issues and, conversely, are likely to contain requirements that are not applicable to a reprocessing facility. The application of the whole of Part 50 to the licensing of a commercial reprocessing facility would present significant challenges to the applicant and to the NRC. If Part 50 is used to license a commercial reprocessing facility, the regulations would have to be reviewed to determine which apply, which do not apply, and which may partially apply. Additional requirements would also need to be established to address reprocessing facility-specific design and safety issues.

In SECY -08-0134, Regulatory Structure for Spent Fuel Reprocessing (September 12, 2008), the staff expressed the view that "it would not be effective or efficient to revise Part 50 to license reprocessing facilities." NEI agrees that a reprocessing facility is more like a complex fuel cycle facility than a reactor and it does not make sense to revise Part 50.

The staff noted in SECY-08-0134 that:

> [T]he existing Part 70 currently regulates many different types of fuel cycle facilities. 10 CFR 70 provides a model of a regulation capable of licensing several different types of facilities, yet adequately ensures safe facility operation. As such, the staff believes that it is possible to either include a new subpart to Part 70 that would provide new regulatory requirements for reprocessing facilities, or create a new Part specific for reprocessing. These new regulations could be capable of licensing aqueous separation techniques, as well as any potential pyroprocessing techniques.

In our view, Part 70 with its performance base approach should be the model for the new framework. Amending Part 70 to provide the necessary framework for a recycling facility was considered. However, a number of significant changes would need to be made to Part 70 to address procedural and substantive requirements necessary under the AEA including both the two-step licensing process (construction permit and operating license) and combined license process for production facilities. Additional substantive requirements are also needed because of the nature of a recycling facility with a greater source term than other fuel cycle facilities. Part 70 has been amended from time to time over the years and adding these additional provisions would add significant complexities to an already complex part 70. It would be a significant challenge to integrate the new requirements into Part 70. For example, requirements for the application would be located in numerous sections throughout Part 70. It is doubtful that the resulting amended Part 70 would have a clear path through the regulation to understand the requirements applicable to a recycling facility. In also has the potential to confuse the existing regulatory requirements applicable to a recycling facility, such as technical specifications, operator licensing, and additional baseline design criteria (BDC), that would not be applicable to the numerous other activities regulated under Part 70. A new part offers the benefit of establishing the requirements for the recycling facility that will clearly state what is needed with the minimum need to refer to numerous other sections in the regulations and the need to except out provisions which are not applicable. A new part would not impact the existing licensing

framework for existing licensees. NEI, therefore, concluded that it made more sense to develop a new part for the regulation of recycling facilities.

B. Safety Envelope

In developing this proposed regulatory framework, the Part 70 concepts of ISA, Integrated Safety Analysis Summary (ISA Summary), performance requirements, BDC, and IROFS have been used. To combine many of these technical aspects of Part 70 into the application for a fuel recycling facility the proposed framework introduces the term "Safety Report" to define the technical portions of the application in §7x.30. It contains (1) the description of the facility and application of the BDC, (2) the ISA Summary, and (3) the safety program. The safety program provides a description of the applicant's processes for (i) ISA, (ii) fire protection, (iii) chemical safety, (iv) nuclear criticality, (v) radiation protection, (vi) management measures, and (vii) process safety information. Applicants and licensees must maintain the safety program, ISA, and ISA Summary. The Safety Report is expected to be made up of multiple volumes. The Safety Report may include sub reports on application topics such as quality assurance or technical specifications. Sensitive information, e.g., safeguards information, would be expected to be placed in separate volumes.

The proposed framework in § 7x.66 provides a configuration management change process to evaluate, implement, and track each change to site, structures, processes, systems, equipment, components, computer programs, procedures, and activities of personnel described in the Safety Report and allow changes similar to the process described in 10 CFR 70.72.

C. Baseline Design Criteria

Part 50 currently requires design criteria for production and utilization facilities. For reactors this is addressed by the General Design Criteria of 10 CFR Part 50. It is noteworthy that footnote 8 to 10 CFR 50.34 states that "General design criteria for chemical processing facilities are being developed." While that may have been true in 1971 when Appendix A was first issued, there is no indication that the effort was completed.

Consistent with Part 70, good engineering practice dictates that certain minimum requirements are applied as design and safety considerations for any new nuclear process or facility. In addition, a fundamental element of NRC's safety philosophy is that designs and operations should provide for defense-in-depth protection against accidents. The regulations in 10 CFR 70.64 provides BDC in ten areas. The proposed framework in §7x.34 adopts the philosophy and introductory language 10 CFR 70.64(a) and expands the BDC in 10 CFR 70.64 by adding applicable criteria from 10 CFR Part 50 and 10 CFR Part 72, as well as, newly developed criteria. The resulting 28 design criteria have been termed BDC for a fuel recycling facility. BDC provide the design criteria that must be applied to the design and in the ISA to demonstrate that there is reasonable assurance that the performance objectives of §7x.32 are met under accident and normal conditions including the consequences of natural phenomena. As provided in §7x.30, the applicant will need to explain in a summary format how the BDC in §7x.34 are addressed to achieve the performance requirements of § 7x.32. It is not envisioned that the

applicant will necessarily be required to describe on a system by system basis how the BDC are met as this will ultimately be captured by the ISA and the identification of IROFS.

The BDC, as applied in the application and approved by the NRC, cannot be changed during construction of the facility without Nuclear Regulatory Commission approval and would remain applicable for the life of the facility unless it could be demonstrated in the ISA that the BDC as applied is not required for or to support any IROF, in which case the application of the BDC could be modified pursuant to the change process in §7x.66.

As with Part 70, the BDC do not provide relief from compliance with the safety performance requirements. The BDC are generally an acceptable set of initial design safety considerations, which potentially may not be sufficient to ensure adequate safety for all new processes and facilities. The ISA process is intended to identify additional safety features that may be needed. On the other hand, it is recognized that there may be processes or aspects of a fuel recycling facility for which some of the BDC may not be necessary or appropriate, based on the results of the ISA. For these processes and facilities, any design features that are inconsistent with the BDC will need to be identified and justified. However, given the source term involved with the "production facility" aspect of a fuel recycling facility, it is expected that a higher standard will apply to the review of any proposed justification to not include a BDC for that aspect of the facility.

Using the BDC and considering defense-in-depth practices in the design should result in a facility design that is based on providing successive levels of protection such that health and safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating BDC and defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance for equipment failures, human errors, and external challenges. The risk insights obtained through performance of the ISA can be then used to supplement the final design by focusing attention on the prevention and mitigation of the potential accidents having higher risk.

D. Threshold Criteria for Technical Specifications and quantitative assessments in ISAs

The AEA requires technical specifications for production facilities. It does not require technical specifications for fuel fabrication and other activities under Part 70. The proposed framework establishes a threshold criteria in §7x.40(a) that requires technical specifications be developed for those IROFS which have been applied to protect against or mitigate the potential accident consequences which could result in a high consequence event, as defined in §7x.32, involving fission product releases to an individual located outside the controlled area (essentially off-site). This limits technical specifications to those aspects of the fuel recycling facility that are generally unique to the "production facility" and have source terms and accident scenarios that are more significant than fuel fabrication facilities.

The ISA requires the identification of the consequences and likelihood of each identified potential accident consequence from internal and external hazards. For accident scenarios that could result in a high consequence event involving fission product releases to an individual located outside the controlled area, the ISA is to be supported by a quantitative assessment of the

risk to the extent practicable based on the availability of data to support quantitative analysis including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. This is consistent with the threshold for technical specifications.

The threshold criteria being applied here is appropriate from the perspective of both 10 CFR Part 50 and 10 CFR Part 70. Under 10 CFR Part 70 an ISA is done to understand accident scenarios and potential consequences to both the onsite workers and the off-site public. The proposed framework provides that for this relatively limited subset of IROFS, the ISA likelihood determination will be supported by quantitative analysis and by technical specifications. This is consistent with the concept that for a high source term, a quantitative safety analysis is needed and will result in a requirement which is consistent with the requirement for technical specifications required by the AEA.

E. Operator Licensing

The AEA requires that operators be licensed for production facilities but does not specify the process. The proposed framework requires that the applicant will certify to the NRC the operators as trained and technically, medically, and physically competent based on an NRC approved certification program. Based on this NRC approved certification program, NRC will approve and issue an operator license to the certified operator allowing an individual to perform licensed activities.

The application will include, in addition to the management measures that require training and qualification of the non-licensed operators and other facility staff, the applicant's program for training, periodic proficiency training, requalification, and certification of operators who will be approved by NRC as licensed operators. It is expected that NRC, as part of the process to license operators who have been certified, will audit the facility's certification process to be satisfied that the certified operators are competent and capable of performing licensed operations.

Recognizing that fuel cycle facility operators are not required to be licensed, the threshold for licensed operators under the proposed framework are operators whose actions are necessary to prevent or mitigate identified and defined accident scenarios involving fission products that could result in a high consequence event to an individual outside the controlled area. This is the same threshold proposed for technical specifications and quantitative risk assessments.

F. Inspection, Tests, Analysis, and Acceptance Criteria (ITAAC)

In accordance with the AEA, the framework provides that ITAAC be established for combined licenses. ITAAC provide reasonable assurance that if the inspections, tests, and analyses are performed and the acceptance criteria met, the IROFS have been appropriately identified and implemented as described in the Safety Report and the facility has been constructed and will be operated in conformity with the combined license, the provisions of the Act, and the Commission's rules and regulations.

G. Licensing Flexibility

It is recognized that a fuel recycling facility is made up of several individual operations that could be licensed separately and in some cases under different parts of Chapter I of 10 CFR. Not all of these operations are production facilities. An applicant in developing its facility may choose to construct and license the project in a one step combined license process. Alternatively, an applicant may choose to adopt a two-step licensing process allowed by the AEA rather than adopt the combined license approach. The proposed framework allows flexibility in several areas as follows:

1. It allows the applicant a choice of either a one or two-step licensing process and includes criteria for a construction permits as well as combined licenses. It also provides for a limited work authorization to allow early construction. It does not provide for an early site permit.

2. It allows an applicant to choose to license parts of the facility early (e.g. spent fuel pool) under existing regulations and later transfer to a single license without reopening, except under limited circumstances, the licensing process if the licensee desires to do so.

3. It allows the applicant a choice to either limit its application for a fuel recycling facility to just recycling activities or to include in its application one or more associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel.

H. Hearing Process

Included in the proposed framework are amendments to 10 CFR Part 2, Rules of Practice. The intent of the amendments is to treat a fuel recycling facility similarly to a power reactor for purposes of the hearing process. The Part 2 procedures for Part 50 and Part 52 construction permits, operating licenses, and combined licenses application acceptance, noticing, and proceedings were adopted.

Under the two-step licensing process, the procedures in the proposed framework provide that a public hearing would be held before a construction permit is issued for a fuel recycling facility. A public hearing would not be mandatory or automatic for operating license applications. However, the NRC would publish a notice in the Federal Register that it received an application for an operating license, has accepted it for review, and is considering issuance of the license. The notice would provide the public an opportunity for those whose interest might be affected by the issuance of the license to request a hearing.

Under the combined licensing approach, the procedures in the proposed framework would also provide for a mandatory hearing similar to the first step of the two-step licensing approach. After issuing a combined license, the Commission would authorize operation of the facility only after verifying that the licensee completed required inspections, tests, and analyses and that the acceptance criteria were met. At periodic intervals during construction, the NRC would publish

notices of these completions in the Federal Register. Then, not less than 180 days before the date scheduled for commencement of operations, the NRC would publish a notice of intended operation of the facility in the Federal Register. There would be an opportunity for a hearing at this time, but the NRC would consider petitions for a hearing only if the petitioner demonstrates that the licensee has not met or will not meet the acceptance criteria of an ITAAC. Before a plant could operate, the Commission would determine that the acceptance criteria have been met.

IV. Section by Section Discussion

A. Explanation for Part 7x Licensing Requirements for Recycling Facilities

The sections of the proposed framework are discussed below. Greater details are provided for the more significant sections. Some sections are discussed as a group.

Subpart A. - General Provisions

§ 7x.1 Basis, purpose, and scope procedures applicable

This section is derived from 10 CFR 50.1 and 70.2. Paragraph (a) provides that a fuel recycling facility at a minimum contains fuel recycling operations. Other activities can be included in the application, but the applicant is not required to do so. In addition, the scope addresses licensing of individual operators.

§7x.2 Requirements for a License

This section is derived from 10 CFR 50.10 and contains the requirements for licenses and construction permits to construct, transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any fuel recycling facility.

§7x.3 Definitions

This section contains applicable definitions from 10 CFR 70.4. Additional definitions were added either from other parts or to define terms used in this new part. These include definitions for:

"Combined license" which was added to address a license that combines into one license a construction permit and operating license.

"Construction" which was added from 10 CFR 50.10 to support limited work authorizations under the new §7x.10.

"Controlled area" which was added from 10 CFR Part 20.

"Creditor" which was added from10 CFR 70.44.

"Facility" which was added to mean a fuel recycling facility.

"Fuel recycling facility" which was added consistent with the scope of the new Part 7x.

"General Emergency" which was added to clarify the emergency planning requirements for an application. It was derived from NUREG 0654 and the "Backgrounder on Emergency Planning" from the NRC web page.

"High-level radioactive waste (HLW)." This definition is from the Nuclear Waste Policy Act replacing "reprocessing" with "recycling." In addition, a clarification of the phrase "liquid waste produced directly in recycling" was added from Part 60, i.e., "liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent." The Statements of Consideration for Part 63 noted that originally it included the clarifying words but took them out to be more consistent with the EPA language that was similar to the NWPA. In so doing the Commission stated that there "is no substantial difference" between the definitions. 66 FR 55732 (November 2, 2001). The clarification is important because the new Part 7x directly addresses recycling. The definition also addresses incidental waste from reprocessing/recycling consistent with past NRC positions.

"License" which was expanded to include "construction permits" consistent with 10 CFR Part 50 and the AEA.

"Plutonium processing and fuel fabrication" was expanded from the definition in 10 CFR 70.4 to "plutonium and/or minor actinide processing" to ensure that the framework encompassed technology neutral fuel recycling, processing and manufacturing. It will allow the framework to apply to technologies which may be used to remove transuranic actinides from spent fuel to facilitate long term disposal. This change was also made throughout Part 7x.

"Presiding officer" which was added from the definitions in 10 CFR 2.4

"Production facility" which was added from the definitions in 10 CFR Part 50.

"Recycling" which was added based on the process used by a production facility as defined in 10 CFR 50.2. Consistent with paragraph (2) of this definition and paragraph (3) of the definition of a "production facility," fuel which is only slightly irradiated need not be processed under Part 7x and could be processed under 10 CFR Part 70 as had been done in the past.

"Safety Report" which was added as that is a key term in the new Part 7x. While the Safety Report is a new term, it is not a new concept and is intended to include those existing aspects of current license application content requirements under 10 CFR Part 70 that are not clearly identified as being part of a particular document, as well as, the application of the BDC, the ISA Summary, and the safety program. It is expected to contain multiple volumes with separate sub reports.

"Spent fuel" which was modified from 10 CFR 72.3 to remove the limitation for at least one year of decay to provide for flexibility.

"Waste incidental to recycling (WIR)" which was added to clarify what was not HLW. This definition was derived from the Commission's decision in the "Decommissioning Criteria for the

West Valley Demonstration Project (M-32) at the West Valley Site," 67 FR 5003 (February 1, 2002) and section 3116 of the Ronald Reagan National Defense Authorization Act (NDAA) for Fiscal Year 2005. It is not contemplated that WIR material would be disposed of on site. Rather WIR material would be disposed of off-site as low-level waste. This definition does not relieve the Department of Energy from its responsibility for the disposal of radioactive material which is greater than Class C under the Low-Level Radioactive Waste Policy Act of 1985.

§ 7x.4 Communications; § 7x.5 Interpretations; § 7x.6 Employee protection; § 7x.7 Information collection requirements: OMB approval; § 7x.8 Completeness and accuracy of information; and § 7x.9 Deliberate misconduct

These sections were taken from 10 CFR 70.5 -70.10.

Subpart B. - Requirement of License, Exceptions and exemptions

§ 7x.10 License required for Construction; limited work authorization

This section is derived from 10 CFR 50.10 and prohibits construction of a fuel recycling facility until a construction permit or combined license is issued. It provides a process to authorize limited construction work associated with IROFS of the facility for which either a construction permit or combined license is otherwise required under this part.

§ 7X.11 Exceptions and exemptions from licensing requirements

This section is derived from 10 CFR 50.11 and 70.11. It addresses the licensing for certain activities of the Department of Energy and certain contractors of the Department and the NRC.

§ 7x.12 Specific exemptions

This section adopts the exemption provisions of 10 CFR 50.12(b) and 70.17. Section 50.12(b) addresses exemptions for early site work.

§ 7x.13 Attacks and destructive acts by enemies of the United States; and defense activities

This section is derived from 10 CFR 50.13 and provides that NRC applicants and licensees do not need to design their facilities against an enemy of the United States or the effects of weapons incident to U.S. defense activities.

§ 7x.14 Class 103 licenses; for commercial and industrial facilities

This section is derived from 10 CFR 50.22 and provides that a fuel recycling facility is licensed under section 103 of the AEA.

§ 7x.15 Construction permits and combined licenses

This section is derived from 10 CFR 50.23 and addresses the relation between construction permits and operating licenses, combined licenses, and amendments to operating and combined licenses.

Subpart C. - Requirements for Applicants

§ 7x.20 Filing of application; oath or affirmation

This section is derived from 10 CFR 50.30, 50.37, and 70.21 and addresses the requirements for filing an application including the submittal of an environmental report meeting the requirements of 10 CFR Part 51.

§ 7x.22 Combining and separation of licenses

It is recognized that a fuel recycling facility is made up of several individual operations that could be licensed separately and in some cases under different parts of chapter I of 10 CFR. Not all of these operations are production facilities. An applicant may in developing its facility choose to construct and license the project in separate segments. This section allows the applicant a choice to either limit its application for a fuel recycling facility to just recycling activities or to include in its application one or more associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel. It also allows an applicant to choose to license parts of the facility early (e.g. spent fuel pool) under existing regulations and later transfer to a single license without reopening, except under limited circumstances, the licensing process if the licensee desires to do so. This section is derived in part from 10 CFR 50.31 and 52.8

§ 7x.24 Ineligibility of certain applicants

This section is derived from 10 CFR 50.38 and implements section 103 of the AEA.

§ 7X.26 Hearings and report of the Advisory Committee on Reactor Safeguards

This section is derived from 10 CFR 50.58, 52.85, and 52.87. It addresses AEA requirements applicable to the licensing process for a fuel recycling facility since it is a production facility.

§ 7x.28 Contents of applications; general information

This section is derived from 10 CFR 50.33 and 70.22.

§ 7x.30 Contents of applications; Technical information

This section is derived from 10 CFR 50.33, 50.34, 50.34a, 50.36b, 70.22, 70.62, and 70.65 and consolidates in one section the technical requirements for the application. While this section covers all applications for construction permits, operating licenses, and combined licenses, different provisions apply to applicants for each such license

An important part of this section is paragraph (c), the Safety Report, which addresses the radiological and chemical safety requirements for the facility. The Safety Report includes (1) the description of the facility and application of BDC set out in § 7x.34, (2) the ISA Summary, and (3) the safety program. The safety program addresses the ISA, fire protection, chemical safety, nuclear criticality, radiation protection, management measures, and process safety information. Requirements for the safety program including the ISA and the ISA Summary are provided in this section. These requirements are based on 10 CFR 70.62 and 65. Section 7x.36 requires that the safety program including the ISA and the ISA Summary to be established and maintained by the applicant. Section 7x.60 (a) provides the same requirement for licensees. The Safety Report is a living document of the radiological licensing basis that is controlled through the change process of §7x.66 which is based on 10 CFR 70.72.

Consistent with 10 CFR 70.62(c)(v) the ISA must identify the consequence and the likelihood of occurrence of each potential accident sequence. However, unlike Part 70, Part 7x specifically requires for accident scenarios that could result in a high consequence event involving fission product releases to an individual located outside the controlled area, that the ISA shall be supported by a quantitative assessment of the risk to the extent practicable based on the availability of data to support quantitative analysis including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

Paragraph (d) addresses the application requirements for decommissioning the facility and disposition of any waste streams remaining at the facility when operations cease.

Paragraph (e) addresses the application requirements to include technical specifications which are required by section 182 of the AEA for production facilities. As described in § 7x.38, the threshold for technical specifications is the same as that for quantitative analysis in the ISA.

Paragraph (f) addresses the application requirements for providing estimated effluent releases, plans for waste management and disposal during operations, proposed conditions to protect the environment during construction, operation, and decommissioning based on the applicant's Environmental Report.

Paragraph (g) addresses the application requirements for financial assurance. It requires information about costs for construction, operation and decommissioning. Funding for decommissioning must address the requirements in §7x.38.

Paragraph (h) addresses the application requirements for emergency preparedness. This section is consistent with the emergency planning criteria of 10 CFR70.22(i) for fuel fabrication facilities unless it is determined that there is a need for a General Emergency Classification in which case the requirements of Appendix E of 10 CFR Part 50 are invoked.

Paragraphs (i)-(m) address the application requirements for material control and accounting program, plan for physical security in transport, plan for site physical security, safeguards contingency security plan, and program to protect classifies material and information, safeguards

information and information associated with various security programs. These requirements are derived from 10 CFR 70.22 (b), (g), (h), ((j), (k), (l), and (m) and Parts 73 and 74.

Paragraph (n) addresses the application requirements for financial protection and indemnity provisions of 10 CFR Part 140.

Paragraph (o) addresses the application requirements for ITAAC in accordance with the AEA. ITAAC are required for combined licenses. The ITAAC process provides reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria are met, the IROFS will have been appropriately identified and implemented as described in the Safety Report and the facility will have been constructed and will be operated in conformity with the combined license, the provisions of the Act, and the Commission's rules and regulations. Inspection, tests, analysis, and acceptance criteria will validate the application of the BDC as reflected in the IROFS. It is expected that ITAAC will be addressed throughout the construction schedule and not wait until construction is completed. While the ITAAC process focuses on validating IROFS, the BDC will also be validated as part of the ITAAC process since the safety features of BDC will be reflected in IROFS.

Paragraph (p) addresses the application requirements for the applicant's licensed operator certification program for those operators whose actions are necessary to prevent or mitigate identified and defined accident scenarios involving fission products that could result in a high consequence event to an individual outside the controlled area. It is derived in part from 10 CFR Part 55 and Part 72, subpart I. This paragraph requires that the applicant indicate to the NRC the operator positions including supervisory positions the applicant will certify to the NRC as trained and NRC will approve and license based on an NRC approved certification program, before allowing an individual to perform licensed activities. The application will include in addition to the management measures that require training and qualification of non-licensed operators and other facility staff, the applicant's program to determine that the applicants to be certified to become licensed operators are technically, mentally, and physically competent to be licensed. NRC would need to approve this program. Elements of the program would include for example training, periodic proficiency training, requalification, and certification of operators who will be approved by NRC as licensed operators. It is important to note that this section only addresses licensed operators. The facility licensee will have many other operators who will not need to be licensed by the NRC but will need to be trained and qualified in accordance with the licensee's safety program.

It would be expected that the training program include, for example, process theory and design; facility risk and safety bases; safety, design, and performance functions of facility structures, systems, and components; facility technical specifications and license conditions; normal and abnormal operations; procedures; displays and alarms; solid, liquid and gaseous radioactive waste processing and controls; control of confinement; area radiation monitoring; facility process control and protective systems; accidents and emergency procedures. The description of the licensed operator training program shall be included in the facility license application and shall be approved by the NRC as a prerequisite to licensing individual operators. To the extent practical, a systems approach to training would be utilized. If available, training would include use of a plant referenced simulator.

Since NRC would be licensing operators on the basis of the licensee's certification, the materials used to implement the training program would be made available to the NRC staff for review and inspection. Such training materials would likely include lesson plans, procedures, handouts, drawings, calculations, video and audio aids, computer based training, quizzes and examinations and their graded results, and examination grading keys and criteria.

Similarly, the NRC would be provided the opportunity to observe classroom training, practical training in the facility, and simulator training, to the extent that a simulator is available and is appropriately configured for operator training. The NRC would need to be informed of the licensee's plans for training activities so that NRC staff members can observe the training as it is conducted.

The certification program would be expected to be based on results of written and oral examinations, the individual's demonstrated skill in performing plant manipulations and the individual's performance on any simulator that can be used for training. Documentation of an individual's certification would be included as part of each individual's application for a process operator or senior process operator license. The certification process would also need to consider the applicant's medical and physical fitness as part of the certification to the NRC.

§ 7x.32 Performance requirements

This section is identical to 10 CFR 70.61 and sets the performance requirements for the fuel recycling facility.

§ 7x.34 Baseline Design Criteria

This section sets out the BDC for the facility. The BDC are applied from the outset to new design work and are primarily focused on physical design and facility features. The BDC is a key part of the overall safety envelope of the facility. The BDC set out minimum requirements to be applied as design and safety considerations for the facility and future modifications and incorporate a fundamental element of NRC's safety philosophy that designs and operations should provide for defense-in-depth protection against accidents. The intent is to achieve a conservatively designed facility tolerant of both upsets and human errors. Training, testing, and qualification of personnel to maintain the BDC during construction and operation must be addressed under management measures required by the safety program described in §7x.30(c)(3). It is recognized as noted above, and in the development of 10 CFR 70.64, that BDC are generally an acceptable set of initial design safety considerations, which may not be sufficient to ensure adequate safety for all new processes and facilities. The ISA process is intended to identify additional safety features that may be needed. 64 FR 41338 (July 30, 1999).

The application for new facilities must describe in §7x.30 (c)(1) how the BDC were applied to the design and operation. As provided in §7x.30, the applicant will need to explain in a summary format how the applicant addressed the BDC in §7x.34 to achieve the performance requirements of § 7x.32. It is not envisioned that the applicant will necessarily be required to describe on a system by system basis how the BDC are met as this will ultimately be captured by the ISA and the identification of IROFS. In addition licensees are required to address the BDC in the design

of new processes at existing facilities that require a license amendment under § 7x.66. The BDC, as applied in the application and approved by the NRC, cannot be changed during construction of the facility without Nuclear Regulatory Commission approval and would remain applicable for the life of the facility unless it could be demonstrated in the ISA that a baseline design criterion as applied is not required for or to support any IROFS, in which case the application of the BDC could be modified pursuant to the change process in §7x.66. Given the scope of activities and many processes that will exist at a fuel recycling facility, there may be processes or portions of the facility for which some of the BDC may not be necessary or appropriate, or need to be fully applied based on the results of the ISA. Any design features that are inconsistent with the BDC will need to be identified and justified. However, given the source term involved with the "production facility" aspect of a fuel recycling facility, it is expected that a higher standard will apply to the review of any proposed justification to not include a BDC for that aspect of the facility.

The proposed framework in §7x.34 adopts the introductory language of 10 CFR 70.64(a) and expands the BDC in 10 CFR 70.64 adding applicable general design criteria from 10 CFR Part 50 and from 10 CFR Part 72, as well as, newly developed criteria. It also includes applicable provisions from Appendix F of part 50. The resulting 28 design criteria have been termed BDC (BDC) for a fuel recycling facility.

Each criterion is addressed below:

I. Overall Requirements

(1) *Criterion 1- Design concepts*. This criterion is derived from 10 CFR 70.64(b) and was developed to be consistent with the defense-in-depth design philosophy as defined in WASH-1250 and to reflect the Commission's current guidance on the relationship between defense-in-depth and risk-informed regulation that is discussed in the Commission policy white paper, "Risk-Informed and Performance-Based Regulation."

(2) *Criterion 2-Quality Standards and records*. This criterion is derived from 10 CFR 70.64(a)(1) and was developed to help protect the public from the potentially large source term which is present at a recycling facility. To accomplish this consistent with other licensed facilities with large source terms, the structures, systems, and components that supports IROFS should be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. It adopts the quality assurance criteria of 10 CFR Part 50, Appendix B in a graded manner. A graded approach is warranted based on the scope of the facility and its range of consequences and likelihoods that could be licensed under this part. It is not expected that all aspects of the facility will need to be subject to the full application of Appendix B. Where generally recognized codes and standards are used, they should be identified and evaluated to determine their applicability, adequacy, and sufficiency and they should be supplemented or modified as necessary to assure a quality product in keeping with the required safety function. A quality assurance program should be established and implemented in order to provide adequate assurance that these structures, systems, and components will satisfactorily support and/or function as an item relied on for safety. Appropriate records of the design, fabrication, erection, and testing of structures, systems, and

components required to support, or used as an item relied on for safety should be maintained by or under the control of the licensee throughout the life of the unit.

(3) *Criterion 3- Design bases for protection against natural phenomena*. This criterion is derived from 10 CFR 70.64(a)(2) and 72.122(b) and was developed to ensure the protection of the facility and hence the public from potentially large source term releases from recycling facilities which could result from the occurrence of natural phenomena. This criterion was developed to ensure that IROFS or systems or components which support IROFS are designed with consideration from the impacts posed by natural phenomena which are known to exist for the recycling facility's site location. A list of natural phenomena to be addressed is cited in the criterion. Additional natural phenomena may need to be addressed depending upon the site specifics of the location.

(4) *Criterion 4- Site selection*. This criterion is derived from 10 CFR Part 72, subpart E and Appendix F. of Part 50. To ensure adequate protection to the off-site public the site must be selected such that the site can comply with the siting evaluation factors of Part 72 as if the fuel recycling facility was an ISFSI or MRS and the dose at the site boundary must not exceed the doses in 10 CFR 72.106. The provision concerning private land comes from Paragraph (1) of Appendix F.

(5) *Criterion 5- Fire protection*. This criterion is derived from 10 CFR 70.64(a)(3) and 72.122(c). To help protect the public from the risk of exposure to radioactive materials, this criterion was developed to ensure that IROFS or systems or components which support IROFS are designed and located to minimize, consistent with other safety requirements, the likelihood and effect of fires and explosions. Consistent with this approach is the need to utilize where possible noncombustible and heat resistant materials. Fire detection and fighting systems of appropriate capacity and capability should be provided and designed to minimize the adverse effects of fires on structures, systems, and components in support of or used as an item relied on for safety. Firefighting systems should also be designed to assure that their rupture or inadvertent operation does not significantly impair the safety capability of these structures, systems, and components.

(6) *Criterion 6- Environmental and Dynamic effects design bases*. This criterion is derived from 10 CFR 70.64(a)(4) and environmental qualification requirements of Part 50. For those components and systems which do not support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, the baseline design criterion on environmental and dynamic effects does not require a formal Equipment Environmental Qualification Program. This criterion applies to new facilities and new processes and is intended to ensure that potential dynamic conditions are considered during the design of the facility.

For those portions of the recycling facility with inherent large source terms, such that the components and systems support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, the baseline design criterion on

environmental and dynamic effects requires a formal Equipment Environmental Qualification Program, similar to that required under 10 CFR 50.49 and Regulatory Guide 1.89.

(7) *Criterion 7- Control rooms*. This criterion is derived from 10 CFR 50.34 and Part 50, Appendix A, Criterion 19. To help protect the public from the risk of exposure to radioactive materials, this criterion was developed to ensure that operators are able and available to perform safety related functions for the facility. To allow flexibility in operations the framework does not require that all these actions need be taken from one central control room and it recognizes that in some applications multiple control rooms may be afforded to achieve the needed protection. The rule requires that one or more control rooms be provided from which actions can be taken to operate the fuel recycling facility safely under normal conditions and to maintain it in a safe condition under accident conditions. These control rooms are also to be designed to provide adequate protection from chemical or radiological releases. The design is to consider the need for simulator capability that correctly models the control room in addressing actions to prevent or mitigate high consequence events, as defined in 7x.32, for identified accident scenarios involving fission product releases to an individual outside the controlled area.

II. Radiological Protection

(8) *Criterion 8- Criticality control*. This criterion is derived from 10 CFR 70.64(a)(9). The rule proposes that a separate performance requirement for nuclear criticality prevention is appropriate and this is in conjunction with application of the double contingency principle It is recognized because of the design of the facility that not all nuclear criticality accidents would reasonably be expected to result in worker doses that exceed the high- and intermediate-consequence standards in §7x.32. However, regardless of the dose directly resulting from the accident, an inadvertent nuclear criticality must be avoided. This is consistent with the Commission's goal to prevent inadvertent criticalities, as reflected in the NRC Strategic Plan.

(9) *Criterion 9- Radiation shielding.* This criterion is derived from 10 CFR 50.34 (f)(2)(viii) and ensures that adequate radiation shielding is incorporated into the design. To ensure access to areas needed to both conduct operations and mitigate against consequences of operational upsets or accidents, shielding is needed to prevent unnecessary exposure to the facility operators. To provide adequate protection of the public from exposure to radiological materials shielding is also needed to protect the public.

(10) *Criterion 10-Fuel storage and handling and radiological control*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 61 and is to ensure that systems designed to handle radioactive materials, including both fuel product and wastes, are designed to ensure adequate safety under normal and postulated accident conditions. To ensure that the systems accomplish these objectives the design must address several attributes which are described in the Criterion. Achieving these objectives during the design of these systems will ensure that safety for the public and for the facility operators is achieved and maintained.

(11) *Criterion 11- Monitoring fuel and waste storage*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 63. With large source terms and the associated decay heat produced, heat removal systems must be available at a recycling facility to remove the heat and maintain

the materials within the design temperature limitations of the facility. This criterion ensures that the needed systems to accomplish these objectives as described in Criterion 10 are provided with adequate and reliable monitoring systems to ensure that adequate protection is available.

(12) *Criterion 12- Monitoring radioactive releases*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 64. To preclude the release of radioactive materials from the facility to the environment resulting in exposure to the public and to prevent unnecessary exposure of the operators to radiological materials, a confinement is provided for the facility. This criterion provides that a means be provided to measure the confinement atmosphere and plant environs for radioactivity that may be released during normal operations, including anticipated operational occurrences, and from postulated accidents. This will ensure that any facility releases to the confinement will be detected and addressed promptly, further ensuring that the public will not be exposed to radioactive releases.

(13) *Criterion 13- Control of releases of radioactive materials to the environment.* This criterion is derived from 10 CFR 50.34a and Part 50, Appendix A, Criterion 60. The proposed framework recognizes that the dose limits for normal operation are contained in 10 CFR Part 20 [viz., 0.05 Sv (5 rem) Total Effective Dose Equivalent (TEDE)/yr for a trained worker]. It also views "anticipated occurrences" to be conditions of normal operations, and believes that the measures currently used to comply with Part 20 have been and will continue to be successful in protecting workers and the public during normal operations. However to add clarity to the specific waste issues embodied in the application of recycling technology, the framework has provided additional requirements to control the release of gaseous and liquid effluents which contain radioactive materials and specifies additional design requirements to allow the adequate and safe disposition of these waste streams.

(14) *Criterion 14- Inventory limitation*. This criterion is derived from 10 CFR Part 50, Appendix F, paragraph (2). This criterion ensures that liquid waste products not be allowed to accumulate on site beyond a reasonable inventory defined in the criterion as that waste which is 5 years of age or less. Increasing inventories of waste products increases the site source term and the potential risk to the public and the environment. The criterion also requires that high level liquid radioactive wastes be converted to a dry solid to comply with this inventory limitation. Dry solids pose less risk off-site to the public and the environment.

III. Chemical and Hazardous Materials Protection

(15) *Criterion 15- Chemical protection*. This criterion is derived from 10 CFR 70.64(a)(5). Potentially hazardous chemicals are utilized at recycling facilities to achieve operational objectives. This criterion ensures that adequate measures are in place to afford protection of the public and the operators from chemical risks produced from licensed material, facility conditions which affect the safety of licensed materials, and hazardous chemicals produced from licensed materials.

(16) *Criterion 16- Emergency capability*. This criterion is derived from 10 CFR 70.64(a)(6). Because of the off-site risk to the public from the inventory of fission products on-site, the facility must provide for on-site and off-site emergency capability as defined in Criterion 16.

IV. Equipment Services Protection

(17) *Criterion 17- Utility services*. This criterion is derived from 10 CFR 70.64(a)(7). To ensure adequate protection of the public from the source term of the facility, the design must provide for continued operation of essential services for IROFS and their necessary components. Continued operation of utility services will ensure that adequate heat removal of fission product decay heat and an operable facility confinement are maintained thus protecting the off-site public from radiological exposure.

(18) *Criterion 18- Electric power systems*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 17 and requires an adequate electrical system which will achieve the necessary diversity and redundancy to ensure reliable electric supply, such that the design for those portions of the recycling facilities with inherent large source terms, including the components and systems that do support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, will be provided. It is also intended to ensure that potential accident and dynamic conditions which could result from these releases which occur as a result of a loss of the electric power systems are considered and addressed during the design of the facility.

(19) *Criterion 19-Inspection and testing of electric power systems*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 18. It requires an adequate inspection and testing regime for the electrical system to ensure that the electrical system achieves the necessary diversity and redundancy to ensure reliable electric supply, such that the design for those portions of the recycling facilities with inherent large source terms, including the components and systems that do support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, will be provided. It is also intended to ensure that potential accident and dynamic conditions which could result from these releases which occur as a result of a loss of the electric power systems are considered and addressed during the design of the facility.

(20) *Criterion 20- Inspection, testing, and maintenance*. This criterion is derived from 10 CFR 70.64(a)(8). The BDC are applied from the outset of new design work and are primarily focused on physical design and facility features. The intent is to achieve a conservatively designed facility tolerant of both upsets and human errors. Adequate training, testing, and qualification for site personnel will be required as management measures under §§7x.30(c)(3) and 7x.36

(21) *Criterion 21- Instrumentation and controls.* This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 13. To achieve and maintain safety for the onsite personnel and the off-site public, the facility must have adequate instrumentation and control. This criterion is intended to provide for inclusion of instrumentation and control systems to monitor and control the behavior of all IROFS and to ensure that instrumentation is available to monitor variables and systems over their anticipated ranges for normal operations, for anticipated operational occurrences, and for accident conditions as appropriate to assure safety.

V. Facility Confinement Protection

(22) *Criterion 22- Confinement design.* This criterion is derived from 10 CFR 50.34 (f)(2)(vi) and Part 50, Appendix A, Criterion 16. It requires that facility confinement, process equipment, and associated systems shall be designed to establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment and to assure that the confinement conditions, i.e., design components and systems needed to support or function as IROFS, are not exceeded for as long as postulated accident conditions require. This ensures that the confinement design will protect the on-site operators and the off-site public from a radiological release from the facility during normal or upset conditions and ensures that following an accident, the confinement system will be operational and will maintain its safety function in protecting the operators and the public from the effects of a radiological release. The design attributes specified in the criterion provide additional design performance detail needed to ensure that the system remains operational and functional during operations and following upset and accident conditions.

(23) *Criterion 23- Residual Heat removal*. This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 34. Removal of residual heat and transfer of decay heat and other residual heat from the confinement system ensures that the confinement will continue to perform its safety function such that the confinement performance requirements are not exceeded. This heat removal is essential for the confinement system operation and helps ensure that the confinement system will provide protection to the operators and the public from the release of radioactive materials.

(24) *Criterion 24- Cooling* . This criterion is derived from 10 CFR Part 50, Appendix A, Criterion 44. With the production of heat from decay heat and facility components, an ultimate heat sink must be provided to ensure facility safety during normal operations and during and following postulated accidents. This criterion ensures that the residual heat removal system, which is needed to ensure component and confinement safety has an ultimate heat sink to which to direct waste and decay heat.

(25) *Criterion 25- Hydrogen control*. This criterion is derived from 10 CFR 50.34 (f)(2)(ix). Hydrogen generation occurs as a result of chemical reactions at a recycling facility. Hydrogen also is created during the radiolytic decomposition of radioactive materials. This hydrogen which is produced must be prevented from accumulating in areas where it could cause in inadvertent conflagration, detonation or explosion which in turn could endanger personnel onsite or could through rupture of facility confinement expose the off-site public to radioactive materials. This criterion requires that the facility be designed to safely accommodate this hydrogen generated. Specific design attributes in the criterion define how this may be done.

(26) *Criterion 26- Leakage control and detection*. This criterion is derived from 10 CFR 50.34 (f)(2)(xxvi). Systems which provide a pathway from the confinement to the outside environment must be monitored for leakage to ensure that a pathway is not created which would allow the release of radioactive materials which the design intended to be contained within the

confinement, to reach the outside environment. This protects the public and the environment from the potential release of radioactive materials.

(27) *Criterion 27- Spent fuel cladding*. This criterion is derived from 10 CFR 72.122(h)(1). Consistent with the requirements of 10 CFR Part 72 this criterion requires that the design provide that for spent fuel in storage that the spent fuel cladding must be protected during storage against degradation that leads to gross ruptures. The cladding of the fuel provides a barrier against the release of radioactive materials contained in spent fuel. Protecting this cladding provides additional assurance that radiological materials will not be released to the environment or cause unnecessary exposure to onsite personnel.

(28) *Criterion 28- Underwater storage*. This criterion is derived from 10 CFR 72.122(h)(2). Consistent with the requirements of 10 CFR Part 72 this criterion requires that underwater storage of spent fuel be designed such that the pool water serves as a shield and a confinement medium for radioactive materials. To provide protection to onsite personnel and to preclude the likelihood of an accident which could cause the spent fuel pool to drain the criterion provides additional detail to ensure a safe and robust spent fuel pool.

§ 7x.36 Safety Program, Integrated Safety Analysis and Summary

This section requires the applicant to establish and maintain (1) a safety program including an ISA and (2) an ISA Summary that is based on its ISA. The applicant in accordance with §7x.30(c) must describe its safely program and ISA Summary. The requirements the applicant needs to meet for its safety program and ISA Summary are described in §7x.30 (c). This section is derived from 10 CFR 70.62 and 70.65 and the definitions in § 70.4.

§ 7x.38 Financial assurance and recordkeeping for decommissioning.

This section is derived from 10 CFR 70.25.

§ 7x.40 Technical specifications

This section addresses technical specifications for the facility. The AEA requires technical specifications for a fuel recycling facility because it is a production facility. However, since many aspects of the facility may not involve production activities, the use of technical specifications is limited to the risk significant aspects of producing special nuclear materials. As a result technical specifications under Part 7x focus on IROFS designed to protect against identified accident scenarios as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area. Applicants are required to propose technical specifications to address IROFS derived from the analyses and evaluation included in the ISA prepared pursuant to § 7x.36. IROFS are the focus of technical specifications because IROFS are structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 7x.32 or to mitigate their potential consequences and are developed from the ISA.

Technical specifications must address two categories of IROFS: (1) loss of all IROFS and (2) loss of one or more IROFS that results in failure to meet the performance requirement of § 7x.32. Depending on the category level, the licensee is required to take specific actions and make reports within the time frames required by §7x.90 to the NRC concerning the occurrence of the event or condition. If a notification is required to a State or local agency for an emergency response purpose, such notification should be made before notifying the NRC. The notification times have some flexibility because a licensee needs to ensure that reporting does not interfere with plant operations. However, this does not mean that a licensee should automatically wait until close to the time limit expiration before reporting to the NRC.

Subpart D. –License Issuance and Conditions

§ 7x.50 Issuance of licenses

This section is derived from 10 CFR 50.40, 50. 42, 50.45, 50.50, 50.51, 50.53, 52.104, 70.23, 70.31, and 70.66. Section 7x.50 provides general approval conditions which are applicable for all licenses. Additional specific approval conditions applicable to different types of licenses are found in §§ 7x.52-56. In the past Parts 50 and 70 had separate sections for the requirements for approval of applications and the standards for license issuance. Section 7x.50 combines these separate sections into one section entitled "issuance of licenses." It requires that the applicant satisfy the NRC that: all the applicable requirements which would include the application requirements in part 7x, subpart C have been met; any required notifications to other agencies or bodies have been made; the applicant is technically and financially qualified to engage in the activities authorized; issuance of the license will not be inimical to the common defense and security nor constitute an unreasonable risk to the health and safety of the public; and the proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material or source material to be utilized. In addition the section addresses the term of license and license termination.

§ 7x.52 Additional requirements for issuance of construction permits

This section is derived from 10 CFR 50.35, 50.45, 50.56, 52.97, and 70.23(b). This section addresses the findings that must be made by the NRC, after the hearing process and Advisory Committee on Reactor Safeguards (ACRS) reviews are completed, to issue a construction permit. It recognizes that the design might not be complete but that there is reasonable assurance that (1) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (2) taking into consideration the site criteria contained in Part 7x, the design bases of the principal structures, systems, and components, and the quality assurance program provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents in order to meet the performance requirements in §7x.32 such that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

It also provides that a construction permit will constitute an authorization to the applicant to proceed with construction but will not constitute NRC approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such

approval is incorporated in the permit. In addition, it provides that a license authorizing operation of the facility will not be issued by the NRC until it has found that the final design provides reasonable assurance that the health and safety of the public will not be endangered by operation of the facility in accordance with the requirements of the license and the regulations in this chapter.

This section also provides that alteration of a license to operate a fuel recycling facility will require a construction permit.

§ 7x.54 Additional requirements for issuance of operating license

This section is derived from 10 CFR 50.57 and 52.97. This section addresses the findings that must be made by the NRC, after any hearing process and ACRS reviews are completed, to issue an operating license. It requires the findings made for a reactor operating license under Part 50.

§ 7x.56 Additional Requirements for Issuance of combined licenses

This section is derived from 10 CFR 52.97. This section addresses the findings that must be made by the NRC, after any hearing process and ACRS reviews are completed, to issue a combined license. It requires the findings made for a reactor combined license under Part 52.

§ 7x.58 Requirements applicable to combined licenses

This section is derived from 10 CFR 52.98, 52.99, and 52. 103. It provides the requirements from Part 52 that address finality of combined licenses, inspection during construction, and operation under a combined license. Some of the requirements from §52.98 not included in this section are in §§ 7x.60 and 7x.72.

§ 7x.60 Conditions of licenses.

This section is derived from 10 CFR 50.54, 50.74, 52.98, 70.24, 70.25, 70.32, and 70.62. The conditions prescribed by this section are applicable whether or not they are also stated in the license. Conditions addressed include: maintaining the safety program including the ISA and ISA Summary; bankruptcy notification; requests for additional information; maintaining the decommissioning funding plan; maintaining the operator certification program and prohibiting non-licensed operators from performing certain operations; maintaining the emergency plan, material control and accounting program, plan for physical protection of special nuclear material in transit, security plan, and safeguards contingency plan; protecting physical security, safeguards contingency, and guard qualification and training plans and other related Safeguards Information; criticality monitoring and emergency procedures; procedures to depart from certain requirements under emergency conditions; possession of byproduct, source, or special nuclear material associated with operation of the facility; and antitrust matters. The change process in §7x.66 governs the changes that affect the Safety Report descriptions except for changes to the quality assurance program described in the Safety Report, as required by the management measures in §7x.30(c)(3)(vi). The change process for quality assurance is adopted from 10 CFR

50.54 (a). Other change processes are based on 10 CFR Part 70. Many of these sections include change processes based on 10 CFR 70.32.

§ 7x.62 Environmental conditions.

This section is derived from 10 CFR 50.36b and address conditions to protect the environment during construction, operation, and decommissioning based on the applicant environmental report and NRC's environmental evaluations.

§ 7x.64 Conditions for construction under construction permits and combined licenses.

This section is derived from 10 CFR 50.55. It includes a change process for the quality assurance programs for holders of construction permits and combined licenses prior to the date that the Commission makes the finding under § 7x.58(c)(7). The reporting process of 10 CFR 50.55 (e) was not included because 10 CFR Part 21 is applicable to these licensees. In addition, it included a provision for providing IAEA with information and implementing the US/IAEA Safeguards Agreement consistent with § 7x.20(i) and 10 CFR 50.78.

§ 7x.66 Facility changes and change process.

This section is derived from 10 CFR 50.59 (c)(3), 50.71, and 70.72. It requires that the facility and operation be maintained as described by the Safety Report unless the procedures for change described in this section are followed. Included in the threshold for NRC approval are changes that are prohibited by Part 7x and technical specifications. The section adopts language from §§50.59 and 50.71 that makes it clear that the updated Safety Report, based on changes resulting from evaluations performed pursuant to this section, analyses performed pursuant to §7x.70, and any other analysis performed by or for the licensee at the request of the NRC since submittal of the last update of the Safety Report, becomes the baseline for future evaluations under this section. It also requires an annual certification similar to §50.71 be certified by a licensee official that the submittal accurately presents changes made since the last submittal

§ 7x.68 Backfitting.

This section is derived from 10 CFR 70.76.

Subpart E. - Amendment of License or Construction Permit at Request of Holder, Renewal, and Termination

§ 7x.70 Application for amendment of license or construction permit.

This section is derived from 10 CFR 50.90.

§ 7x.72 Notice for public comment; State consultation.

This section is derived from 10 CFR 50.91. It provides for issuing amendments without a prior hearing based on exigent circumstances as in Part 50. However, the exception for emergency

situations that are contained in 10 CFR 50.91 were not included because of the nature of the facility, i.e., it is not providing electricity to the public. However, if an emergency situation occurs where a timely amendment must be issued to prevent an imminent danger to the health or safety of the public, the NRC may do so without prior notice and a hearing.

§ 7x.74 Issuance of amendment.

This section is derived from 10 CFR 50.92. It adopts the significant hazards standards from Part 50.

§ 7x.76 Renewal of licenses.

This section is derived from 10 CFR70.33 and 70.35.

§ 7x.78 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

This section is derived from 10 CFR 50.51 and 70.38.

Subpart F-Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights

§ 7x.80 Authorized use of special nuclear material.

This section is derived from 10 CFR 70.41.

§ 7x.82 Transfer of licenses.

This section is derived from 10 CFR 50.80 and 70.36.

§ 7x.84 Creditor regulations.

This section is derived from 10 CFR 70.44. The definition of “creditor” has been placed in §7x.3.

Subpart G—Reports, Records, and Inspections

§ 7x.90 Reporting requirements.

This section is derived from 10 CFR 70.50, 70.52, and 70.74 including Appendix A to Part 70.

§ 7x.92 Additional Reporting Requirements.

This section is derived from 10 CFR 50.71(b) and 70.59.

§ 7x.94 Records requirements.

This section is derived from 10 CFR 50.71(a) and 70.51.

§ 7x.96 Inspections.

This section is derived from 10 CFR 50.70 and 70.55

§ 7x.98 Tests.

This section is derived from 10 CFR 70.56.

Subpart H--Modification and Revocation of Licenses

§ 7x.100 Modification and revocation of licenses.

This section is derived from 10 CFR 70.81.

§7x.102 Suspension and operation in war or national emergency.

This section is derived from 10 CFR 50.103.

Subpart I—Licensed operators

This subpart is derived from the applicable sections from 10 CFR Part 55 adjusted to provide for licenses issued on the basis for a certification by the facility licensee rather than testing by the NRC. The facility licensee's certification program is discussed above in the discussion of §7x.30(p). In addition, this subpart licenses only an operator and not both an operator and senior operator. The certification program is designed to ensure technical competency. The facility licensee should decide which of its certified operators should be supervisors.

This subpart only addresses requirements for the applicant or licensed operator. Requirements for the facility licensee are in §§7x.30(p) and 7x.60 (m). It is important to note that this subpart only addresses licensed operators. The facility licensee will have many other operators who will not need to be licensed by the NRC but will need to be trained and qualified in accordance with the licensee's safety program.

§ 7x.110 Operator license requirements.

This section is derived from 10 CFR 55.3 and 55.13.

§ 7x.112 Definitions.

This section is derived from applicable definitions in 10 CFR 55.4.

§ 7x.114 Medical examination.

This section is derived from 10 CFR 55.21.

§ 7x.116 Medical Certification.

This section is derived from 10 CFR 55.23.

§ 7x.118 Incapacitation because of disability or illness.

This section is derived from 10 CFR 55.25.

§ 7x.120 Documentation.

This section is derived from 10 CFR 55.27.

§ 7x.122 Application requirements.

This section is derived from 10 CFR 55.21.

§ 7x. 124 Disposition of an initial application.

This section is derived from 10 CFR 55.33.

§ 7x.126 Integrity of examinations and tests.

This section is derived from 10 CFR 55.49.

§ 7x.128 Issuance of operator licenses.

This section is derived from 10 CFR 55.51.

§ 7x.130 Conditions of operator licenses.

This section is derived from 10 CFR 55.53.

§ 7x.132 Expiration.

This section is derived from 10 CFR 55.55.

§ 7x.134 Renewal of operator licenses.

This section is derived from 10 CFR 55.57.

§ 7x.136 Modification and revocation of operator licenses.

This section is derived from 10 CFR 55.55.61.

Subpart J-- Enforcement

§ 7x.140 Violations.

This section is derived from 10 CFR 70.91.

§ 7x.142 Criminal penalties.

This section is derived from 10 CFR 70.92.

B. Explanation for Proposed Amendments to Other Parts of 10 CFR

In order to establish a new regulatory framework for licensing fuel recycling facilities under the proposed Part 7x, amendments will be needed to various rules of the Commission in Title 10 of the Code of Federal Regulations. This section discusses the reasons for the changes. Many of the changes reflect references to the new Part 7x and to new sections within Part 7x corresponding to the former sections that would be applicable to a reprocessing facility under Part 50.

PART 2--RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

The changes to Part 2 are intended to apply the same procedures to a fuel recycling facility as would be applied to a power reactor since a fuel recycling facility is a production facility and subject to essentially the same procedural provisions as a power reactor under the AEA. Part 7x references and addition of fuel recycling facilities were added to §§ 2.101, 2.104, 2.105, 2.106, 2.109, 2.202, 2.309, 2.310, 2.239, 2.339, 2.340, 2.341, 2.1202, and 2.1301.

PART 19--NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

The changes to Part 19 are intended to make a fuel recycling facility subject to the same requirements as any other licensee. Part 7x references were added to §§ 19.2 and 19.20.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

The changes to Part 20 are intended to make a fuel recycling facility subject to the same requirements as any other licensee. Part 7x references were added to §§ 20.1002, and 20.1401.

PART 21--REPORTING OF DEFECTS AND NONCOMPLIANCE

The changes to Part 20 are intended to make a fuel recycling facility subject to the same requirements as any other licensee. Part 7x references and addition of fuel recycling facility were added to §§ 21.2, 21.3, and 21.21.

PART 25—ACCESS AUTHORIZATION

The change to Part 25 is intended to make a fuel recycling facility subject to the same requirements as any other licensee. A reference to Part 7x references was added to § 25.17.

PART 26--FITNESS FOR DUTY PROGRAMS

The changes to Part 26 are intended to apply the same requirements to a fuel recycling facility as would be applied to a power reactor. Part 7x references and addition of fuel recycling facilities were added to § 26.3.

PART 50--DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

The changes to Part 50 are intended to remove the regulation and licensing of fuel reprocessing facilities. Part 50 would continue to apply to other production facilities. Section 50.1 would be changed to state that Part 50 does not apply to a fuel recycling facility subject to Part 7x. A footnote in §50.34 that provided that general design criteria were being developed for chemicals facilities was deleted. Changes to the following sections of Part 50 were made to delete applicability or references to fuel reprocessing facilities: §§ 50.30, 50.34, 50.36, 50.54, and 50.55. In addition changes were made to Appendix B. Appendix F was deleted.

PART 51--ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

The changes to Part 51 are intended to apply the same requirements to a fuel recycling facility as would be applied to a power reactor. Part 7x references and addition of fuel recycling facilities were added to § 51.4, 51.20, 51.22, 51.49, 51.50, 51.33, 51.101, 51.103, 51.105, 51.107, and 51.108.

PART 70--DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

The changes to Part 70 are intended to remove the regulation and licensing of fuel recycling facilities. Section 70.1 would be changed to state that Part 70 does not apply to a fuel recycling facility subject to Part 7x. A definition is added to define the term fuel recycling facility in § 70.4.

PART 95—FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

The change to Part 95 is intended to make a fuel recycling facility subject to the same requirements as a reactor. A reference to Part 7x references was added to § 95.5.

PART 150--EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

The change to Part 150 is intended to make a fuel recycling facility regulated under Part 7x be subject to the same requirements as was a reprocessing facility regulated under Part 50. In §150.3 the definition for “production facility” is amended and a definition for “fuel recycling facility” is added and §150.15 is amended.

Appendix B

This appendix provides conceptional text for a new Part 7x to provide the licensing framework for a fuel recycling facility. The text follows:

PART 7X - LICENSING REQUIREMENTS FOR RECYCLING FACILITIES

Authority:

Subpart A General Provisions

§ 7x.1 Basis, purpose, and scope procedures applicable.

§7x.2 Requirements for a License.

§7x.3 Definitions.

§ 7x.4 Communications.

§ 7x.5 Interpretations.

§ 7x.6 Employee protection.

§ 7x.7 Information collection requirements: OMB approval.

§ 7x.8 Completeness and accuracy of information.

§ 7x.9 Deliberate misconduct.

Subpart B - Requirement of License, Exceptions and exemptions

§ 7x.10 License required for Construction; limited work authorization.

§ 7X.11 Exceptions and exemptions from licensing requirements.

§ 7x.12 Specific exemptions.

§ 7x.13 Attacks and destructive acts by enemies of the United States; and defense activities.

§ 7x.14 Class 103 licenses; for commercial and industrial facilities.

§ 7x.15 Construction permits and combined licenses.

Subpart C – Requirements for Applicants

§ 7x.20 Filing of application; oath or affirmation.

§ 7x.22 Combining and separation of licenses.

§ 7x.24 Ineligibility of certain applicants.

§ 7X.26 Hearings and report of the Advisory Committee on Reactor Safeguards.

§ 7x.28 Contents of applications; general information.

§ 7x.30 Contents of applications; Technical information.

§ 7x.32 Performance requirements.

§ 7x.34 Baseline Design Criteria.

§ 7x.36 Safety Program, Integrated Safety Analysis and Integrated Safety Analysis Summary.

§ 7x.38 Financial assurance and recordkeeping for decommissioning.

§ 7X.40 Technical specifications.

Subpart D - Licenses and License Conditions

§ 7x.50 Issuance of licenses.

§ 7x.52 Additional requirements for issuance of construction permits.

§ 7x.54 Additional requirements for issuance of operating license.

§ 7x.56 Additional requirements for issuance of combined licenses.

§ 7x.58 Requirements applicable to combined licenses.

§ 7x.60 Conditions of licenses.

§ 7x.62 Environmental conditions.

§ 7x.64 Conditions for construction under construction permits and combined licenses.

§ 7x.66 Facility changes and change process.

§ 7x.68 Backfitting.

Subpart E - Amendment of License or Construction Permit at Request of Holder, Renewal, and Termination

§ 7x.70 Application for amendment of license or construction permit.

§ 7x.72 Notice for public comment; State consultation.

§ 7x.74 Issuance of amendment.

§ 7x.76 Renewal of licenses.

§ 7x.78 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

Subpart F-Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights

§ 7x.80 Authorized use of special nuclear material.

§ 7x.82 Transfer of licenses.

§ 7x.84 Creditor regulations.

Subpart G—Reports, Records, and Inspections

§ 7x.90 Reporting requirements.

§ 7x.92 Additional Reporting Requirements.

§ 7x.94 Records requirements.

§ 7x.96 Inspections.

§ 7x.97 Tests.

Subpart H--Modification and Revocation of Licenses.

§ 7x.100 Modification and revocation of licenses.

§ 7x.102 Suspension and operation in war or national emergency.

Subpart I—Licensed operators

§ 7x.110 Operator license requirements.

§ 7x.112 Definitions.

§ 7x.114 Medical examination.

§ 7x.116 Medical Certification.

§ 7x.118 Incapacitation because of disability or illness.

§ 7x.120 Documentation.

§ 7x.122 Application requirements.

§ 7x. 124 Disposition of an initial application.

§ 7x.126 Integrity of examinations and tests.

§ 7x.128 Issuance of operator licenses.

§ 7x.130 Conditions of operator licenses.

§ 7x.132 Expiration.

§ 7x.134 Renewal of operator licenses.

§ 7x.136 Modification and revocation of operator licenses.

Subpart J-- Enforcement

§ 7x.140 Violations.

§ 7x.142 Criminal penalties.

PART 7X LICENSING REQUIREMENTS FOR RECYCLING FACILITIES

Subpart A. General Provisions

§ 7x.1 Basis, purpose, and scope procedures applicable.

a) The regulations in this part are promulgated by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), to provide for the licensing of fuel recycling facilities that includes recycling spent fuel and may include it's associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing, waste processing, waste storage, fuel fabrication, and storage of new fuel. The regulations also provide for the licensing of operators certified as fuel recycling operators by the facility applicant and licensee to the NRC.

b) The regulations in this part also establish procedures and criteria for the issuance of licenses to operators certified as fuel recycling operators by the facility applicant and licensee to the NRC.

c) This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, or consultant of any of them components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 7x.9.

d) Except as provided in § 7x.11, the regulations in this part apply to all persons in the United States. In addition, the regulations in this part do not apply to the Department of Defense to the extent that the Department receives, possesses and uses special nuclear material in accordance with the direction of the President pursuant to section 91 of the Act.

§7x.2 Requirements for a License.

(b) *Requirement for license*. Except as provided in § 7x.11 of this chapter, no person within the United States shall transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use any fuel recycling facility except as authorized by a license issued by the Commission.

(c) *Requirement for construction permit, combined license, or limited work authorization*. No person may begin the construction of a fuel recycling facility on a site on which the facility is to be operated until that person has been issued either a construction permit, a combined license, or a limited work authorization under this part.

§7x.3 Definitions.

This section provides definitions to be used in this part. Section 7x.112 provides definitions to be used in subpart I of this part. As used in this part:

Act means the Atomic Energy Act of 1954 (68 Stat 919), including any amendments thereto;

Acute, as used in 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).

Agreement State as designated in part 150 of this chapter means any State with which the Commission has entered into an effective agreement under subsection 274b. of the Act. Non-agreement State means any other State.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material[s] but that the release is not expected to require a response by an off-site response organization to protect persons off-site.

Atomic energy means all forms of energy released in the course of nuclear fission or nuclear transformation;

Atomic weapon means any device utilizing atomic energy, exclusive of the means for transporting or propelling the device (where such means is a separable and divisible part of the device), the principal purpose of which is for use as, or for development of, a weapon, a weapon prototype, or a weapon test device;

Available and reliable to perform their function when needed, as used in this part, means that, based on the analyzed, credible conditions in the ISA, IROFS will perform their intended safety function when needed, and management measures will be implemented that ensure compliance with the performance requirements of this part, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

Combined license means a combined construction permit and operating license.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives;

Common defense and security means the common defense and security of the United States;

Configuration management (CM) means a management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of IROFS to perform their functions when needed.

Construction means the activities in sub paragraph (1) below, and does not mean the activities in sub paragraph (2):

(1) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(i) IROFS;

(ii) Structures, systems, and components necessary to comply with 10 CFR part 73; and

(iii) Onsite emergency facilities, that is, technical support and operations support centers, necessary to comply with the emergency preparedness requirements of this part.

(2) Construction does not include:

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities, such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines;

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility.

Contiguous sites means licensee controlled locations, deemed by the Commission to be in close enough proximity to each other, that the special nuclear material must be considered in the aggregate for the purpose of physical protection.

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Creditor means, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

Critical mass of special nuclear material 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.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Department and Department of Energy means the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.), to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the ISA can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

Double contingency principle means that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Effective dose equivalent means the sum of the products of the dose equivalent to the body organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Facility means a fuel recycling facility.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U-235)+2.5 (grams U-233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

Fuel recycling facility means a facility for recycling and its associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel to the extent such associated activities are included in the application and or license for the fuel recycling facility. A fuel recycling facility is a production facility.

General Emergency mean events may occur, are in progress, or have occurred that could lead to radioactive releases that can reasonably be expected to exceed the Environmental Protection Agency's Protection Action Guidelines for more than the immediate site area.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

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; and 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.

High-level radioactive waste (HLW) means: the highly radioactive material resulting from recycling of spent nuclear fuel, including liquid wastes produced directly in recycling (i.e., liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent) and any solid material derived from such liquid waste that contains fission products in sufficient concentrations. HLW does not include waste incidental to recycling.

Integrated safety analysis (ISA) means a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the IROFS. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

Integrated safety analysis summary (ISA Summary) means a document or documents that provides a synopsis of the results of the ISA and contains the information specified in §7x.30(c)(2).

Items relied on for safety (IROFS) mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 7x.32 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as IROFS.

License, except where otherwise specified, means a license including a construction permit issued pursuant to the regulations in this part;

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to IROFS, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance,

training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

Person means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

Plutonium and/or minor actinides processing and fuel fabrication plant means a plant in which the following operations or activities are conducted: (1) Operations for manufacture of reactor fuel containing plutonium including any of the following: (i) Preparation of fuel material; (ii) formation of fuel material into desired shapes; (iii) application of protective cladding; (iv) recovery of scrap material; and (v) storage associated with such operations; or (2) Research and development activities involving any of the operations described in paragraph (1) of this definition except for research and development activities utilizing unsubstantial amounts of plutonium.

Presiding officer means the Commission, an administrative judge, an Atomic Safety and Licensing Board, or other person designated in accordance with the provisions of this part, presiding over the conduct of a hearing conducted under this chapter.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Produce, when used in relation to special nuclear material, means (1) to manufacture, make, produce, or refine special nuclear material; (2) to separate special nuclear material from other substances in which such material may be contained; or (3) to make or to produce new special nuclear material;

Production facility means:

(1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233; or

(2) Any facility designed or used for the separation of the isotopes of plutonium, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material, except (i) laboratory scale facilities designed or used for experimental or

analytical purposes, (ii) facilities in which the only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U-235 and plutonium produced by the irradiation, if the material processed contains not more than 10^{-6} grams of plutonium per gram of U-235 and has fission product activity not in excess of 0.25 millicuries of fission products per gram of U-235, and (iii) facilities in which processing is conducted pursuant to a license issued under parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special nuclear material.

Recycling means the process used for (1) the separation of the isotopes of uranium and transuranic actinides including plutonium or mixtures of uranium, plutonium or other actinides from spent fuel, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(2) the processing of irradiated materials containing special nuclear material, except (i) laboratory scale facilities designed or used for experimental or analytical purposes, (ii) facilities in which the only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U-235 and plutonium produced by the irradiation, if the material processed contains not more than 10^{-6} grams of plutonium per gram of U-235 and has fission product activity not in excess of 0.25 millicuries of fission products per gram of U-235, and (iii) facilities in which processing is conducted pursuant to a license issued under parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special nuclear material.

Research and development means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes;

Restricted Data means all data concerning (1) design, manufacture or utilization of atomic weapons; (2) the production of special nuclear material; or (3) the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to section 142 of the Act.

Safety Report means the report submitted with the application as described in § 7x.30 and is updated in accordance with §7x.66 and contains (1) the description of the facility and application of the baseline design criteria (BDC), (2) the ISA Summary, and (3) the safety program.

Sealed source means any special nuclear material that is encased in a capsule designed to prevent leakage or escape of the special nuclear material.

Site Area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off-site.

Source material means source material as defined in section 11z. of the Act and in the regulations contained in part 40 of this chapter;

Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material;

Special nuclear material of low strategic significance means:

(1) Less than an amount of special nuclear material of moderate strategic significance as defined in paragraph (1) of the definition of strategic nuclear material of moderate strategic significance in this section, but more than 15 grams of uranium-235 (contained in uranium enriched to 20 percent or more in U-235 isotope) or 15 grams of uranium-233 or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U-235) + (grams plutonium) + (grams U-233); or

(2) Less than 10,000 grams but more than 1,000 grams of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope); or

(3) 10,000 grams or more of uranium-235 (contained in uranium enriched above natural but less than 10 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category III quantity of material.

Special nuclear material of moderate strategic significance means:

(1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation, grams = (grams contained U-235) + 2 (grams U-233 + grams plutonium); or

(2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category II quantity of material.

Special nuclear material scrap means the various forms of special nuclear material generated during chemical and mechanical processing, other than recycle material and normal process

intermediates, which are unsuitable for use in their present form, but all or part of which will be used after further processing.

Spent Nuclear Fuel or *Spent Fuel* means fuel that has been withdrawn from a nuclear reactor following irradiation, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

Strategic special nuclear material means uranium-235 (contained in uranium enriched to 20 percent or more in the U235 isotope), uranium-233, or plutonium.

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

Waste incidental to recycling or WIR means: Waste material resulting from recycling of spent nuclear fuel, including liquid wastes produced directly in recycling and any solid material derived from such liquid waste that contains fission products that is not so highly radioactive or contains insufficient concentrations of fission products to be classified as HLW. Such waste is not so highly radioactive or of sufficient concentration if it (1) has been processed to remove key radionuclides to the maximum extent that is technically and economically practical, and (2) either meets Class C concentrations under 10 CFR part 61 or will meet the performance objectives in 10 CFR part 61, subpart C if disposed of in a near surface disposal site based on a site specific performance assessment. This definition does not relieve the Department of Energy from its responsibility for the disposal of radioactive material which is greater than Class C under the Low-Level Radioactive Waste Policy Act of 1985.

Worker means an individual who receives an occupational dose as defined in 10 CFR 20.1003.

§ 7x.4 Communications.

Any communication or report concerning the regulations in this part and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed to: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards or Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) By hand delivery to the Director, Office of Nuclear Material Safety and Safeguards or Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response at the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, and CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by

calling (301) 415-0439, by e-mail to *EIE@nrc.gov*, or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission,Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(4) Copies of all correspondence submitted under this part be also provided to the appropriate Regional Office, and to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility.

(5) Classified communications shall be transmitted to the NRC Headquarters' classified mailing address as specified in appendix A to part 73 of this chapter or delivered by hand in accordance with paragraph (a)(2) of this section.

§ 7x.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 7x.6 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for--

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to *forms@nrc.gov*, or by accessing the NRC Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

§ 7x.7 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number _____.

(b) The approved information collection requirements contained in this part appear in _____

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

_____

§ 7x.8 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This

requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 7x.9 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Subpart B. Requirement of License, Exceptions and exemptions

§ 7x.10 License required for Construction; limited work authorization.

(a) *Requirement for construction permit, combined license, or limited work authorization.* No person may begin the construction of a fuel recycling facility until that person has been issued either a construction permit or a combined license under this part, or a limited work authorization under paragraph (b) of this section.

(b) *Request for limited work authorization.* (1) Any person to whom the Commission may otherwise issue either a license or permit under Sections 103 or 185 of the Act for a facility of the type specified in §7x.14 of this part may request a limited work authorization allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of the foundation, including

placement of concrete, any of which are for an IROFS of the facility for which either a construction permit or combined license is otherwise required under this part.

(2) An application for a limited work authorization may be submitted as part of an application for a construction permit or combined license.

(3) The application must include:

(i) A Safety Report required by §7x.30 of this part, a description of the activities requested to be performed, and the design and construction information A description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a construction permit or combined license, but limited to those portions of the facility that are within the scope of the limited work authorization. The Safety Report must demonstrate that activities conducted under the limited work authorization will be conducted in compliance with the technically-relevant Commission requirements in this part applicable to the design of those portions of the facility within the scope of the limited work authorization;

(ii) An environmental report meeting the provisions of part 51 of this chapter; and

(iii) A plan for redress of activities performed under the limited work authorization, should limited work activities be terminated by the holder or the limited work authorization be revoked by the NRC, or upon effectiveness of the Commission's final decision denying the associated construction permit or combined license application, as applicable.

(c) *Issuance of limited work authorization.* (1) The Director of NMSS may issue a limited work authorization only after:

(i) The NRC staff issues the final environmental impact statement for the limited work authorization in accordance with subpart A of part 51 of this chapter;

(ii) The presiding officer makes the finding in part 51 of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the Act, and the Commission's regulations applicable to the activities to be conducted under the limited work authorization, have been met. The applicant is technically qualified to engage in the activities authorized. Issuance of the limited work authorization will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common defense and security; and

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the limited work authorization that would constitute good cause for withholding the authorization.

(2) Each limited work authorization will specify the activities that the holder is authorized to perform.

(d) *Effect of limited work authorization.* Any activities undertaken under a limited work authorization are entirely at the risk of the applicant and, except as to the matters determined under paragraph (c)(1) of this section, the issuance of the limited work authorization has no bearing on the issuance of a construction permit or combined license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act. The environmental impact statement for a construction permit or combined license application for which a limited work authorization was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of limited work authorization in determining the proposed action (*i.e.*, issuance of the construction permit or combined license).

(e) *Implementation of redress plan.* If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the limited work authorization is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the limited work authorization, or upon effectiveness of the Commission's final decision denying the associated construction permit application or the underlying combined license application, as applicable.

§ 7X.11 Exceptions and exemptions from licensing requirements.

Nothing in this part shall be deemed to require a license for:

(a) Except to the extent that Administration facilities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved;

(1)(i) The processing, fabrication or refining of special nuclear material or the separation of special nuclear material, or the separation of special nuclear material from other substances by a prime contractor of the Department under a prime contract for:

(A) The performance of work for the Department at a United States government-owned or controlled site;

(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(C) The use or operation of a production facility in a United States owned vehicle or vessel; or

(ii) By a prime contractor or subcontractor of the Commission or the Department under a prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety;

(2)(i) The construction or operation of a production facility for the Department at a United States government-owned or controlled site, including the transportation of the production or utilization facility to or from such site and the performance of contract services during temporary

interruptions of such transportation; or the construction or operation of a production facility for the Department in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a production facility for the Department in a United States government-owned vehicle or vessel: Provided, That such activities are conducted by a prime contractor of the Department under a prime contract with the Department.

(ii) The construction or operation of a production facility by a prime contractor or subcontractor of the Commission or the Department under its prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

(b) The transportation or possession of any production facility by a common or contract carrier or warehousemen in the regular course of carriage for another or storage incident thereto.

§ 7x.12 Specific exemptions.

(a)The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any person may request an exemption permitting the conduct of activities prior to the issuance of a construction permit prohibited by § 7x.10. The Commission may grant such an exemption upon considering and balancing the following factors:

(1) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;

(2) Whether redress of any adverse environment impact from conduct of the proposed activities can reasonably be effected should such redress be necessary;

(3) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and

(4) The effect of delay in conducting such activities on the public interest.

Issuance of such an exemption shall not be deemed to constitute a commitment to issue a construction permit. During the period of any exemption granted pursuant to this paragraph (b), any activities conducted shall be carried out in such a manner as will minimize or reduce their environmental impact.

§ 7x.13 Attacks and destructive acts by enemies of the United States; and defense activities.

An applicant for a license to construct and operate a production facility, or for an amendment to such license, is not required to provide for design features or other measures for the specific purpose of protection against the effects of (a) attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person, or (b) use or deployment of weapons incident to U.S. defense activities.

§ 7x.14 Class 103 licenses; for commercial and industrial facilities.

A class 103 license will be issued, to an applicant who qualifies, for any one or more of the following: To transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or use a fuel recycling facility for industrial or commercial purposes; *Provided, however,* That in the case of a production facility which is useful in the conduct of research and development activities of the types specified in section 31 of the Act, such facility is deemed to be for industrial or commercial purposes if the facility is to be used so that more than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services, other than research and development or education or training.

§ 7x.15 Construction permits and combined licenses.

A construction permit for the construction of a fuel recycling facility will be issued at the request of the applicant before the issuance of a license if the application is otherwise acceptable, and will be converted upon completion of the facility and Commission action, into a license as provided in § 7x.52(g). However, if a combined license is issued under this part, the construction permit and operating license are deemed to be combined in a single license. A construction permit for the alteration of a facility will be issued before the issuance of an amendment of a license, if the application for amendment is otherwise acceptable, as provided in § 7x.72.

Subpart C – Requirements for Applicants

§ 7x.20 Filing of application; oath or affirmation.

(a) *Serving of applications.* (1) Each filing of an application for a license to construct and/or operate, a fuel recycling facility (including a combined license), and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 7x.4 of this part, as applicable.

(2) The applicant shall maintain the capability to generate additional copies of the general information and the Safety Report, or part thereof or amendment thereto, for subsequent distribution in accordance with the written instructions of the Director, Office of Nuclear Material Safety and Safeguards.

(3) Each applicant for a construction permit, combined license shall, upon notification by the presiding officer appointed to conduct the public hearing required by the Atomic Energy Act, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the

presiding officer. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 7x.4.

(4) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(5) At the time of filing an application, the Commission will make available at the NRC Web site, *http:// www.nrc.gov*, a copy of the application, subsequent amendments, and other records pertinent to the matter which is the subject of the application for public inspection and copying in accordance with the provisions of the regulations contained in part 2 of this chapter.

(6) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 7x.4, to enable the Director, Office of Nuclear Material Safety and Safeguards, to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation*. Each application for a license, including, a construction permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) *Application for operating licenses*. The holder of a construction permit for a fuel recycling facility may file an application for an operating license. The application shall state the name of the applicant, the name, location and capacity, of the facility and the time when the facility is expected to be ready for operation, and may incorporate by reference any pertinent information submitted in accordance with the application for a construction permit.

(d) *Filing fees*. Each application shall be accompanied by the fee prescribed in part 170 of this chapter. No fee will be required to accompany an application for renewal, amendment, or termination of a construction permit, operating license, or combined license, except as provided in § 170.21 of this chapter.

(e) *Environmental report*. An application for a construction permit, operating license, and combined license shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

(f) *Incorporation by reference*. Information contained in previous applications, statements, or reports filed with the Commission may be incorporated by reference if the references are clear and specific.

(g) *Other licensed activities*. An application for license filed pursuant to the regulations in this part will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided the application specifies the additional activities for

which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(h) *Restricted data.* Any application which contains Restricted Data shall be prepared in such manner that all Restricted Data are separated from the unclassified information.

(i) *IAEA.* In response to a written request by the Commission, an applicant shall file with the Commission the installation information described in § 75.11 of this chapter on Form N-71. The applicant shall also permit verification of such installation information by the International Atomic Energy Agency and take such other action as may be necessary to implement the US/IAEA Safeguards Agreement, in the manner set forth in § 75.6 and §§ 75.11 through 75.14 of this chapter.

(j) *Agreement limiting access to Classified Information.* As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license the applicant shall agree in writing that it will not permit any individual to have access to any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license, or construction permit.

(k) *Requests for additional information.* The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked. All applications and statements shall be signed by the applicant or licensee or a corporate officer thereof.

(l) *Complete and accurate disclosure.* Each application and statement shall contain complete and accurate disclosure as to all matters and things required to be disclosed.

§ 7x.22 Combining and separation of licenses.

(a) An applicant for a license under this part may combine in its application several applications for different kinds of licenses under the regulations of this chapter such as spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel.

(b) The Commission may combine in a single license the activities on the same site of an applicant which would otherwise be licensed separately. In addition, the Commission may combine into one license activities previously licensed such as combining into the license for a fuel recycling facility a previous license issued for an independent spent fuel storage facility on the same site if such a license had been previously issued. Absent significant new information that substantially affects the determination to license the previous facility that is to be incorporated into the fuel recycling facility, information that demonstrates an adverse impact for a finding of reasonable assurance of adequate protection for the public health and safety from the remainder of the fuel recycling facility, or other good cause, the previous licensing determination

shall be relied upon during the review of the fuel recycling facility application and the associated hearing process.

(c) An applicant for a fuel recycling facility is not required to include in its application activities associated with recycling conducted on a contiguous site that individually could be separately licensed such as spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel.

§ 7x.24 Ineligibility of certain applicants.

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government shall be ineligible to apply for and obtain a license.

§ 7X.26 Hearings and report of the Advisory Committee on Reactor Safeguards.

(a) Each application for a construction permit, an operating license, or a combined license for a facility shall be referred to the Advisory Committee on Reactor Safeguards (ACRS) for a review and report. An application for an amendment to such a construction permit, operating, or combined license may be referred to the ACRS for review and report. Any report shall be made part of the record of the application and available to the public in accordance with the provisions of the regulations contained in part 2 of this chapter.

(b)(1) The Commission will hold a hearing after at least 30-days' notice and publication once in the FEDERAL REGISTER on each application for a construction permit or combined license for a fuel recycling facility. If an applicant for a combined license requests a Commission finding on certain inspections, tests, analysis, and acceptance criteria (ITAAC) with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings are governed by the procedures contained in 10 CFR part 2.

(2) When a construction permit has been issued for a facility following the holding of a public hearing, and an application is made for an operating license or for an amendment to a construction permit or operating license, the Commission may hold a hearing after at least 30-days' notice and publication once in the FEDERAL REGISTER, or, in the absence of a request therefore by any person whose interest may be affected, shall issue an operating license or an amendment to a construction permit or operating license without a hearing, upon 30-days' notice and publication once in the FEDERAL REGISTER of its intent to do so.

(3) If the Commission finds that exigent circumstances exist, as described in § 7x.72, it may reduce the period provided for public notice and comment.

(4) In the case of exigent circumstances, the Commission will provide 30 days notice of opportunity for a hearing, though this notice may be published after issuance of the amendment if the Commission determines that no significant hazards consideration is involved.

(5) The Commission will use the standards in § 7x.74 to determine whether a significant hazards consideration is presented by an amendment to an operating license and may make the amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

(6) No petition or other request for review of or hearing on the staff's significant hazards consideration determination will be entertained by the Commission. The staff's determination is final, subject only to the Commission's discretion, on its own initiative, to review the determination.

§ 7x.28 Contents of applications; general information.

Each application shall state:

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is a partnership, state name, citizenship and address of each partner and the principal location where the partnership does business.

(3) If applicant is a corporation or an unincorporated association, state:

(i) The state where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers;

(3) Provide information known to the applicant concerning the control or ownership, if any, exercised over the applicant by any alien, foreign corporation, or foreign government;

(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph with respect to such principal.

(e) The class of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility.

(f) If the applicant, other than an applicant for a combined license, proposes to construct or alter a fuel recycling facility, the application shall state the earliest and latest dates for completion of the construction or alteration.

§ 7x.30 Contents of applications; Technical information.

The following information is required to be submitted by an applicant for a construction permit, operating license, or a combined license. Unless otherwise stated, an applicant for a construction permit need not supply initially all of the technical information required below to complete the application. However, the construction permit will not be granted unless the requirements in §7x.52 are met.

(a) ***Material to be licensed.*** The name, amount, and specifications (including the chemical and physical form and, where applicable, isotopic content) of the special nuclear material the applicant proposes to use or produce;

(b) ***Technical qualifications.*** The technical qualifications, including training and experience of the applicant and members of its staff to engage in the proposed activities in accordance with the regulations in this part;

c) ***Safety Report.*** The applicant shall include in its application the following information:

(1)***Description of the Facility and Application of Baseline Design Criteria.*** A summary of the facility to be built and operated explaining how the applicant addressed the BDC in §7x.34 in the design and operation of the facility with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations and achieved the performance requirements of § 7x.32.

(2) ***Integrated Safety Analysis Summary (ISA Summary).*** The ISA Summary must be submitted with the license or renewal application (and amendment application as necessary. The ISA Summary must contain:

(i) A general description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

(ii) A general description of equipment, processes, and facilities which will be used by the applicant to protect health and minimize danger to life or property (such as handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems, etc.). This is to include a description and safety assessment of the design bases of the principal structure, systems, and components of the facility that provide the safety controls identified in the application of the BDC as providing protection against the consequences of accidents or natural phenomena to achieve the performance requirements of §7x.32. The description is also to contain information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the facility design will conform to the design bases. The ISA Summary for a construction permit application is to identify those structures, systems, or components of the facility, if any, which require research and development to confirm the adequacy of their design; and identification and description of the research and development program which will be conducted to resolve any safety questions associated with such structures, systems or components; and a schedule of the research and

development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility

(iii) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the ISA in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the ISA pursuant to §7x.36 (a) and 7x.30(c)(3)(i)(A-C) and a general description of the types of accident sequences;

(iv) Information that demonstrates the licensee's compliance with the performance requirements of § 7x.32, including a description of the management measures; the requirements for criticality monitoring and alarms in § 7x.60(t); and the requirements of § 7x.34;

(v) A description of the team, qualifications, and the methods used to perform the ISA;

(vi) A list briefly describing each item relied on for safety which is identified pursuant to §7x.32(e) in sufficient detail to understand their functions in relation to the performance requirements of § 7x.32;

(vii) A description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in § § 7x.32 (b)(4) and (c)(4);

(viii) A descriptive list that identifies all IROFS that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 7x.32; and

(ix) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the ISA.

(3) ***Safety Program.*** The application shall provide a description of the applicant’s safety program. The description should include proposed plans and procedures to protect health and minimize danger to life or property and shall include a description of the applicant’s processes for:

(i) ***Integrated safety analysis (ISA)*** to be conducted and maintained in an appropriate detail for the complexity of the process that identifies:

(A) Radiological hazards related to possessing or processing licensed material at its facility;

(B) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(C) Facility hazards that could affect the safety of licensed materials and thus present an increased radiological risk;

(D) Potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;

(E) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to sub paragraph (D) above, and the methods used to determine the consequences and likelihoods. For identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, the ISA shall be supported by a quantitative assessment of the risk to the extent practicable based on the availability of data to support quantitative analysis including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents; and

(F) Each item relied on for safety identified pursuant to § 7x.32 (e) of this subpart, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of § 7x.32.

(G) ISA team qualifications. To assure the adequacy of the ISA, the analysis must be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific ISA methodology being used.

(ii) ***Fire protection*** to provide reasonable assurance that the facility will provide adequate protection against fires and explosions consistent with the performance requirements of 7x.32.

(iii) ***Chemical safety*** to provide reasonable assurance that the facility will provide adequate protection against chemical hazards consistent with the performance requirements of 7x.32.

(iv) ***Nuclear criticality*** to provide reasonable assurance that the facility will provide adequate protection against criticality consistent with the requirements of 7x.32 and 7x.60(t).

(v) ***Radiation protection*** to meet the requirements of 10 CFR Part 20.

(vi) ***Management measures*** including configuration management, maintenance, training and qualifications, surveillances, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements to meet the criteria in Appendix B of 10 CFR Part 50. These plans may be based on a graded approach considering risk and consequences of the particular hazards being protected against. The management measures shall ensure that engineered and administrative controls and control systems that are identified as IROFS are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of § 70.32 of this part. Management measures includes maintaining records of failures readily retrievable and

available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 7x.32 are not satisfied. These records must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected IROFS or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an item relied on for safety or management measure. In addition, records maintained shall demonstrate compliance with subparagraph (vii) below and the ISA described in paragraph (c)(3)(i) of this section

(vii) ***Process safety information*** to enable the performance and maintenance of an ISA. 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.

(d) ***Decommissioning.*** The applicant shall include in its application its proposed decommissioning program, plans for meeting 10 CFR 20.1406, and its plan for the disposal of any radioactive waste generated from fuel recycling activities that are not planned to be disposed of during normal operations.

(e) ***Technical specifications***. The applicant shall include in its application proposed technical specifications to meeting the provisions of §7x.40.

(f) ***Environment, effluent releases and waste management***

(1)Each application shall include:

(i) An estimate of:

(A) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal operations;

(B) The quantity of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal operations; and

(C) The quantity, waste classification and average concentration of each of the principal radionuclides expected in each waste stream on an annual basis and over the life of the facility that will be stored on the site for future treatment, stored on site for disposal off-site after normal operations cease, or disposed of off-site during normal operations.

(ii) A description of the provisions for packaging, storage, and shipment off-site of solid waste containing radioactive materials resulting from treatment of gaseous and liquid effluents and from other sources. The description shall include the applicant's plans for the treatment and disposal of radioactive waste generated during operations including the waste's classification under 10 CFR part 61.

(2) (i) Applications for a construction permit and combined license shall include conditions to protect the environment during construction. These conditions will be derived from information contained in the environmental report and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(ii) Applications for an operating license and combined license shall include conditions to protect the environment during operation and decommissioning. These conditions will be derived from information contained in the environmental report and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(g) ***Financial qualification.*** Information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following shall be provided:

(1) If the application is for a construction permit, the applicant shall submit information that demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs, operating costs, and decommissioning costs. The applicant shall submit estimates of the total construction costs of the facility and operating and decommissioning costs, and shall indicate the source(s) of funds to cover these costs.

(2) If the application is for an operating license, the applicant shall submit information that demonstrates

(i) The applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant shall submit estimates for total annual operating costs for each of the first five years of operation of the facility. The applicant shall also indicate the source(s) of funds to cover these costs.

(ii) The applicant possess or has reasonable assurance of obtaining the funds to decommission the facility and to provide for the removal and disposal of radioactive wastes, during operation and upon decommissioning of the facility, in accordance with the Commission's regulations. This includes as provided by § 7x.38, a proposed decommissioning funding plan or a certification of financial assurance for decommissioning and waste removal.

(3) If the application is for a combined license, the applicant shall submit the information described in paragraphs (g)(1) and (g)(2) of this section.

(4) Each application for a construction permit, operating license, or combined license submitted by a newly-formed entity organized for the primary purpose of constructing and/or operating a facility must also include information showing:

(i) The legal and financial relationships it has or proposes to have with its stockholders or owners;

(ii) The stockholders' or owners' financial ability to meet any contractual obligation to the entity which they have incurred or proposed to incur; and

(iii) Any other information considered necessary by the Commission to enable it to determine the applicant's financial qualification.

(5) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee’s ability to continue the conduct of the activities authorized by the license and to decommission the facility.

(h) ***Emergency preparedness.*** Each application must contain an emergency planning and preparedness plan that will provide reasonable assurance that adequate protective measures will be taken in the event of a radiological or chemical emergency for those aspects of the facility that could reasonably result in a (1) maximum dose to a member of the public off-site exceeding 1 rem effective dose equivalent, (2) a maximum dose to a member of the public off-site exceeding an intake of 2 milligrams of soluble uranium, or (3) the maximum exposure to hazardous chemicals produced from licensed materials resulting in more than mild transient health effects to any individual located outside the controlled area. Emergency plans submitted under this section must be prepared and submitted in accordance with the applicable provisions in Appendix E of Part 50 of this chapter if it is determined that a General Emergency Classification is necessary. Otherwise, the plan must include the following information:

(i) *Facility description*. A brief description of the applicant’s facility and area near the site.

(ii) *Types of accidents*. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) *Classification of accidents*. A classification system for classifying accidents as alerts or site area emergencies.

(iv) *Detection of accidents*. Identification of the means of detecting each type of accident in a timely manner.

(v) *Mitigation of consequences.* A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) *Assessment of releases.* A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) *Responsibilities.* A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination.* A commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The applicant shall also commit to notify the NRC operations center immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the NRC.

(x) Training. A brief description of the frequency, performance objectives and plans for the training that the applicant will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most likely for the specific site, including the use of team training for such scenarios.

(xi) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be

known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the special nuclear material.

(4) The applicant shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to NRC. The applicant shall provide any comments received within the 60 days to the NRC with the emergency plan.

(i) ***Material control and accounting.*** Each application must contain a full description of the applicant's program for control and accounting of such special nuclear material that will be in the applicant's possession under license to show how compliance with the requirements of part 74 this chapter, as applicable, will be accomplished.

(j) ***Plan for physical protection of special nuclear material in transit.*** (1) Each application for a license that would authorize the transport or delivery to a carrier for transport of special nuclear material in an amount specified in § 73.1(b)(2) of this chapter must include (i) a description of the plan for physical protection of special nuclear material in transit in accordance with part 73 for 10 kg or more of special nuclear material of low strategic significance including, as appropriate, a plan for the selection, qualification, and training of armed escorts, or the specification and design of a specially designed truck or trailer, and (ii) a licensee safeguards contingency plan or response procedures, as appropriate, for dealing with threats, thefts, and radiological sabotage relating to the special nuclear material in transit.

(2) Each application must include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information, as set forth in appendix C to part 73 of this chapter, are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix. The fifth category of information, Procedures, does not have to be submitted for approval.)

(k) ***Physical security plan*** Each application must include a physical security plan. The plan must describe how the applicant will meet the applicable requirements of part 73 of this chapter in the conduct of the activity to be licensed, including the identification and description of jobs as required by 10 CFR 11.11(a). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(l) ***Safeguards contingency plan*** (1) Each application must include a licensee safeguards contingency plan for dealing with threats, thefts, and radiological sabotage, as defined in part 73

of this chapter, relating to nuclear facilities licensed under part 50 of this chapter or to the possession of special nuclear material licensed under this part.

(2) Each application for such a license must include the first four categories of information contained in the applicant's safeguards contingency plan. (The first four categories of information, as set forth in appendix C to part 73 of this chapter, are Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix.) The fifth category of information, Procedures, does not have to be submitted for approval.

(m) ***Protection of classified safeguards information and material.*** Each application must contain a full description of the applicant's security program to protect against theft, and to protect against unauthorized viewing of (1) plans for physical security, safeguards contingency, guard qualification and training, (2) other related Safeguards Information, and (3) classified equipment, and unauthorized disclosure of classified matter in accordance with the requirements of 10 CFR parts 25, 73, and 95.

(n) ***Financial protection and indemnity.*** The application shall include the applicant's plan to meet the requirements of 10 CFR part 140.

(o) ***Inspections, tests, analyses and acceptance criteria (ITAAC)***. The application for a combined license must contain the proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the IROFS have been appropriately identified and implemented as described in the Safety Report and the facility has been constructed and will be operated in conformity with the combined license, the provisions of the Act, and the Commission's rules and regulations.

(p) ***Operators to be licensed.*** The application shall indicate which operator positions including supervisory positions the applicant will certify to the NRC as trained and NRC will approve and license, based on an NRC approved certification program before allowing an individual to perform licensed activities. The application shall include in addition to the measurement measures that require training and qualification of the facility staff, the applicant's program for training, periodic proficiency testing, requalification, and certification of operators whose actions are necessary to prevent or mitigate identified accident scenarios as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area. This program must be submitted to the Commission for approval with the license application. The program must also address the physical condition and the general health of certified operators to minimize the potential of such operators causing operational errors that could endanger other in-plant personnel or the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel. These conditions need not categorically disqualify a person if appropriate provisions are made to accommodate such defect.

§ 7x.32 Performance requirements.

(a) Each applicant shall evaluate, in the ISA performed in accordance with § 7x.36, its compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

(b) The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both, shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those in paragrahs (b)(1)-(4) of this section. High consequence events are those internally or externally initiated events that result in:

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or

(4) 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) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. 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 information submitted pursuant to § 7x.30(c)(3) of this subpart.

(c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1)-(4) of this section. 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 of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(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 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) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. 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 information submitted pursuant to § 7x.30(c)(3) of this subpart.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to § 7x.36 of this subpart, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

(f) Each licensee must establish a controlled area, as defined in § 20.1003. In addition, the licensee must retain the authority to exclude or remove personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in § 7x.3, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

(1) Demonstrates and documents, in the ISA, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA, and conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

§ 7x.34 Baseline Design Criteria.

(a) *Baseline design criteria (BDC).* Each applicant or licensee shall address the following BDC in the design of new facilities. Each existing licensee shall address the following BDC in the design of new processes at existing facilities that require a license amendment under § 7x.66. The BDC must be applied to the design of new facilities and new processes. All facilities and processes must also comply with the performance requirements in § 7x.32. The application of these criteria shall be maintained unless the ISA performed pursuant to § 7x.36 or §7x.60(a) demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

I. Overall Requirements.

(1) *Criterion 1—Design concepts.* Facility and system design and facility layout must be based on defense-in-depth practices that are based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the ISA can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

The design shall identify the extent to which generally accepted engineering standards are applied to the design of the recycling facility and the extent to which the facility incorporates unique, unusual or enhanced safety features having a significant bearing on the likelihood or consequences of accidental release of radioactive materials. The design must incorporate, to the extent practicable:

(i) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(ii) Features that enhance safety by reducing challenges to IROFS.

(2) *Criterion 2--Quality standards and records*. The design must be developed and implemented in accordance with management measures, to provide adequate assurance that IROFS will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility. The elements of the quality assurance program are to be based on 10 CFR part 50, Appendix B applied in a graded manner considering the risk and consequences of the particular hazard being protected against.

(3) *Criterion 3--Design bases for protection against natural phenomena*. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site. IROFS or systems or components which support IROFS shall be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions in support of or used as an item relied on for safety. The BDC for these structures, systems, and components in support of or used as an item relied on for safety shall reflect: (1) Appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated, (2) appropriate combinations of the effects of normal and accident conditions with the effects of the natural phenomena and (3) the importance of the safety functions to be performed.

(4) *Criterion 4—Site Selection.* Site characteristics must comply with the provisions of part 72, subpart E of this chapter as if the fuel recycling facility was a an ISFSI or MRS. The design shall provide that individuals at the boundary of the controlled areas will not exceed the doses in 10

CFR 72.106. Fuel recycling facilities are not required to be located on land owned and controlled by the Federal Government. Such facilities, including their operations for the temporary storage of high-level radioactive wastes, may be located on privately owned property.

(5) *Criterion 5--Fire protection*. The design must provide for adequate protection against fires and explosions. Items relied on for safety or systems or components which support IROFS shall be designed and located to minimize, consistent with other safety requirements, the likelihood and effect of fires and explosions.

(6) *Criterion 6--Environmental and dynamic effects design bases*. The design must provide for adequate protection of structures, systems, and components in support of or used as an item relied on for safety from environmental conditions associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions. These structures, systems, and components shall also be appropriately protected against dynamic effects, including the effects of missiles, pipe whipping, and discharging fluids, that may result from equipment failures and from events and conditions outside the fuel recycling facility. At a minimum, this should include a formal environmental qualification program for components and systems needed to support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area.

(7) *Criterion 7--Control rooms.* The design shall provide for one or more control rooms from which actions can be taken to operate the fuel recycling facility safely under normal conditions and to maintain it in a safe condition under accident conditions. Protection shall be provided from chemical hazards impacting the control room. Adequate radiation protection shall be also be provided to permit access and occupancy of the control room under accident conditions without personnel receiving radiation exposures in excess of 5 rem whole body, or its equivalent to any part of the body,[.05 Sv (5 rem) total effective dose equivalent (TEDE] for the duration of the accident. The design shall consider in addressing actions to prevent or mitigate high consequence events, as defined in 7x.32 involving fission product releases to an individual outside the controlled area, the need for: (i) simulator capability that correctly models the control room; (ii) a control room design that reflects state-of-the-art human factor principles; (iii) plant safety parameter display consoles that will display to operators a minimum set of parameters defining the safety status of the plant, capable of displaying a full range of important plant parameters and data trends on demand, and capable of indicating when process limits are being approached or exceeded; and (iv) automatic indication of the bypassed and operable status of safety systems.

II. Radiological Protection

(8) *Criterion 8 -- Criticality control.* The design must provide for criticality control including adherence to the double contingency principle where necessary to meet the performance requirements of §7x.32.

(9) *Criterion 9—Radiation shielding.* The design shall address radiation shielding of spaces around systems that may, as a result of normal or accident conditions, contain radioactive

materials as necessary to permit required access to important areas and to protect safety equipment from the radiation environment.

(10) *Criterion 10--Fuel storage and handling and radioactivity control*. The fuel storage and handling, radioactive waste, and other systems which may contain radioactivity shall be designed to assure adequate safety under normal and postulated accident conditions. These systems shall be designed (i) with a capability to permit appropriate periodic inspection, maintenance, and testing of components, (ii) with suitable shielding for radiation protection, (iii) with appropriate containment, confinement, and filtering systems, (iv) with a residual heat removal capability having reliability and testability that reflects the importance to safety of decay heat and other residual heat removal, and (iv) to prevent significant reduction in fuel storage coolant inventory under accident conditions.

(11) *Criterion 11--Monitoring fuel and waste storage*. Appropriate systems shall be provided in fuel storage and radioactive waste systems and associated handling areas (i) to detect conditions that may result in loss of residual heat removal capability and excessive radiation levels and (ii) to initiate appropriate safety actions.

(12) *Criterion 12--Monitoring radioactivity releases*. Means shall be provided for monitoring the confinement atmosphere and the plant environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

(13) *Criterion 13--Control of releases of radioactive materials to the environment*. The fuel recycling facility design shall include means to control suitably the release of radioactive materials in gaseous and liquid effluents and to handle radioactive solid wastes produced during normal operation, including expected operational occurrences. Sufficient holdup capacity shall be provided for retention of gaseous and liquid effluents containing radioactive materials, particularly where unfavorable site environmental conditions can be expected to impose unusual operational limitations upon the release of such effluents to the environment. The design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable are to be described. The term "as low as is reasonably achievable" as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest.

(14) *Criterion 14—Inventory limitation.* A fuel recycling plant's inventory of high-level liquid radioactive wastes will be limited to that produced in the prior 5 years. High-level liquid radioactive wastes shall be converted to a dry solid as required to comply with this inventory limitation, and placed in a sealed container prior to transfer to a Federal repository in a shipping cask meeting the requirements of 10 CFR part 71.

III. Chemical and Hazardous Materials Protection

(15) *Criterion 15 --Chemical protection*. The design must provide for adequate protection against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

(16) *Criterion 16--Emergency capability.* The design must provide for emergency capability to maintain control of:

(i) Licensed material and hazardous chemicals produced from licensed material;

(ii) Evacuation of on-site personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available off-site services.

IV. Equipment Services Protection

(17) *Criterion 17--Utility services.* The design must provide for continued operation of essential services for IROFS and their necessary components.

(18) *Criterion 18--Electric power systems*. The design must provide for an onsite electric power system and an off-site electric power system to ensure functioning of components and systems needed to support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area. The safety function for each power system (assuming the other system is not functioning) shall be to provide sufficient capacity and capability to assure that the item relied on for safety dependent upon this system is capable of meeting or achieving its intended function. The onsite electric power supplies, including the batteries, and the onsite electric distribution system, shall have sufficient independence, redundancy, and testability to ensure functioning of their dependent components and systems needed to support or function as IROFS.

(19) *Criterion 19--Inspection and testing of electric power systems*. The electric power systems must be designed to ensure functioning of components and systems needed to support or function as IROFS to prevent or mitigate identified accident scenarios, as defined in §7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area, to permit appropriate periodic inspection and testing of important areas and features, such as wiring, insulation, connections, and switchboards, to assess the continuity of the systems and the condition of their components. The systems shall be designed with a capability to test periodically (i) the operability and functional performance of the components of the systems, such as onsite power sources, relays, switches, and buses, and (ii) the operability of the systems as a whole and, under conditions as close to design as practical, the full operation sequence that brings the systems into operation, including operation of applicable portions of the protection system.

(20) *Criterion 20-- Inspection, testing, and maintenance.* The design of IROFS must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(21) *Criterion 21 -- Instrumentation and controls.* The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of IROFS. Instrumentation shall be provided to monitor variables and systems over their anticipated ranges for normal operation, for anticipated operational occurrences, and for accident conditions as appropriate to assure adequate safety, including those variables and systems that can affect the safe operation of the facility and the confinement of the facility and its associated systems. Appropriate controls shall be provided to maintain these variables and systems within prescribed operating ranges.

V. Facility Confinement Protection

(22) *Criterion 22--Confinement design*. Facility confinement, process equipment, and associated systems shall be designed to establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment and to assure that the confinement design conditions, i.e., components and systems (including remote and control room operated components and systems) needed to support or function as IROFS, are not exceeded for as long as postulated accident conditions require. The design shall identify safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. High point venting of non-condensable gases, if needed, must be designed so as not to conflict with the confinement design under normal operating conditions. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. For design purposes, a source term with which the facility is reasonably expected to operate is to be assumed. The design shall include an evaluation and analysis of the postulated radiological release, using the expected confinement leak rate and any systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the off-site radiological consequences.

(23) *Criterion 23--Residual heat removal*. The design shall provide a system to remove residual heat when necessary. The system shall be designed to transfer decay heat and other residual heat at a rate such that the confinement performance requirements are not exceeded.

(24) *Criterion 24--Cooling water*. The design shall provide a system to transfer heat from the components and systems needed to support or function as IROFS to an ultimate heat sink. The system shall be designed to transfer the combined heat load of these components and systems needed to support or function as IROFS under normal operating and accident conditions.

(25) *Criterion 25 --Hydrogen control.* The facility will be designed for a system for hydrogen control that can safely accommodate hydrogen generated by the equivalent of the maximum throughput of the facility. The hydrogen control system and associated systems shall provide, with reasonable assurance that:

(i) Uniformly distributed hydrogen concentrations in the confinement will not support hydrogen combustion;

(ii) Combustible concentrations of hydrogen will not collect in areas where unintended combustion or detonation could cause loss of confinement integrity or loss of appropriate mitigating features;

(iii) Equipment necessary for achieving and maintaining safe shutdown of the facility and maintaining confinement integrity will perform its safety function during and after being exposed to the environmental conditions attendant with the release of the hydrogen including the environmental conditions created by activation of the hydrogen control system; and

(iv) If the method chosen for hydrogen control is a post-accident inerting system, inadvertent actuation of the system can be safely accommodated during plant operation.

(26) *Criterion 26-- Leakage control and detection.* The design will provide for leakage control and detection in the design of systems outside confinement that contain (or might contain) radioactive materials following an accident.

(27) *Criterion 27 – Spent fuel cladding.* The design must provide that for spent fuel in storage the spent fuel cladding must be protected during storage against degradation that leads to gross ruptures or the fuel must be otherwise confined such that degradation of the fuel during storage will not pose operational safety problems with respect to its removal from storage.

(28) *Criterion 28 – Underwater storage.* The design must provide that for underwater storage of spent fuel in which the pool water serves as a shield and a confinement medium for radioactive materials, systems for maintaining water purity and the pool water level must be designed so that any abnormal operations or failures in those systems from any cause will not allow the water level to fall below safe limits. The design must preclude installations of drains, permanently connected systems, and other features that could, by abnormal operations or failure, cause a significant loss of water. Pool water level equipment must be provided to alarm in a continuously manned location if the water level in the storage pool falls below a predetermined level.

§ 7x.36 Safety Program, Integrated Safety Analysis and Summary.

(a) Each applicant shall establish and maintain (1) a safety program including an ISA and (2) an ISA Summary that is based on its ISA. Changes to the safety program including the ISA and the ISA Summary shall meet the conditions of § 7x.66.

(b) The safety program shall address the information required by §7x.30(c)(3), maintain the records described in §7x.30(c)(3)(vi) and (vii), and demonstrate compliance with the performance requirements of §7x.32.

(c) The ISA is a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the IROFS. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC

requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material. An ISA can be performed process by process, but all processes must be integrated, and process interactions considered. The ISA shall address the information required by §7x.30(c)(3)(i).

(d) The ISA Summary is one or more documents submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the ISA and contains the information required by § 7x.30(c)(2). It is not incorporated in the license. However, changes to the ISA Summary shall meet the conditions of § 7x.66. The ISA Summary can be submitted as one document for the entire facility, or as multiple documents that cover all portions and processes of the facility.

§ 7x.38 Financial assurance and recordkeeping for decommissioning.

(a) The applicant shall prepare and maintain a decommissioning funding plan as described in paragraph (b) of this section.

(b) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from paragraph (c) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (c) of this section.

(c) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D

to part 30. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to part 30. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licenssee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in paragraph (f)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in paragraph (d) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) Each person licensed under this part shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. If records important to the decommissioning of a facility are kept for other purposes,

reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after cleanup of any leak), a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003;

(ii) All areas outside of restricted areas that require documentation under § 7x.38(d)(1);

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

§ 7x.40 Technical specifications.

(a) Each applicant for a license authorizing operation of a fuel recycling facility shall include proposed technical specifications addressing IROFS to prevent or mitigate identified accident scenarios as defined in § 7x.32 that could result in a high consequence event involving fission product releases to an individual outside the controlled area in accordance with the requirements of this section. The technical specifications will be derived from the analyses and evaluation included in the ISA prepared pursuant to § 7x.36.

(b) Technical specifications will address:

(1) for loss of all IROFS that prevent or mitigate a high consequence event involving fission product releases to an individual outside the controlled area; placing the affected process or the entire facility in a safe condition and making notifications to the Commission in accordance with the provisions of § 7x.90(a). Unless the Commission notifies the licensee otherwise, operation may be resumed without concurrence of the Commission following completion of the licensee's corrective action to prevent recurrence. The licensee shall retain the record of the results of each review until the Commission terminates the license for the plant.

(2) for loss of one or more IROFS that prevent or mitigate a high consequence event involving fission product releases to an individual outside the controlled area, that results in failure to meet the performance requirement of § 7x.32; placing the affected process or the entire facility in a safe condition or taking compensatory actions to provide the safety function(s) of the IROFS that were lost and making notifications to the Commission in accordance with provisions of §7x.90(b). Unless the Commission notifies the licensee otherwise, operation may be resumed without concurrence of the Commission following completion of the licensee's corrective action to prevent recurrence. The licensee shall retain the record of the results of each review until the Commission terminates the license for the plant.

Subpart D –License Issuance and Conditions

§ 7x.50 Issuance of licenses.

(a) The Commission will issue a license in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the act upon the Commission finding that:

(1) The applicant and application meets with the requirements of the act and the regulations in this chapter;

(2) The applicable requirements of 10 CFR part 51 have been satisfied;

(3) Any required notifications to other agencies or bodies have been duly made;

(4) The applicant is technically and financially qualified to engage in the activities authorized;

(5) Issuance of the license will not be inimical to the common defense and security;

(6) Issuance of the license will not constitute an unreasonable risk to the health and safety of the public as there is reasonable assurance that (i) activities authorized by the license can be conducted without endangering the health and safety of the public and (ii) that such activities will be conducted in compliance with the regulations in this chapter; and

(7) The proposed activities will serve a useful purpose proportionate to the quantities of special nuclear material or source material to be utilized.

(b) Each license will be issued for a fixed period of time to be specified in the license but in no case to exceed 40 years from date of issuance, however, in the case of a combined license, from the date on which the Commission makes a finding that acceptance criteria are met under §7x.58(c)(7) or allowing operation during an interim period under the combined license under §7x.58(c)(3). Where the operation of a facility is involved, the Commission will issue the license for the term requested by the applicant or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested. Where construction of a facility is involved, the Commission may specify in the construction permit the period for which the license will be issued if approved pursuant to § 7x..52(g). Licenses may be renewed by the Commission upon the expiration of the period.

(c) No license under this part shall be deemed to have been issued for activities which are not under or within the jurisdiction of the United States.

§ 7x.52 Additional requirements for issuance of construction permits.

(a) After conducting a hearing in accordance with § 7x.26 and receiving the report submitted by the ACRS, the Commission may issue a construction permit if the Commission finds, in addition to the findings required by § 7x.50, that there is reasonable assurance that the facility will be constructed in conformity with the construction permit, the provisions of the Act, and the Commission's regulations.

(b) When an applicant has not supplied initially all of the technical information required to complete the application and support the issuance of a construction permit which approves all proposed design features, the Commission may issue a construction permit if the Commission finds that:

(1) the applicant has described the proposed design of the facility and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) such further technical or design information as may be required to complete the application as required below, and which can reasonably be left for later consideration, will be supplied at the time an operating license is applied for;

(3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and that

(4) on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in this part, the design bases of the principal structures, systems, and components, and the quality assurance program provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents in order to meet the performance requirements in §7x.32

such that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public. When an applicant has supplied initially all of the technical information required to complete the application, including the final design of the facility, the findings required above will be appropriately modified to reflect that fact.

(c) A construction permit will constitute an authorization to the applicant to proceed with construction but will not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the construction permit or, from time to time, by amendment of its construction permit. The Commission may, in its discretion, incorporate in any construction permit provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

(d) Any construction permit will be subject to the limitation that a license authorizing operation of the facility will not be issued by the Commission until (1) the applicant has submitted to the Commission, by amendment to the application, the complete Safety Report, portions of which may be submitted and evaluated from time to time, and (2) the Commission has found that the final design provides reasonable assurance that the health and safety of the public will not be endangered by operation of the facility in accordance with the requirements of the license and the regulations in this chapter.

(e) An applicant for an operating license or an amendment of an operating license who proposes to alter a fuel recycling facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of this part.

(f) A holder of a combined license who proposes, after the Commission makes the finding that the acceptance criteria in the combined license has been met (see § 7x.58(c)(7) to alter the licensed facility will be initially granted a construction permit if the application is in conformity with and acceptable under the criteria of this part.

(g) Upon completion of the construction or alteration of a facility, in compliance with the terms and conditions of the construction permit and subject to any necessary testing of the facility for health or safety purposes, the Commission will, in the absence of good cause shown to the contrary issue a license of the class for which the construction permit was issued or an appropriate amendment of the license, as the case may be.

§ 7x.54 Additional requirements for issuance of operating license.

(a) After receiving the report submitted by the ACRS and conducting a hearing, if one is held in accordance with § 7x.26, the Commission pursuant to § 7x.52(g) shall issue an operating license if the Commission finds, in addition to the findings required by § 7x.50, that:

(1) Construction of the facility has been substantially completed, in conformity with the construction permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission; and

(2) The facility will operate in conformity with the application as amended, the provisions of the Act, and the rules and regulations of the Commission.

(b) Each operating license will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(c) An applicant may, in a case where a hearing is held in connection with a pending proceeding under this section make a motion in writing, under this paragraph (c), for an operating license authorizing limited testing and further operations short of full operation. Action on such a motion by the presiding officer shall be taken with due regard to the rights of the parties to the proceedings, including the right of any party to be heard to the extent that the party's contentions are relevant to the activity to be authorized. Before taking any action on such a motion that any party opposes, the presiding officer shall make findings on the matters specified in paragraph (a) of this section and § 7x.50 (a) as to which there is a controversy in the form of an initial decision with respect to the contested activity sought to be authorized. The Director of Nuclear Materials Safety and Safeguards will make findings on all other matters specified in paragraph (a) of this section and § 7x.50 (a). If no party opposes the motion, the presiding officer will issue an order in accordance with 10 CFR 2.319(p) authorizing the Director of Nuclear Materials Safety and Safeguards to make appropriate findings on the matters specified in paragraph (a) of this section and in § 7x.50 (a) and to issue a license for the requested operation.

§ 7x.56 Additional Requirements for Issuance of combined licenses.

(a) After conducting a hearing in accordance with § 7x.26 and receiving the report submitted by the ACRS, the Commission shall issue a combined license if the Commission finds, in addition to the findings required by § 7x.50, that there is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations; and

(b) The Commission shall identify within the combined license the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that, if met, are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Act, and the Commission's rules and regulations.

(c) A combined license shall contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 7x.58 Requirements applicable to combined licenses

(a) Finality of combined licenses.

(1)After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests,

analyses, and acceptance criteria contained in the license except in accordance with the provisions of § 7x.58(c)(6) or § 7x.68, as applicable.

(2) A licensee may make changes in the facility as described in the Safety Report (as updated), make changes in the procedures as described in the Safety Report (as updated), and conduct tests or experiments not described in the Safety Report (as updated) under the applicable change processes in this part (e.g., §§ 7x.60, 7x.66, or 7x.70).

(3) The Commission may issue and make immediately effective any amendment to a combined license upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed in accordance with the procedures specified in 10 CFR 50.91.

(4) Any modification to, addition to, or deletion from the terms and conditions of a combined license, including any modification to, addition to, or deletion from the inspections, tests, analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

(b) Inspection during construction.

(1) The licensee shall submit to the NRC, no later than 1 year after issuance of the combined license or at the start of construction as defined in §7x.3, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee shall submit updates to the ITAAC schedules every 6 months thereafter. Within 1 year of its scheduled date for commencement of operations, the licensee shall submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (b)(3)(i) of this section.

(2) With respect to activities subject to an ITAAC, an applicant for a combined license may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and pre-operational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria have been met.

(3)(i) The licensee shall notify the NRC that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met. The notification must contain sufficient information to demonstrate that the prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria have been met.

(ii) If the licensee has not provided, by the date 225 days before the scheduled date for commencement of operations the notification required by paragraph (b)(3)(i) of this section for all ITAAC, then the licensee shall notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for commencement of operations, and must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed

and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria have been met.

(4) The NRC shall ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(i) At appropriate intervals until the last date for submission of requests for hearing under paragraph (c)(1) of this section, the NRC shall publish notices in the **Federal Register** of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(ii) The NRC shall make publicly available the licensee notifications under paragraph (c)(1), and, no later than the date of publication of the notice of intended operation required by paragraph (c)(1) of this section, make available all licensee notifications under paragraphs (c)(1) and (c)(2) of this section.

(c) Operation under a combined license.

(1) The licensee shall notify the NRC of its scheduled date for commencement of operations no later than 270 days before the scheduled date and shall notify the NRC of updates to its schedule every 30 days thereafter. Not less than 180 days before the date scheduled for commencement of operations by a licensee that has been issued a combined license under this part, the Commission shall publish notice of intended operation in the **Federal Register**. The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license.

(2) A request for hearing under paragraph (c)(1) of this section must show, prima facie, that—

(i) One or more of the acceptance criteria of the ITAAC in the combined license have not been, or will not be, met; and

(ii) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(3) The Commission, acting as the presiding officer, shall determine whether to grant or deny the request for hearing in accordance with the applicable requirements of 10 CFR 2.309. If the Commission grants the request, the Commission, acting as the presiding officer, shall determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's *prima facie* showing and any answers thereto. If the Commission determines there is such reasonable assurance, it shall allow operation during an interim period under the combined license.

(4) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (c)(1) of this section, and shall state its reasons therefore.

(5) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (c)(1) of this section or by the anticipated date for commencement of operations, whichever is later.

(6) A petition to modify the terms and conditions of the combined license will be processed as a request for action in accordance with 10 CFR 2.206. The petitioner shall file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (e.g. operations) commences, the Commission shall determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Commencement of operations under the combined license will not be affected by the granting of the petition unless the order is made immediately effective.

(7) The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met.

(8) After the Commission has made the finding in paragraph (c)(7) of this section, the ITAAC do not, by virtue of their inclusion in the combined license, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (c)(1) of this section, all ITAAC expire upon final Commission action in the proceeding. However, subsequent changes to the facility or procedures described in the Safety Report (as updated) must comply with the requirements in paragraph (a)(3) or (4), as applicable.

§ 7x.60 Conditions of licenses.

Whether stated therein or not, the following shall be deemed conditions in every license issued:

(a) Each licensee shall establish and maintain a safety program including an ISA, and ISA Summary meeting the requirements of §7x.36. Changes to the safety program, ISA, and ISA Summary shall meet the conditions of § 7x.66 except for changes to the NRC accepted quality assurance (QA) program described in management measures of the licensee's Safety Report required by §§7x.30(c)(3)(vi) and 7x.36. The following change process applies to the QA program except for construction permit holders and combined license holders prior to the date that the Commission makes the finding under § 7x.58(c)(7):

(1) Each licensee may make a change to a previously accepted QA program description included or referenced in the Safety Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QA program description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of §7x.66. In addition to QA program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(i) The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change;

(ii) The use of a QA alternative or exception approved by an NRC safety evaluation provided that the bases of the NRC approval are applicable to the licensee's facility;

(iii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(iv) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(v) The elimination of QA program information that duplicates language in QA regulatory guides and QA standards to which the licensee is committed; and

(vi) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(2) Changes to the QA program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the QA program description as presented in the Safety Report or in a topical report must be submitted as specified in §7x.4.

(ii) The submittal of a change to the Safety Report QA program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of 10 CFR part 50, appendix B and the Safety Report QA program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the QA program description included or referenced in the Safety Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(b) reserved

(c) Neither the license, nor any right there under, nor any right to utilize or produce special nuclear material shall be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person,

unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the act and give its consent in writing as provided in §7x.82.

(d) All special nuclear material shall be subject to the right of recapture or control reserved by section 108 and to all other provisions of the Act.

(e) No special nuclear material may be used in any fuel recycling facility except in accordance with the provisions of the Act.

(f) The licensee shall not use the special nuclear material to construct an atomic weapon or any component of an atomic weapon.

(g) The licensee may possess and use byproduct, source, or special nuclear material without restriction to chemical or physical form, for sample analysis, instrument calibration, associated with radioactive apparatus or component, and for operation of the facility.

(h) The license shall be subject to and observe the provisions of the Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license shall be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the act. Commission may incorporate in any license such additional conditions and requirements with respect to the licensee's ownership, receipt, possession, use, and transfer of special nuclear material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Guard against the loss or diversion of special nuclear material;

(5) Require such reports and the keeping of such records, and to provide for such inspections, of activities under the license as may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

(i)(1) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(14) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(a) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(j) The license shall be subject to revocation, suspension, modification, or amendment for cause as provided in the act and regulations, in accordance with the procedures provided by the act and regulations.

(k) The licensee shall at any time before expiration of the license, upon request of the Commission, submit, as specified in § 7x.4, written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

(l) The licensee shall maintain its decommissioning fund plan meeting the requirements of §7x.38.

(m) (1) The licensee shall maintain its NRC approved operator certification and requalification programs. The licensee shall certify each operator to the NRC that it needs to use to perform activities set out in the license as reserved for licensed operators. Only operators certified to the NRC and, thereafter, approved, as licensed by the Commission, based on meeting the requirements of the licensee's certification program, may perform activities set out in the license as reserved for licensed operators. For training purposes, an operator trainee may manipulate the controls if in the presence of and subject to the direct, immediate, and continuous supervision of a licensed operator whose sole function is this supervision.

(2) Each licensee shall notify the appropriate Regional Administrator as listed in appendix D to part 20 of this chapter within 30 days of the following in regard to a licensed operator:

(A) Permanent reassignment from the position for which the licensee has certified the need for a licensed operator;

(B) Termination of any licensed operator;

(C) A licensed operator becomes incapacitated because of a permanent disability or illness such that the operator cannot perform licensed activities.

(n) The licensees shall follow the emergency plan approved by the Commission. The licensee may change the approved plan without Commission approval if the changes do not decrease the

effectiveness of the plan. Within six months after each change is made, the licensee shall, using an appropriate method listed in § 7x.4, furnish the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response, a copy of each change, with copies to the appropriate NRC Regional Office specified in appendix D to part 20 of this chapter and to affected off-site response organizations. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(o)(1) Each license, shall maintain its material control and accounting program prepared pursuant to §7x.30 (i) and approved by the Commission and other material control procedures as the Commission determines to be essential for the safeguarding of special nuclear material. The licensee shall make no change that would decrease the effectiveness of the material control and accounting program without the prior approval of the Commission. A licensee desiring to make changes that would decrease the effectiveness of its material control and accounting program or its measurement control program shall submit an application for amendment to its license pursuant to § 7x.70.

(2) The licensee shall maintain records of changes to the material control and accounting program made without prior Commission approval for a period of 5 years from the date of the change. Licensees shall furnish to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response, using an appropriate method listed in § 7x.4, a report containing a description of each change within:

(i) Two months of the change if it pertains to uranium-233, uranium-235 contained in uranium enriched 20 percent or more in the uranium-235 isotope, or plutonium, except plutonium containing 80 percent or more by weight of the isotope Pu-238, and

(ii) Six months of the change if it pertains to uranium enriched less than 20 percent in the uranium-235 isotope, or plutonium containing 80 percent or more by weight of the isotope Pu-238.

(p) Each license, shall maintain its plan for physical protection of special nuclear material in transit prepared pursuant to § 7x.30(j) and approved by the Commission. The licensee shall make no change which would decrease the effectiveness of the plan for physical protection of special nuclear material in transit without the prior approval of the Commission. A licensee desiring to make such changes shall submit an application for a change to the license pursuant to § 7x.70 of this part. The licensee may make changes to the plan for physical protection of special nuclear material without prior Commission approval if these changes do not decrease the effectiveness of the plan. The licensee shall retain a copy of the plan for physical protection of special nuclear material in transit and the safeguards contingency plan or safeguards response procedures, and each change to the plan or procedures as a record for a period of three years following the date on which the licensee last possessed the appropriate type and quantity of special nuclear material requiring this record under each license. Within two months after each change, a report containing a description of the change must be furnished to the Director of the NRC's Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 7x.4; and a copy

must be sent to the appropriate NRC Regional Office shown in appendix A to part 73 of this chapter.

(q) Each license, shall maintain its plan for physical protection of special nuclear material prepared pursuant to § 7x.30(k) and approved by the Commission. The licensee shall make no change which would decrease the effectiveness of the plan for physical protection of special nuclear material without the prior approval of the Commission. A licensee desiring to make such a change shall submit an application for an amendment to its license pursuant to § 7x.70. The licensee shall maintain records of changes to the plan made without prior Commission approval, for three years from the effective date of the change, and shall, within two months after the change is made, furnish a report containing a description of each change to the Director, Division of Nuclear Security, Office of Nuclear Security and Incident Response; the report may be sent using an appropriate method listed in § 7x.4, and a copy of the report must be sent to the appropriate NRC Regional Office shown in appendix A to part 73 of this chapter. The licensee shall retain a copy of this physical security plan, and each change to the plan as a record for a period of three years following the date on which the licensee last possessed the appropriate type and quantity of special nuclear material requiring this record.

(r) Each license shall maintain its safeguards contingency plan pursuant to § 7x.30(l) and approved by the Commission. The licensee shall retain the current safeguards contingency plan procedures as a record for the entire period during which the licensee possesses the appropriate type and quantity of special nuclear material under each license for which the procedures were developed and, if any portion of the plan is superseded, retain that superseded portion for 3 years after the effective date of the change. The licensee shall not make a change that would decrease the safeguards effectiveness of the first four categories of information (i.e., Background, Generic Planning Base, Licensee Planning Base, and Responsibility Matrix) contained in any licensee safeguards contingency plan prepared pursuant to this part, §§ 72.184, 73.20(c), 73.26(e)(1), 73.46(h)(1), or 73.50(g)(1) of this chapter without the prior approval of the NRC. A licensee desiring to make such a change shall submit an application for an amendment to its license pursuant to § 7x.70. The licensee may make changes to the licensee safeguards contingency plan without prior NRC approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall maintain each change to the plan made without prior approval as a record during the period for which possession of a formula quantity of special nuclear material is authorized under a license and retain the superseded portion for 3 years after the effective date of the change, and shall, within 60 days after the change is made, furnish a report containing a description of each change to the Director of Nuclear Material Safety and Safeguards; the report may be sent using an appropriate method listed in § 7x.4, and a copy of the report must be sent to the Regional Administrator of the appropriate NRC Regional Office as specified in appendix A to part 73 of this chapter.

(s) Each licensee shall ensure that physical security, safeguards contingency, and guard qualification and training plans and other related Safeguards Information are protected against unauthorized disclosure in accordance with the requirements of § 73.21 of this chapter.

(t) (i) Each licensee shall maintain in each area in which such licensed special nuclear material is handled, used, or stored, a monitoring system meeting the requirements of either paragraph

(i)(A) or (i)(B), as appropriate, and using gamma- or neutron-sensitive radiation detectors which will energize clearly audible alarm signals if accidental criticality occurs. This section is not intended to require underwater monitoring when special nuclear material is handled or stored beneath water shielding or to require monitoring systems when special nuclear material is being transported when packaged in accordance with the requirements of part 71 of this chapter.

(A) The monitoring system shall be capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within one minute. Coverage of all areas shall be provided by two detectors.

(B) The licensee shall maintain emergency procedures for each area in which this licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm. These procedures must include the conduct of drills to familiarize personnel with the evacuation plan, and designation of responsible individuals for determining the cause of the alarm, and placement of radiation survey instruments in accessible locations for use in such an emergency. The licensee shall retain a copy of current procedures for each area as a record for as long as licensed special nuclear material is handled, used, or stored in the area. The licensee shall retain any superseded portion of the procedures for three years after the portion is superseded.

(ii) Each licensee prior to receipt of special nuclear material shall:

(A) Provide the means for identifying quickly which individuals have received doses of 10 rads or more from a criticality event.

(B) Maintain facilities and supplies at the site for decontamination of personnel, arrangements for the services of a physician and other medical personnel qualified to handle radiation emergencies, arrangements for transportation of injured or contaminated individuals to treatment facilities, and arrangements for treatment of individuals at treatment facilities outside the site boundary.

(u) A licensee may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under this part) in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent provided the action is approved by a licensed operator, if the actions are within a licensed operator's licensed responsibility, or for other actions by a designated competent licensee authority.

(v) A licensee may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under this part) in a national security emergency:

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission, and

(2) No action consistent with license conditions and technical specifications that can meet national security objectives is immediately apparent.

A national security emergency is established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph must be exercised in accordance with law, including section 57e of the Act, and is in addition to the authority granted under paragraph (u) of this section, which remains in effect unless otherwise directed by the Commission during a national security emergency.

(w) The issuance or existence of the license shall not be deemed to waive, or relieve the licensee from compliance with, the antitrust laws, as specified in subsection 105a of the Act. In the event that the licensee should be found by a court of competent jurisdiction to have violated any provision of such antitrust laws in the conduct of the licensed activity, the Commission may suspend or revoke the license or take such other action with respect to it as shall be deemed necessary.

§ 7x.62 Environmental conditions.

(a) Each construction permit and combined license under this part may include conditions to protect the environment during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a fuel recycling facility, including a combined license may include conditions to protect the environment during operation and decommissioning. These conditions are to be set out in an attachment to the license which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 7x.64 Conditions for construction under construction permits and combined licenses.

Each construction permit is subject to the following terms and conditions and each combined license is subject to the terms and conditions in paragraphs (d) and (e) of this section until the date that the Commission makes the finding under § 7x.58(c)(7) of this chapter:

(a) The construction permit shall state the earliest and latest dates for completion of the construction or modification.

(b) If the proposed construction or modification of the facility is not completed by the latest completion date, the construction permit shall expire and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

(c) At or about the time of completion of the construction or modification of the facility, the applicant will file any additional information needed to bring the original application for license up to date, and will file an application for an operating license or an amendment to an application for a license to construct and operate the facility for the issuance of an operating license, as appropriate, as specified in § 7x.20(c) of this part.

(d) Each construction permit holder may make a change to a previously accepted quality assurance program description included or referenced in the Safety Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program description that do reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(1) Changes to the Safety Report must be submitted for review as specified in § 7x.4. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted as specified in § 7x.4.

(2) The submittal of a change to the Safety Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of 10 CFR part 50 and the Safety Report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.

(4) Changes to the quality assurance program description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(e) Each holder of a construction permit and each holder of a combined license shall, if requested by the Commission, submit installation information on Form–71, permit verification thereof by the International Atomic Energy Agency, and take other action as may be necessary to

implement the US/IAEA Safeguards Agreement, in the manner set forth in § 75.6 and §§ 75.11 through 75.14 of this chapter.

§ 7x.66 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, procedures, and activities of personnel described in the Safety Report. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the ISA, ISA Summary, or other safety program information, required by § 7x.36.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, procedures, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, and documented before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with § 7x.70.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) Does not:

(i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of § 7x.32 and that have not previously been described in the ISA Summary; or

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

(2) Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the ISA Summary and is necessary for compliance with the performance requirements of § 7x.32;

(3) Does not alter any item relied on for safety, listed in the ISA Summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of § 7x.32; and

(4) Is not otherwise prohibited by the requirements of this chapter, license condition, technical specification, or order.

(d)(1) For changes that require pre-approval under this section, the licensee shall submit an amendment request to the NRC in accordance with § 7x.30 and § 7x.70 of this part.

(2) For changes that do not require pre-approval under this section, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, a brief summary of all changes to the records required by § 7.36(b) of this subpart. The summary is to contain a brief explanation of each change, why the change was made, and why it did not require pre-approval.

(3) For all changes that affect the Safety Report, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised Safety Report pages and a brief explanation of each change, why the change was made, and why it did not require pre-approval. Each replacement page shall include a change indicator for the area changed and a page change identification (date of change or change number or both). This submittal shall be certified by a licensee official that it accurately presents changes made since the last submittal.

(e) If a change covered by paragraph (a) of this section is made, the affected on-site documentation must be updated promptly.

(f) In implementing this section, the Safety Report is considered to include changes resulting from evaluations performed pursuant to this section, analyses performed pursuant to §7x.70, and any other analysis performed by or for the licensee at the request of the NRC since submittal of the last update of the Safety Report pursuant to this section.

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

§ 7x.68 Backfitting.

(a) (1) Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition

of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position after issuance of a license including a construction permit.

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

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

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

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

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

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

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

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

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

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

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from licensed material;

(4) Potential impact on radiological exposure or exposure to hazardous chemicals produced from licensed material of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime;

(6) The potential safety impact of changes in facility or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No license will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee

Subpart E. - Amendment of License or Construction Permit at Request of Holder, Renewal, and Termination

§ 7x.70 Application for amendment of license or construction permit.

Whenever a holder of a license under this part desires to amend the license application for an amendment must be filed with the Commission, as specified in §7x.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

§ 7x.72 Notice for public comment; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an operating license or a combined license. For amendments subject to 10 CFR part 2, subpart L, the following procedures will apply only to the extent specifically referenced in § 2.309(b) of this chapter, except that notice of opportunity for hearing must be published in the **Federal Register** at least 30 days before the requested amendment is issued by the Commission:

(a) *Notice for public comment.* (1) At the time a licensee requests an amendment, it must provide to the Commission, in accordance with the distribution requirements specified in § 7x.4, its analysis about the issue of no significant hazards consideration using the standards in § 7x.74.

(2)(i) The Commission may publish in the Federal Register under § 2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic Federal Register notice of proposed actions which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will (A) contain the staff's proposed determination, under the standards in § 7x.74, (B) provide a brief description of the amendment and of the facility involved, (C) solicit public comments on the proposed determination, and (D) provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(3) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination on no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

(4) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(5) Where the Commission finds that significant hazards considerations are involved, it will issue a Federal Register notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(6) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a Federal Register notice allowing 30 days for prior public comment, and determines that the amendment involves no significant hazards considerations, it:

(i)(A) Will either issue a Federal Register notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(2) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter;

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it, and use its normal public notice and comment procedures in paragraph (a)(2) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(7) Where the Commission finds that significant hazards considerations are involved, it will issue a Federal Register notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation*. (1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so. (The Commission will make available to the licensee the name of the appropriate State official designated to receive such amendments.)

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the Federal Register notice.

(3) The Commission will make available to the State official designated to consult with it about its proposed determination the names of the Project Manager or other NRC personnel it designated to consult with the State. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to telephone that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration.)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to telephone the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.* (1) The State consultation procedures in paragraph (b) of this section do not give the State a right:

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for nuclear power plants.

§ 7x.74 Issuance of amendment.

(a) In determining whether an amendment to a license or construction permit will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses or construction permits to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to the facility under a combined license before the date that the Commission makes the finding under § 7x.58(c)(7) of this part, no application for a construction permit is

required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action:

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a fuel recycling facility).

(c) The Commission may make a final determination, under the procedures in § 7x.72, that a proposed amendment to an operating license or a combined license involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the likelihood or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 7x.76 Renewal of licenses.

(a) Applications for renewal of a license should be filed in accordance with §7x.20. Information contained in previous applications, statements or reports filed with the Commission under the license may be incorporated by reference: *Provided*, that such references are clear and specific.

(b) In considering an application by a licensee to renew, the Commission will apply the criteria in this part.

§ 7x.78 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a)Each license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 7x.76 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each license continues in effect, beyond the expiration date if necessary, to authorize ownership and possession, but not operation, of the fuel recycling facility and possession of special nuclear material, source material, and byproduct material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(1) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control, and maintenance of special nuclear material, source material, and byproduct material in a safe condition; and

(2) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the facility's license.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 7x.4, each licensee shall provide notification to the NRC in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release in accordance with NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 70.25 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v) of this section. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days

before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) The procedures listed in paragraph (g)(1) of this section may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

(vii) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Special nuclear material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by §7x.94(b) have been received

Subpart F-Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights

§ 7x.80 Authorized use of special nuclear material.

(a) Each licensee shall confine its possession and use of special nuclear material to the locations and purposes authorized in its license. Except as otherwise provided in the license, each license issued pursuant to the regulations in this part shall carry with it the right to receive title to, own, acquire, receive, possess and use special nuclear material. Preparation for shipment and transport of special nuclear material shall be in accordance with the provisions of part 71 of this chapter.

(b) The possession, use and transfer of any special nuclear material produced by a licensee, in connection with or as a result of use of special nuclear material received under its license, shall be subject to the provisions of the license and the regulations in this part.

§ 7x.82 Transfer of licenses.

(a) No license granted under the regulations in this part and no right to possess or utilize special nuclear material granted by any license issued pursuant to the regulations in this part shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Commission shall after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(b) An application for transfer of a license shall include as much of the information described in §§ 7x.28 and 7x.30 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(2) The application shall include also a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data pursuant to § 7x.20. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines:

(1) That the proposed transferee is qualified to be the holder of the license; and

(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

§ 7x.84 Creditor regulations.

(a) Pursuant to section 184 of the Act, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any fuel recycling facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility: *Provided*:

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Atomic Energy Act of 1954, as amended, and regulations issued by the Commission pursuant to said Act; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

Subpart G—Reports, Records, and Inspections

§ 7x.90 Reporting requirements.

Licensees shall make the reports required by this section.

(a) *One hour reports.* Each licensee shall notify the NRC within 1 hour of discovery, supplemented with the information in paragraph (d) of this section as it becomes available, followed by a written report within 30 days:

(1) The discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(2) An inadvertent or accidental nuclear criticality.

(3) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in § 7x.32(b)(4).

(5) An event or condition such that no IROFS, as documented in the ISA Summary, remain available and reliable, in an accident sequence evaluated in the ISA, to perform their function:

(i) In the context of the performance requirements in § 7x.32(b) and § 7x.32(c), or

(ii) Prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).

(6) Loss of controls such that only one item relied on for safety, as documented in the ISA Summary, remains available and reliable to prevent a nuclear criticality accident, and has been in this state for greater than eight hours.

(b) *Twenty-four hour report*. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(5) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the ISA, and which results in failure to meet the performance requirements of § 7x.32.

(6) Loss or degradation of IROFS that results in failure to meet the performance requirement of § 7x.32.

(7) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of § 7x.32(c)(4).

(8) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more IROFS.

(9) An occurrence of an event or process deviation that was considered in the ISA and:

(i) Was dismissed due to its likelihood; or

(ii) Was categorized as unlikely and whose associated unmitigated consequences would have exceeded those in § 7x.32(b) had the item(s) relied on for safety not performed their safety function(s).

(10)(i) Any airborne radioactive release that, when averaged over a time period of 1 hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeded 20 times the applicable concentration limits specified in appendix B to part 20, table 2, column 1.

(ii) Any liquid effluent release that, when averaged over a time period of 1 hour, exceeds 20 times the applicable concentrations specified in appendix B to part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(c) *Concurrent Reports.* Each licensee shall notify the NRC of any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made concurrent to the news release or other notification.

(d) *Preparation and submission of reports*. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a), (b), and (c) of this section to the NRC Operations Center via the Emergency Notification System. If the Emergency Notification System is inoperative, the licensee shall make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Operations Center (The commercial telephone number for the NRC Operations Center is (301) 816-5100.). In addition:

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

(ii) The information provided must include a description of the event and other related information as described in paragraph (d) of this section;

(iii) Follow-up information to the reports must be provided until all information required to be reported in paragraph (d) of this section; and

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

(2) *Contents of the report.* To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) Caller's name, position title, and call-back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including:

(A) Radiological or chemical hazards involved, including isotopes, quantities, and chemical and physical form of any material released;

(B) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures to radiation or radioactive materials or hazardous chemicals produced from licensed materials (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function;

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

(vi) Status of the event (e.g., whether the event is on-going or was terminated);

(vii) Current and planned site status, including any declared emergency class;

(viii) Notifications, related to the event, that were made or are planned to any local, State, or other Federal agencies;

(ix) Status of any press releases, related to the event, that were made or are planned.

(3) *Written report*. Each licensee that makes a report required by paragraph (a), (b), or (c) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all the necessary information, and the appropriate distribution is made. These written reports must be sent to the NRC's Document Control Desk, using an appropriate method

listed in § 7x.4, with a copy to the appropriate NRC regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) Complete applicable information required by paragraph (d) of this section

(ii) The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) Whether the event was identified and evaluated in the ISA.

§ 7x.92 Additional Reporting Requirements

(a) *Effluent monitoring reporting requirements*. Within 60 days after January 1 and July 1 of each year, and using an appropriate method listed in § 7x.4, each holder of an operating license, and each holder of a combined license after the Commission has made the finding under §7x.58(c)(7) of this chapter, shall submit a report addressed: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter. The report must specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and gaseous effluents during the previous six months of operation, and such other information as the Commission may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting periods are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may from time to time require the licensee to take such action as the Commission deems appropriate.

(b) *Financial reports.* Each licensee and each holder of a construction permit shall submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 7x.4, upon issuance of the report. However, licensees and holders of a construction permit who submit a Form 10-Q with the Securities and Exchange Commission need not submit the annual financial report or the certified financial statement under this paragraph.

§ 7x.94 Records requirements.

(a) Each licensee, including each holder of a construction permit, shall maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations, and orders of the Commission in effectuating the purposes of the Act, and the Energy Reorganization Act of 1974, as amended. Reports must be submitted in accordance with § 7x.4

(b) Before license termination, licensees shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under 10 CFR 20.2002, 20.2003, 20.2004, 20.2005;

(2) Records required by 10 CFR 20.2103(b)(4); and

(3) Records required by § 7x.38(d).

(c) If licensed activities are transferred or assigned in accordance with § 7x.82, the licensee shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 10 CFR 20.2002, 20.2003, 20.2004, 20.2005;

(2) Records required by 10 CFR 20.2103(b)(4); and

(3) Records required by § 7x.38(d).

(d)(1) Records which must be maintained pursuant to this part may be the original or a reproduced copy, or microform if the reproduced copy or microform is duly authenticated by authorized personnel, and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for these records shall apply unless the Commission, under § 7x.12 has granted a specific exemption from the record retention requirements specified in the regulations in this part.

§ 7x.96 Inspections.

(a) Each applicant for or holder of a license, including a construction permit, shall permit inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license or construction permit as may be necessary to effectuate the purposes of the Act and the Energy Reorganization Act of 1974, as amended.

(b)(1) Each licensee including a holder of a construction permit shall upon request by the Director, Office of Nuclear Material Safety and Safeguards or the appropriate NRC Regional

Administrator, provide rent-free office space for the exclusive use of Commission inspection personnel. Heat, air conditioning, light, electrical outlets and janitorial services shall be furnished by each licensee. The office shall be convenient to and have full access to the facility and, shall provide the inspector both visual and acoustic privacy.

(2) For a site with a single facility licensed, the space provided shall be adequate to accommodate a full-time inspector, a part-time secretary and transient NRC personnel and will be generally commensurate with other office facilities at the site. A space of 250 square feet either within the site's office complex or in an office trailer or other on site space is suggested as a guide. Additional space may be requested depending on the activities to be included within the scope of a fuel recycling facility to accommodate additional full-time inspector(s). The office space that is provided shall be subject to the approval of the Director, Office of Nuclear Material Safety and Safeguards or the appropriate NRC Regional Administrator. All furniture, supplies and communication equipment will be furnished by the Commission.

(3) The licensee shall afford any NRC resident inspector assigned to that site or other NRC inspectors identified by the Director, Office of Nuclear Material Safety and Safeguards, as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(4) The licensee or construction permit holder shall ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(3) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 7x.98 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part, including tests of (a) special nuclear material, (b) facilities wherein special nuclear material is utilized, produced or stored, (c) radiation detection and monitoring instruments, and (d) other equipment and devices used in connection with the production, utilization or storage of special nuclear material.

Subpart H--Modification and Revocation of Licenses

§ 7x.100 Modification and revocation of licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification by reason of amendments to the Atomic Energy Act of 1954, or by reason of rules, regulations or orders issued in accordance with the Act or any amendments thereto;

(b) Any license may be revoked, suspended or modified for any material false statements in the application or any statement of fact required under section 182 of the Act or because of conditions revealed by such application or statement of fact or any report, record, or inspection

or other means which would warrant the Commission to refuse to grant a license on an original application, or for failure to construct or operate a facility in accordance with the terms of the construction permit or license, the technical specifications in the application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of any regulation of the Commission.

(c) Upon revocation, suspension or modification of a license, the Commission may immediately retake possession of all special nuclear material held by the licensee. In cases found by the Commission to be of extreme importance to the national defense or security, or to the health and safety of the public, the Commission may recapture any special nuclear material held by the licensee prior to any of the procedures provided under section 551-558 of title 5 of the United States Code.

(d) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

§ 7x.102 Suspension and operation in war or national emergency.

(a) Whenever Congress declares that a state of war or national emergency exists, the Commission, if it finds it necessary to the common defense and security, may,

(1) Suspend any license it has issued.

(2) Cause the recapture of special nuclear material.

(3) Order the operation of any licensed facility.

(4) Order entry into any plant or facility in order to recapture special nuclear material or to operate the facility.

(b) Just compensation shall be paid for any damages caused by recapture of special nuclear material or by operation of any facility, pursuant to this section.

Subpart I—Licensed Operators

§ 7x.110 License requirements.

A person must be authorized by a license issued by the Commission to perform the function of an operator as defined in this part. The regulations in this part do not require a license for an individual who under the direction and in the presence of a licensed operator manipulates the controls of a facility as a part of the individual's training in a facility licensed operator's training program as approved by the Commission to qualify for an operator license under this part.

§ 7x.112 Definitions.

As used in this subpart:

Actively performing the functions of an operator means that an individual has a position on the shift crew that requires the individual to be licensed as defined in the facility's license and that the individual carries out and is responsible for the duties covered by that position.

Controls means the apparatus and mechanisms the manipulation of which affects the prevention or mitigation of high consequence events, as defined in §7x.32 involving fission product releases to an individual outside the controlled area.

Facility licensee means an applicant for or holder of a license for a facility.

Licensee means an individual licensed operator.

Operator means any individual licensed under this part to manipulate a control of a facility.

Physician means an individual licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

Systems approach to training means a training program that includes the following five elements:

(1) Systematic analysis of the jobs to be performed.

(2) Learning objectives derived from the analysis which describes desired performance after training.

(3) Training design and implementation based on the learning objectives.

(4) Evaluation of trainee mastery of the objectives during training.

(5) Evaluation and revision of the training based on the performance of trained personnel in the job setting.

§ 7x.114 Medical examination.

An applicant for a license shall have a medical examination by a physician. A licensed operator shall have a medical examination by a physician every two years. The physician shall determine that the applicant or licensed operator meets the requirements of § 7x.122(a)(1).

§ 7x.116 Medical Certification.

To certify the medical fitness of the applicant, an authorized representative of the facility licensed operator shall complete and sign NRC Form 396RF, "Certification of Medical

Examination by Fuel Recycling Facility Licensed operator," which can be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (301) 415-5877, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

(a) Form NRC-396RF must certify that a physician has conducted the medical examination of the applicant as required in § 7x.114.

(b) When the certification requests a conditional license based on medical evidence, the medical evidence must be submitted on NRC Form 396RF to the Commission and the Commission then makes a determination in accordance with § 7x.124.

§ 7x.118 Incapacitation because of disability or illness.

If, during the term of the license, the licensed operator develops a permanent physical or mental condition that causes the licensed operator to fail to meet the requirements of § 7x.114, the facility licensed operator shall notify the Commission, within 30 days of learning of the diagnosis, in accordance with § 7x.60(m)(2). For conditions for which a conditional license (as described in § 7x.124(b)) is requested, the facility licensed operator shall provide medical certification on Form NRC 396RF to the Commission (as described in § 7x.116).

§ 7x.120 Documentation.

The facility licensed operator shall document and maintain the results of medical qualifications data, test results, and each operator's medical history for the current license period and provide the documentation to the Commission upon request. The facility licensed operator shall retain this documentation while an individual performs the functions of an operator.

§ 7x.122 Application requirements.

In accordance with § 7x.30 (p) of this part, facility applicants for and holders of licenses of recycling facility licenses shall establish and maintain a program to train and certify operators for the facility. Individuals who have successfully completed this training program and who have been certified by an appropriate designated facility manager may apply for an operator license.

(a) The licensed operator applicant shall:

(1) File an original of NRC Form 398RF, ,"Personal Qualification Statement--Licensed Operator for a Fuel Recycling Facility," together with the information required in paragraphs (a)(2),and (3) of this section with the Director, Office of Nuclear Materials Safety and Safeguards for a recycling facility. NRC Form 398RF can be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (301) 415-5877, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page;

(2) The recycling facility licensed operator shall certify to the Commission that the applicant has

satisfactorily completed the requirements of the approved facility operator certification program and has need for the operator to perform assigned duties.

(3) Provide certification by the facility licensed operator of medical condition and general health on Form NRC – 396RF, to comply with §§ 7x.114, 7x.116, and 7x.122(a)(1).

(b) The Commission may at any time after the application has been filed, and before the license has expired, require further information under oath or affirmation in order to enable it to determine whether to grant or deny the application or whether to revoke, modify, or suspend the license.

(c) An applicant whose application has been denied because of a medical condition or general health may submit a further medical report at any time as a supplement to the application.

(d) Each application and statement must contain complete and accurate disclosure as to all matters required to be disclosed. The applicant shall certify that he or she is technically, mentally, and physically competent to operate the controls of the facility and will comply with the Commission requirements including the facility license.

§ 7x. 124 Disposition of an initial application.

(a*) Requirements for the approval of an initial application.* The Commission will approve an initial application for a license pursuant to the regulations in this part, if it finds that:

(1) *Health*. The applicant's medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety. The Commission will base its finding upon the certification by the facility licensed operator as detailed in § 7x.116.

(2) *Licensing of Operators.* In determining whether to approve an application for an operator license, the Commission will rely largely on the facility's certification that the applicant is technically competent based on the facility's NRC approved training and certification program. The Commission may review and observe each applicant's training and certification process to the extent needed to make a determination concerning each application. Recycling facility applicants and licensed operators shall afford the NRC staff access to training materials, tests and test results, practical training both on a simulator, if utilized, and in the facility to allow the staff to make its determination on an application, as well as, to the adequacy of the training and certification program.

(b) *Conditional license.* If an applicant's general medical condition does not meet the minimum standards under § 7x.122(a)(1) of this part, the Commission may approve the application and include conditions in the license to accommodate the medical defect. The Commission will consider the recommendations and supporting evidence of the facility licensed operator and of the examining physician (provided on Form NRC-396RF) in arriving at its decision.

§ 7x.126 Integrity of examinations and tests.

Applicants, licensed operators, and facility licensed operators shall not engage in any activity that compromises the integrity of any application, test, or examination required by this subpart. The integrity of a test or examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, would have affected the equitable and consistent administration of the test or examination. This includes activities related to the preparation and certification of license operator applications and all activities related to the preparation, administration, and grading of the tests and examinations required by the facility licensee's training, requalification, and certification programs.

§ 7x.128 Issuance of operator licenses.

If the Commission determines that an applicant for an operator license meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.

§ 7x.130 Conditions of operator licenses.

Each license contains and is subject to the following conditions whether stated in the license or not:

(a) Neither the license nor any right under the license may be assigned or otherwise transferred.

(b) The license is limited to the facility for which it is issued.

(c) The license is limited to those controls of the facility specified in the license.

(d) The license is subject to, and the licensed operator shall observe all applicable license conditions, regulations, and orders of the Commission.

(e) If a licensed operator has not been actively performing the functions of an operator, the licensed operator may not resume activities authorized by a license issued under this part except as permitted by paragraph (f) of this section. To maintain active status, the licensed operator shall actively perform the functions of an operator on a minimum of seven 8-hour or five 12-hour shifts per calendar quarter.

(f) If paragraph (e) of this section is not met, before resumption of functions authorized by a license issued under this subpart, an authorized representative of the facility licensee shall document the following:

(1) That the qualifications and status of the licensed operator are current and valid; and

(2) That the licensed operator has completed a minimum of 40 hours of shift functions under the direction of an operator and in the position to which the individual will be assigned. The 40 hours must have included a complete tour of the plant and all required shift turnover procedures.

(g) The licensed operator shall notify the Commission within 30 days about a conviction for a

felony.

(h) The licensed operator shall complete the facility licensee's requalification program over a continuous period not to exceed 24 months in duration.

(i) The licensed operator shall have a biennial medical examination.

(j) The licensed operator shall not consume or ingest alcoholic beverages within the controlled access area of the fuel recycling facility. The licensed operator shall not use, possess, or sell any illegal drugs. The licensed operator shall not perform activities authorized by a license issued under this part while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform his or her licensed duties. For the purpose of this paragraph, with respect to alcoholic beverages and drugs, the term "under the influence" means the licensed operator exceeded, as evidenced by a confirmed positive test, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR part 26, appendix A, of this chapter, or as established by the facility licensed operator. The term "under the influence" also means the licensed operator could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the facility licensed operator for its fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform licensed duties.

(k) Each licensed operator shall participate in the drug and alcohol testing programs established pursuant to 10 CFR part 26.

(l) The licensed operator shall comply with any other conditions that the Commission may impose to protect health or to minimize danger to life or property.

§ 7x.132 Expiration.

(a) Each operator license expires six years after the date of issuance, upon termination of employment with the facility licensee, or upon determination by the facility licensee that the licensed individual no longer needs to maintain a license.

(b) If a licensed operator files an application for renewal or an upgrade of an existing license on Form NRC-398RF at least 30 days before the expiration of the existing license, it does not expire until disposition of the application for renewal or for an upgraded license has been finally determined by the Commission. Filing by mail or telegram will be deemed to be complete at the time the application is deposited in the mail or with a telegraph company.

§ 7x.134 Renewal of operator licenses.

(a) The applicant for renewal of a license shall:

(1) Submits an original of NRC Form 398RF to the Director, Office of Nuclear Material Safety and Safeguards for process operator renewal applications.

(2) Provide written evidence of the applicant's experience under the existing license and the approximate number of hours that the licensed operator has operated the facility.

(3) Provide a statement by an authorized representative of the facility licensee that during the effective term of the current license the applicant has satisfactorily completed the requalification program for the facility for which operator license renewal is sought, has been recertified by the facility licensee, and is capable of continuing to competently and safely assume licensed duties.

(4) Provide evidence that the applicant has discharged the license responsibilities competently and safely.

(5) Provide certification by the facility licensed operator of medical condition and general health on Form NRC-396FR, to comply with §§ 7x.114, 7x.116, and 7x.120.

(b) The license will be renewed if the Commission finds that:

(1) The medical condition and the general health of the licensed operator continue to be such as not to cause operational errors that endangers public health and safety. The Commission will base this finding upon the certification by the facility licensed operator as described in § 7x.116.

(2) The facility licensee has certified that the operator has met the requalification program requirements, and has been recertified to be an operator.

(3) There is a continued need for a licensed operator to operate the facility designated in the application.

(4) The past performance of the licensed operator has been satisfactory to the Commission. In making its finding, the Commission will include in its evaluation information such as notices of violations or letters of reprimand in the licensed operator's docket.

§ 7x.136 Modification and revocation of operator licenses.

(a) The terms and conditions of all licenses are subject to amendment, revision, or modification by reason of rules, regulations, or orders issued in accordance with the Act or any amendments thereto.

(b) Any license may be revoked, suspended, or modified, in whole or in part:

(1) For any material false statement in the application or in any statement of fact required under section 182 of the Act,

(2) Because of conditions revealed by the application or statement of fact or any report, record, inspection or other means that would warrant the Commission to refuse to grant a license on an original application,

(3) For willful violation of, or failure to observe any of the terms and conditions of the Act, or the license, or of any rule, regulation, or order of the Commission,

(4) For any conduct determined by the Commission to be a hazard to safe operation of the facility, or

(5) For the sale, use, or possession of illegal drugs; refusal to participate in the facility drug and alcohol testing program; a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 7x.130(j); the consumption of alcoholic beverages within the controlled access area; or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.

Subpart J-- Enforcement

§ 7x.140 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 7x.142 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 70 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 7x that are not issued under sections 161b, 161i, or 161o, for the purposes of section 223 are as follows: _____

Proposed Considerations to Other Parts of 10 CFR

The following changes are needed to Chapter I of Title 10 to implement a new a Part 7x. Additions are underlined and subtractions are strikethrough.

PART 2--RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1) In § 2.101, paragraphs (a)(5) and a(9) are changed as follows:

§ 2.101 Filing of application.

(a)***

(5) An applicant for a construction permit under part 50 or part 7x of this chapter or a combined license under part 52 or part 7x of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 of this chapter or is a testing facility or a fuel recycling facility subject to part 7x of this chapter may submit the information required of applicants by part 50, part 52 , or part 7x of this chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, § 52.80(b) , or § 7x.30, other than (f), of this chapter, as applicable. The other part shall include any information required by§7x. 20(e) and 7x.30 (f) or § 50.34(a) and, if applicable, § 50.34a of this chapter, or §§ 52.79 and 52.80(a), as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director, Office of Nuclear Reactor Regulation, Director, Office of New Reactors, Director, Office of Federal and State Materials and Environmental Management Programs, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required by §7x.20(d) or §§ 50.30(e) and 170.21 of this chapter and the information required by §§ 7x.20, 7x.28, 50.33, 50.34(a)(1), or 52.79(a)(1), as applicable, and § 50.37 of this chapter. The Director, Office of Nuclear Reactor Regulation, Director, Office of New Reactors, Director, Office of Federal and State Materials and Environmental Management Programs, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 7x or 52 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 of this chapter or is a testing facility or a fuel recycling facility subject to part 7x of this chapter where one part of the application as described above is complete and conforms to the requirements of part 50 or part 7x, as applicable, of this chapter. The additional parts will be docketed upon a determination by the Director, Office of Nuclear Reactor Regulation, Director, Office of New Reactors, Director, Office of Federal and State Materials and Environmental Management Programs, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

*****

(9) An applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (b)(3) or § 50.22 of this chapter, an applicant for or holder of an early site permit under part 52 of this chapter, or an applicant for a combined license under part 52 of this chapter, or an applicant for either a construction permit or combined license under part 7x of this chapter, who seeks to conduct the activities authorized under § 50.10(d) or 7x.10 of this chapter may submit a complete application under paragraphs (a)(1) through (a)(4) of this section which includes the information required by § 50.10(d) or §7x.10, as applicable, of this chapter. Alternatively, the applicant (other than an applicant for or holder of an early site permit) may submit its application in two parts:

(i) Part one must include the either the information required by § 50.33(a) through (f) of this chapter, and the information required by § 50.10(d)(2) and (d)(3) of this chapter or the information required by § 7x.20 and 7x.28 of this chapter, and the information required by § 50.10(d)(2) and (d)(3) of this chapter or §7x.10(d((3) of this chapter as applicable.

(ii) ****

2) In § 2.104, paragraphs (a) and (b)(1) are changed as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the **Federal Register**. The notice must be published at least 15 days, and in the case of an application concerning a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in §§ 50.21(b) or 50.22 of this chapter or a testing facility, or a construction permit or combined license under part 7x of this chapter, at least 30 days, before the date set for hearing in the notice.[1] In addition, in the case of an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.22 of this chapter, or a testing facility, or a construction permit or combined license under part 7x of this chapter, the notice must be issued as soon as practicable after the NRC has docketed the application. If the Commission decides, under § 2.101(a)(2), to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice must be issued as soon as practicable after the application has been tendered.

(b) *****

1. If the notice of hearing concerning an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in §§ 50.21(b) or 50.22 of this chapter or a testing facility, or a construction permit or combined license under part 7x of this chapter does not specify the time and place of initial hearing, a subsequent notice will be published in the **Federal Register** which will provide at least 30 days notice of the time and place of that hearing. After this notice is given, the presiding officer may

reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30 days notice.

3) In § 2.105, paragraphs (a), (a)(4), (a)(10), and (b)(3) are changed as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the **Federal Register**, as applicable, either a notice of intended operation under § 52.103(a) or § 7x.58(c) of this chapter and a proposed finding that inspections, tests, analysis, and acceptance criteria for a combined license under subpart C of part 52 or part 7x have been or will be met, or a notice of proposed action with respect to an application for:

(1) *****

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under part 7x or §§ 50.21(b) or 50.22 of this chapter, or for a testing facility, as follows:

(i) If the Commission determines under § 50.58 or § 7x.26 of this chapter that the amendment involves no significant hazards consideration, though it will provide notice of opportunity for a hearing pursuant to this section, it may make the amendment immediately effective and grant a hearing thereafter; or

(ii) If the Commission determines under §§ 50.58 and 50.91 or §§ 7x.26 and 7x.72 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing pursuant to § 2.106 (if a hearing is requested, it will be held after issuance of the amendment);

(5) *****

(10) In the case of an application for an operating license for a facility of a type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, or a fuel <u>recycling</u> facility subject to part 7x of this chapter, a notice of opportunity for hearing shall be issued as soon as practicable after the application has been docketed; or

(11) *****

(b) The notice of proposed action will set forth:

(1) *****

(3) For a notice of intended operation under § 52.103(a) or § 7x.58(c)(1) of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g) or § 7x.58 (c)(7) of this chapter;

(ii) The manner in which the licensee notifications under 10 CFR 52.99(c) which are required to be made available by 10 CFR 52.99(e)(2) or 7x.58(b)(3) may be obtained and examined;

(iii) The manner in which copies of the safety analysis may be obtained and examined; and

(iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g) or §7x.58(c)(7) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

(c) *****

4) In § 2.106, paragraphs (a)(2) and (b)(2) are changed as follows:

§ 2.106 Notice of issuance.

(a) *****

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, or a fuel recycling facility subject to part 7x. whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) or §7x.58(c) of this chapter.

(b) ****:

(1) *****

(2) In the case of a finding under § 52.103(g) or §7x.58(c) of this chapter:

(i) *****

5) In § 2.109, paragraphs (a) and (b) are changed as follows:

§ 2.109 Effect of timely renewal application.

(a) Except for the renewal of an operating license for a nuclear power plant under 10 CFR 50.21(b) or 50.22, an early site permit under subpart A of part 52 of this chapter, a manufacturing license under subpart F of part 52 of this chapter, a combined license under subpart C of part 52 of this chapter, or a license for a fuel recycling facility subject to 10 CFR part 7x of this chapter, if at least 30 days before the expiration of an existing license authorizing any activity of a continuing nature, the licensee files an application for a renewal or for a new

license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

(b) If the licensee of a nuclear power plant licensed under 10 CFR 50.21(b) or 50.22 or a licensee of a fuel recycling facility under 10 CFR part 7x files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) *****

6) In § 2.202, paragraph (e)(1) is changed as follows:

§ 2.202 Orders.

(e)(1) If the order involves the modification of a part 50 or part 7x license and is a backfit, the requirements of § 50.109 or §7x.68, as applicable, of this chapter shall be followed, unless the licensee has consented to the action required.

(2) *****

7) In § 2.309, paragraphs (a), (f)(1)(vi) and (vii) (g), (h)(2), and (i) are changed as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

(a) *General requirements*. Any person whose interest may be affected by a proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions which the person seeks to have litigated in the hearing. In a proceeding under 10 CFR 52.103 or 7x.58(c), the Commission, acting as the presiding officer, will grant the request if it determines that the requestor has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section. *****

(f) *****

(1) *****

(vi) In a proceeding other than one under 10 CFR 52.103 or 7x.58(c), provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. *****

(vii) In a proceeding under 10 CFR 52.103(b) or 7x.58(c)(2), the information must be sufficient, and include supporting information showing, *prima facie*, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable

assurance of adequate protection of the public health and safety. This information must include the specific portion of the report required by 10 CFR 52.99(c) or 7x.58(b) which the requestor believes is inaccurate, incorrect, and/or incomplete (i.e., fails to contain the necessary information required by § 52.99(c) of § 7x.58(b)(3)). If the requestor identifies a specific portion of the § 52.99(c) or §7x.58(b)(3) report as incomplete and the requestor contends that the incomplete portion prevents the requestor from making the necessary *prima facie* showing, then the requestor must explain why this deficiency prevents the requestor from making the *prima facie* showing.

(2) *****

(g) *Selection of hearing procedures*. A request for hearing and/or petition for leave to intervene may, except in a proceeding under 10 CFR 52.103 or 7x.58(c), also address the selection of hearing procedures, taking into account the provisions of § 2.310. *****

(h) *****

(2) Except in a proceeding under 10 CFR 52.103 or 7x.58(c), the requestor/petitioner may file a reply to any answer. The reply must be filed within 7 days after service of that answer.

(3) *****

(i) *Decision on request/petition*. In all proceedings other than a proceeding under 10 CFR 52.103 or 7x.58(c),the presiding officer shall, within 45 days after the filing of answers and replies under paragraph (h) of this section, issue a decision on each request for hearing/petition to intervene, absent an extension from the Commission. The Commission, acting as the presiding officer, shall expeditiously grant or deny the request for hearing in a proceeding under 10 CFR 52.103 or 7x.58(c).The Commission's decision may not be the subject of any appeal under 10 CFR 2.311.

8) In § 2.310, paragraphs (a), (d), and (j) are changed as follows:

§ 2.310 Selection of hearing procedures.

(a) Except as determined through the application of paragraphs (b) through (h) of this section, proceedings for the grant, renewal, licensee-initiated amendment, or termination of licenses or permits subject to parts 30, 32 through 36, 39, 40, 50, 52, 54, 55, 61, 70,72, and 7x of this chapter may be conducted under the procedures of subpart L of this part.

*****

(d) In proceedings for the grant, renewal, licensee-initiated amendment, or termination of licenses or permits for nuclear power reactors and fuel <u>recycling</u> facilities, where the presiding officer by order finds that resolution of the contention or contested matter necessitates resolution of issues of material fact relating to the occurrence of a past activity, where the credibility of an eyewitness may reasonably be expected to be at issue, and/or issues of motive or intent of the

party or eyewitness material to the resolution of the contested matter, the hearing for resolution of that contention or contested matter will be conducted under subpart G of this part.

*****

(j) Proceedings on a Commission finding under 10 CFR 52.103(c) and (g) and 7x.58(c)) (3) and (7) shall be conducted in accordance with the procedures designated by the Commission in each proceeding.

*****

9) In § 2.239, paragraph (a) is changed as follows:

§ 2.329 Prehearing conference.

(a) Necessity for prehearing conference; timing. The Commission or the presiding officer may, and in the case of a proceeding on an application for a construction permit or an operating license for a facility of a type described in §§ 50.21(b) or 50.22 of this chapter, a testing facility, or a fuel recycling facility under part 7x of this chapter, shall direct the parties or their counsel to appear at a specified time and place for a conference or conferences before trial. A prehearing conference in a proceeding involving a construction permit or operating license for a facility of a type described in §§ 50.21(b) or 50.22 of this chapter or a fuel recycling facility subject to part 7x of this chapter must be held within sixty (60) days after discovery has been completed or any other time specified by the Commission or the presiding officer.

(b) *****

10) In § 2.339, paragraph (d) is changed as follows:

§ 2.339 Expedited decisionmaking procedure.

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under 10 CFR 50.10 or 7x.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization, a combined license under subpart C of part 52 or part 7x of this chapter, or a manufacturing license under subpart F of part 52.

11) In § 2.340, paragraphs (a), (b), (c), (f), (i), (j), and (j)(1) are changed as follows:

§ 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

(a) *Initial decision—production or utilization facility operating license*. In any initial decision in a contested proceeding on an application for an operating license (including an amendment to or renewal of an operating license) for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to

the proceeding, any matter designated by the Commission to be decided by the presiding officer, and any matter not put into controversy by the parties, but only to the extent that the presiding officer determines that a serious safety, environmental, or common defense and security matter exists, and the Commission approves of an examination of and decision on the matter upon its referral by the presiding officer. Depending on the resolution of those matters, the Commission, the Director, Office of Nuclear Reactor Regulation, Director, Office of New Reactors, or the Director, Office of Nuclear Materials Safety and Safeguards, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(b) *Initial decision—combined license under 10 CFR parts 52 and 7x*. In any initial decision in a contested proceeding on an application for a combined license (including an amendment to or renewal of a combined license) under subpart C of part 52 of this chapter or part 7x of this chapter, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and any matter designated by the Commission to be decided by the presiding officer. Depending on the resolution of those matters, the Commission, the Director of New Reactors, the Director of Nuclear Reactor Regulation, or the Director, Office of Nuclear Materials Safety and Safeguards, as appropriate, after making the requisite findings, will issue, deny or appropriately condition the license.

(c) *Initial decision on finding under 10 CFR 52.103 or 7x.58(c) with respect to acceptance criteria in nuclear power reactor combined licenses*. In any initial decision under §§ 52.103(g) or 7x.58(c) of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding, and on any matters designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties shall be referred to the Commission for its determination. The Commission may, in its discretion, treat the matter as a request for action under § 2.206 and process the matter in accordance with §§ 52.103(f) 08 7x.58(c)(6) of this chapter. Depending on the resolution of those matters, the Commission, the Director, Office of New Reactors or Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Materials Safety and Safeguards, as appropriate, will make the finding under § 52.103 or§7x.58(c), as applicable, of this chapter, or appropriately condition that finding.

(d) *****

(f) *Immediate effectiveness of certain decisions*. An initial decision directing the issuance or amendment of a limited work authorization under 10 CFR 50.10 or 7x.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 or 7x of this chapter, an operating license under part 50 or 7x of this chapter, a combined license under subpart C of part 52 of this chapter or part 7x of this chapter, a manufacturing license under subpart F of part 52 of this chapter, or a license under 10 CFR part 72 to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS), an initial decision directing issuance of a license under part 61 of this chapter, or an initial decision under 10 CFR 52.103(g) or 7x.58(c)(7) that acceptance criteria in a combined license have been met, is immediately effective upon issuance

unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

(g)*****

(i) *Issuance of authorizations, permits, and licenses—production and utilization facilities.* The Commission, the Director of New Reactors, the Director of Nuclear Reactor Regulation, or the Director, Office of Nuclear Materials Safety and Safeguards, as appropriate, shall issue a limited work authorization under 10 CFR 50.10 or 7x.10, an early site permit under subpart A of part 52 of this chapter, a construction permit or construction authorization under part 50 or 7x of this chapter, an operating license under part 50 or 7x of this chapter, a combined license under subpart C of part 52 of this chapter or part 7x of this chapter, or a manufacturing license under subpart F of part 52 of this chapter within 10 days from the date of issuance of the initial decision:

(1) *****

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103 or 7x.58(c).* The Commission, the Director of New Reactors, the Director of Nuclear Reactor Regulation or the Director, Office of Nuclear Materials Safety and Safeguards, as appropriate, shall make the finding under 10 CFR 52.103(g) or 7x. 58(c)(7)that acceptance criteria in a combined license have been, or will be met, within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the appropriate Director has made the finding under § 52.103(g) or §7x.58(c) that acceptance criteria have been, or will be met, for those acceptance criteria which are not within the scope of the initial decision of the presiding officer; and

(2) *****

12) In § 2.341, paragraph (a)(1) is changed as follows:

§ 2.341 Review of decisions and actions of a presiding officer.

(a)(1) Except for requests for review or appeals under § 2.311 or in a proceeding on the high-level radioactive waste repository (which are governed by § 2.1015), review of decisions and actions of a presiding officer are treated under this section, provided, however, that no party may request a further Commission review of a Commission determination to allow a period of interim operation under 10 CFR 52.103(c) or 7x.58(c).

(2) *****

13) In § 2.1202, paragraph (a)(1) is changed as follows:

§ 2.1202 Authority and role of NRC staff.

(a) *****

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under 10 CFR 50.12 or 7x.10, or an application for a combined license under subpart C of 10 CFR part 52 or under 10 CFR part 7x of this chapter);

(2) *****

14) In § 2.1301, paragraph (b) is changed as follows:

§ 2.1301 Public notice of receipt of a license transfer application.

(b) The Commission will also publish in the Federal Register a notice of receipt of an application for approval of a license transfer involving 10 CFR part 50, part 52, and part 7x licenses, major fuel cycle facility licenses issued under part 70, or part 72 licenses. This notice constitutes the notice required by § 2.105 with respect to all matters related to the application requiring NRC approval.

(c) *****

15) In § 19.2, paragraph (a)(1) and (2) is changed as follows:

PART 19--NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

§ 19.2 Scope.

(a) The regulations in this part apply to:

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50, 52, or 7x of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, 54, and 7x of this chapter;

(3) *****

16) Section 19.20 is changed as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 of this chapter or regulated entity subject to the requirements in this part as delineated in

§ 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76 of this chapter, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, 7x, or 150 of this chapter is prohibited.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

17) Section 20.1002 is changed as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, 72, or 7x of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. *****

18) In § 20.1401, paragraph (a) is changed as follows:

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, 72, and 7x of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. *****

PART 21--REPORTING OF DEFECTS AND NONCOMPLIANCE

19) In § 21.2, paragraphs (a) and (a)(2) are changed as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, 72, or part 7x of this chapter, to:

(1) *****

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50, 52, or 7x of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, 72. or part 7x of this chapter;

(3) *****

20) The definitions of “basic components,” “commercial grade item,” “critical characteristics,” “dedicating entity,” “dedication,” and “substantial safety hazard” are changed as follows:

§ 21.3 Definitions.

As used in this part:

Basic component. (1) *****

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, 72, or 7x of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) *****

Commercial grade item. (1) *****

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, 72, or 7x commercial grade item means an item that is:

(i) *****

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or fuel <u>recycling</u> facilities licensed pursuant to 10 CFR Part 7x, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 or fuel <u>recycling</u> facilities licensed pursuant to 10 CFR Part 7x, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, or fuel <u>recycling</u> facilities licensed pursuant to 10 CFR Part 7x, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to

be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) *****

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, 72, or7x of this chapter.

21) In § 21.21, paragraph (d)(1)(i) and (ii) is changed as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(d)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting --

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, 72, or 7x of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, 72 , or 7x of this chapter.

(2) *****

PART 25—ACCESS AUTHORIZATION

22) In § 25.17, paragraph (a) is changed as follows:

§ 25.17 Approval for processing applicants for access authorization.

(a) Access authorizations must be requested for licensee employees or other persons (e.g., 10 CFR part 2, subpart I) who need access to classified information in connection with activities under 10 CFR parts 50, 52, 54, 60, 63, 70, 72, ~~or~~ 76, or 7x.

(b) *****

PART 26--FITNESS FOR DUTY PROGRAMS

23) In § 26.3, paragraphs (a), (c)(1), (c)(2),(c)(3), and (c)(4) are changed as follows:

§ 26.3 Scope.

(a) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57 or to operate a fuel recycling facility licensed under 10 CFR Part 7x, and holders of a combined license under 10 CFR Parts 52 or Part 7x after the Commission has made the finding under 10 CFR 52.103(g) or 7x.58(c)(7), as applicable, shall comply with the requirements of this part, except for subpart K of this part. Licensees who receive their authorization to operate a nuclear power reactor under 10 CFR 50.57 or authorization to operate a fuel recycling facility licensed under 10 CFR Part 7x, after the date of publication of this final rule in the **Federal Register** and holders of a combined license under 10 CFR Parts 52 or Part 7x after the Commission has made the finding under 10 CFR 52.103(g) or 7x.58(c)(7), as applicable, shall implement the FFD program before the receipt of special nuclear material in the form of fuel assemblies.

(c) *****

(1) Combined license applicants (under Parts 52 or Part 7x of this chapter) who have been issued a limited work authorization under § 50.10(e) or §7x.10(c)(7), as applicable, if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the limited work authorization;

(2) Combined license holders (under Parts 52 or Part 7x of this chapter) before the Commission has made the finding under § 52.103(g) or 7x.58(c)(7), as applicable;

(3) Construction permit applicants (under Parts 50 or 7x of this chapter) who have been issued a limited work authorization under § 50.10(e) or §7x.10(c)(7), if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the limited work authorization;

(4) Construction permit holders (under Parts 50 or 7x of this chapter); and

(5) *****

PART 50--DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

24) Section § 50.1 is changed to read as follows:

§ 50.1 Basis, purpose, and procedures applicable.

The regulations in this part are promulgated by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title I. I of the Energy Reorganization Act of 1974 (88 Stat. 1242), to provide for the licensing of production and utilization facilities other than fuel recycling facilities licensed under Part 7x. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 50.5.

25) In §50.30, paragraph (f) is changed as follows:

§ 50.30 Filing of application; oath or affirmation.

(f) *Environmental report*. An application for a construction permit, operating license, early site permit, combined license, or manufacturing license for a nuclear power reactor, testing facility, or other production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

26) In §50.34, footnote 8 in paragraph (a)(3)(i) is removed. In addition, paragraphs (a)(7) and (b)(6)(ii) are changed as follows:

§ 50.34 Contents of construction permit and operating license applications; technical information.

(a)*****
(7) A description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B will be satisfied.

*****

(b)*****

(6) *****

(i) *****

(ii) Managerial and administrative controls to be used to assure safe operation. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," sets forth the requirements for such controls for nuclear power plants. The information on the controls to be used for a nuclear power

plant shall include a discussion of how the applicable requirements of appendix B will be satisfied.

(iii) *****

27) In §50.34, paragraph (d) is changed as follows:

§ 50.36 Technical specifications.

(d) Technical specifications will include items in the following categories:

(1) *Safety limits, limiting safety system settings, and limiting control settings*. (i Safety limits for nuclear reactors are limits upon important process variables that are found to be necessary to reasonably protect the integrity of certain of the physical barriers that guard against the uncontrolled release of radioactivity. If any safety limit is exceeded, the reactor must be shut down. The licensee shall notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. Operation must not be resumed until authorized by the Commission. The licensee shall retain the record of the results of each review until the Commission terminates the license for the reactor, except for nuclear power reactors licensed under § 50.21(b) or § 50.22 of this part. For these reactors, the licensee shall notify the Commission as required by § 50.72 and submit a Licensee Event Report to the Commission as required by § 50.73. Licensees in these cases shall retain the records of the review for a period of three years following issuance of a Licensee Event Report.

(ii) Limiting safety system settings for nuclear reactors are settings for automatic protective devices related to those variables having significant safety functions. Where a limiting safety system setting is specified for a variable on which a safety limit has been placed, the setting must be so chosen that automatic protective action will correct the abnormal situation before a safety limit is exceeded. If, during operation, it is determined that the automatic safety system does not function as required, the licensee shall take appropriate action, which may include shutting down the reactor. The licensee shall notify the Commission, review the matter, and record the results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. The licensee shall retain the record of the results of each review until the Commission terminates the license for the reactor except for nuclear power reactors licensed under § 50.21(b) or § 50.22 of this part. For these reactors, the licensee shall notify the Commission as required by § 50.72 and submit a Licensee Event Report to the Commission as required by § 50.73. Licensees in these cases shall retain the records of the review for a period of three years following issuance of a Licensee Event Report.

(2) *Limiting conditions for operation*. (i) Limiting conditions for operation are the lowest functional capability or performance levels of equipment required for safe operation of the facility. When a limiting condition for operation of a nuclear reactor is not met, the licensee shall shut down the reactor or follow any remedial action permitted by the technical specifications until the condition can be met. In the case of a nuclear reactor not licensed under § 50.21(b) or § 50.22 of this part the licensee shall notify the Commission, review the matter, and record the

results of the review, including the cause of the condition and the basis for corrective action taken to preclude recurrence. The licensee shall retain the record of the results of each review until the Commission terminates the license for the nuclear reactor. In the case of nuclear power reactors licensed under § 50.21(b) or § 50.22, the licensee shall notify the Commission if required by § 50.72 and shall submit a Licensee Event Report to the Commission as required by § 50.73. In this case, licensees shall retain records associated with preparation of a Licensee Event Report for a period of three years following issuance of the report. For events which do not require a Licensee Event Report, the licensee shall retain each record as required by the technical specifications.

(ii) *****

28) In §50.54, paragraph (a)(1) is changed as follows:

§ 50.54 Conditions of licenses.

(a)(1) Each nuclear power plant licensee subject to the quality assurance criteria in appendix B of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

(2)*****

29) In §50.55, paragraph (f)(1) is changed as follows:

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

(f)(1) Each nuclear power plant plant construction permit holder subject to the quality assurance criteria in appendix B of this part shall implement, pursuant to § 50.34(a)(7) of this part, the quality assurance program described or referenced in the Safety Analysis Report, including changes to that report.

(2) *****

Appendix B to Part 50--Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

30) In Appendix B to Part 50, the title of the Appendix, the first paragraph of the Introduction, the footnote in Criterion I, and Criteria VII, XI, and XIV are changed as follows:

Appendix B to Part 50--Quality Assurance Criteria for Nuclear Power Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after September 27, 2007, every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

*****

I. Organization

The applicant [(1)] shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. *****

[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear power plant has received an early site permit, design approval, design certification, or manufacturing license, as applicable. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits, operating licenses, early site permits, design approvals, combined licenses, and manufacturing licenses.

VII. Control of Purchased Material, Equipment, and Services

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant site prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

VIII. *****

XI. Test Control

A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

XII. *****

XIV. Inspection, Test, and Operating Status

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant.. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant, such as by tagging valves and switches, to prevent inadvertent operation.

XV. *****

Appendix F to Part 50--Policy Relating to the Siting of Fuel Reprocessing Plants and Related Waste Management Facilities

31) Appendix F to Part 50 is removed and reserved.

PART 51--ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

32) The definition of "construction" in § 51.4 is changed as follows:

§ 51.4 Definitions.

Construction *****

(1) *****

(v) *****

(vi) SSCs necessary to comply with 10 CFR 50.48 and criterion 3 of 10 CFR part 50, appendix A;

(vii) Onsite emergency facilities (*i.e.*, technical support and operations support centers), necessary to comply with 10 CFR 50.47 and 10 CFR part 50, appendix E; and

(viii) for purposes of fuel recycling facilities subject to 10 CFR Part 7x, construction activities are defined in 10 CFR 7x.3.

(2) *****

33) Section 51.20(b) is changed as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

(b) *****

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, or testing facility~~, or fuel reprocessing plant~~ under part 50 of this chapter or a fuel recycling facility under part 7x of this chapter, or issuance of an early site permit under part 52 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, or testing facility~~, or fuel reprocessing plant~~ under part 50 of this chapter or a fuel recycling facility under part 7x of this chapter, or a combined license under parts 52 or 7x of this chapter.

(3) *****

34) Section 51.22(c) is changed as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

(c) The following categories of actions are categorical exclusions:

(1) Amendments to Parts 1, 2, 4, 7, 8, 9, 10, 11, 19, 21, 25, 55, 75, 7x, 95, 110, 140, 150, 170, or 171 of this chapter, and actions on petitions for rulemaking relating to Parts 1, 2, 4, 7, 9, 10, 11, 14, 19, 21, 25, 55, 75, 95, 110, 140, 150, 170, or 171.

(2) *****

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 52, 54, 60, 61, 63, 70, 71, 72, 73, 74, 7x, 81, and 100 of this chapter which relate to—

(i) *****

(9) Issuance of an amendment to a permit or license for a reactor under part 50 or part 52 of this chapter or for a fuel recycling facility under part 7x this chapter, which changes a requirement with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter, or which changes an inspection or a surveillance requirement, provided that—

(i) *****

(10) Issuance of an amendment to a permit or license under parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 52, 60, 61, 63, 70, 72, or part 7x of this chapter which—

(i) *****

(12) Issuance of an amendment to a license under parts 50, 52, 60, 61, 63, 70, 72, 75, or 7x of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

(i) *****

(23) The Commission finding for a combined license under § 52.103(g) or § 7x.58(c)(7) of this chapter.

35) Section 51.49 is changed as follows:

§ 51.49 Environmental report—limited work authorization.

(a) *Limited work authorization submitted as part of complete construction permit or combined license application*. Each applicant for a construction permit or combined license applying for a limited work authorization under § 50.10(d) or §7x.10 of this chapter in a complete application under 10 CFR 2.101(a)(1) through (a)(4), shall submit with its application a separate document, entitled, "Applicant's Environmental Report—Limited Work Authorization Stage," which is in addition to the environmental report required by § 51.50 of this part. Each environmental report must also contain the following information:

(1) *****

36) Section 51.50 is changed as follows:

§ 51.50 Environmental report—construction permit, early site permit, or combined license stage.

(a) *Construction permit stage*. Each applicant for a permit to construct a production or utilization facility covered by § 51.20 shall submit with its application a separate document, entitled "Applicant's Environmental Report—Construction Permit Stage," which shall contain the information specified in §§ 51.45, 51.51, and 51.52. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b or §7x.30(f)(2) of this chapter.

(b) *****

(2) The environmental report may address one or more of the environmental effects of construction and operation of a reactor, reactors, or fuel recycling facility, as applicable, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, *provided however*, that the environmental report must address all environmental effects of construction and operation necessary to determine whether there is any obviously superior alternative to the site proposed. The environmental report need not include an assessment of the economic, technical, or other benefits (for example, need for power) and costs of the proposed action or an evaluation of alternative energy sources.

(3) *****

(4) Each environmental report must identify the procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b or 7x.30(f) of this chapter.

(c) *Combined license stage*. Each applicant for a combined license shall submit with its application a separate document, entitled "Applicant's Environmental Report—Combined License Stage." Each environmental report shall contain the information specified in §§ 51.45, 51.51, and 51.52, as modified in this paragraph. For other than light-water-cooled nuclear power

reactors, the environmental report shall contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b or § 7x.30(f)(2) of this chapter. The combined license environmental report may reference information contained in a final environmental document previously prepared by the NRC staff.

(1) *****

37) Section 51.53(d) is changed as follows:

§ 51.53 Postconstruction environmental reports.

(d) *Postoperating license stage*. Each applicant for a license amendment authorizing decommissioning activities for a production or utilization facility either for unrestricted use or based on continuing use restrictions applicable to the site; and each applicant for a license amendment approving a license termination plan or decommissioning plan under § 50.82 or §7x.78 of this chapter either for unrestricted use or based on continuing use restrictions applicable to the site; and each applicant for a license or license amendment to store spent fuel at a nuclear power reactor after expiration of the operating license for the nuclear power reactor shall submit with its application a separate document, entitled "Supplement to Applicant's Environmental Report--Post Operating License Stage," which will update "Applicant's Environmental Report--Operating License Stage," as appropriate, to reflect any new information or significant environmental change associated with the applicant's proposed decommissioning activities or with the applicant's proposed activities with respect to the planned storage of spent fuel.

38) Section 51.101(a) is changed as follows:

§ 51.101 Limitations on actions.

(a) *****

(1) *****

(2) Any action concerning the proposal taken by an applicant which would (i) have an adverse environmental impact, or (ii) limit the choice of reasonable alternatives may be grounds for denial of the license. In the case of an application covered by §§ 30.32(f), 40.31(f), 50.10(c), 70.21(f), §§ 72.16 and 72.34, or §7x.10 (a) of this chapter, the provisions of this paragraph will be applied in accordance with §§ 30.33(a)(5), 40.32(e), 50.10 (c) and (e), 70.23(a)(7) ,§ 72.40(b), or 7x.10 of this chapter, as appropriate.

39) Section 51.103(a) is changed as follows:

§ 51.103 Record of decision--general.

(a) *****

(6) In a construction permit or a combined license proceeding where a limited work authorization under 10 CFR 50.10 or 7x.10 was issued, the Commission's decision on the construction permit or combined license application will not address or consider the sunk costs associated with the limited work authorization in determining the proposed action.

40) In § 51.105, paragraphs (a) and (c) are changed as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

(a) In addition to complying with applicable requirements of § 51.104, in a proceeding for the issuance of a construction permit or early site permit for a nuclear power reactor, testing facility, ~~fuel reprocessing plant~~, isotopic enrichment plant, or fuel recycling facility, the presiding officer will:

(1) *****

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the construction permit or early site permit should be issued as proposed by the NRC's Director, Office of New Reactors, Director, Office of Nuclear Reactor Regulation, Director, Office of Nuclear Materials Safety and Safeguards, as appropriate.

(b) *****

(c)(1) In addition to complying with the applicable provisions of § 51.104, in any proceeding for the issuance of a construction permit for a nuclear power plant or an early site permit under part 52 of this chapter, where the applicant requests a limited work authorization under § 50.10(d) or § 7x.10(b) of this chapter, the presiding officer shall—

(i) *****

41) In §51.107, paragraphs (a) and (d) are changed as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

(a) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under part 52 of this chapter or for a fuel recycling facility under part 7x of this chapter, the presiding officer will:

(1) *****

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the combined license should be issued as proposed by the NRC's Director, Office of

New Reactors, Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Materials Safety and Safeguards, as appropriate.

(b) *****

(d)(1) In any proceeding for the issuance of a combined license where the applicant requests a limited work authorization under § 50.10(d) or §7x.10(b) of this chapter, the presiding officer, in addition to complying with any applicable provision of § 51.104, shall:

(i) *****

(v) In a contested proceeding, determine whether, in accordance with the regulations in this subpart, the limited work authorization should be issued as proposed by the Director, Office of New Reactors, the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Materials Safety and Safeguards, as applicable.

(2) If the limited work authorization is for activities to be conducted at a site for which the Commission has previously prepared an environmental impact statement for the construction and operation of a nuclear power plant, and a construction permit was issued but construction of the plant was never completed, then in making the determinations in paragraph (c)(1) of this section, the presiding officer shall be limited to a consideration whether there is, with respect to construction activities encompassed by the environmental impact statement which are analogous to the activities to be conducted under the limited work authorization, new and significant information on the environmental impacts of those activities, so that the limited work authorization should not be issued as proposed by the Director, Office of New Reactors, the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Materials Safety and Safeguards, as applicable.

(3) *****

42) Section 51.108 is changed as follows:

§ 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met

In any public hearing requested under 10 CFR 52.103(b), the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52 or under part 7x, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under 10 CFR 52.103(g) or 7x.58(c)(7).

PART 70--DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

43) In §70.1, paragraph (a) is changed and paragraph (f) is added as follows:

§ 70.1 Purpose.

(a) Except as provided in paragraphs (c), ~~and~~ (d), and (f) of this section, the regulations of this part establish procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material; and establish and provide for the terms and conditions upon which the Commission will issue such licenses.

(b) *****

(f) The regulations in part 7x of this chapter establish requirements, procedures, and criteria for the issuance of licenses for fuel recycling facilities.

44) In § 70.4, the definition for "fuel recycling facility" is added to read as follows:

§ 70.4 Definitions.

*****

Fuel recycling facility means a facility designed or used for recycling and its associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel to the extent such associated activities are included in the application and or license for the fuel recycling facility.

*****

PART 95—FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

45) In § 95.5, the definition for "license" is changed to read as follows:

§ 95.5 Definitions.

*****
License means a license issued under 10 CFR parts 50, 52, 54, 60, 63, 70, 72, or part 7x.

*****

PART 150--EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

46) In § 150.3, the definition for "production facility" is amended and a definition for "fuel recycling facility" is added to read as follows:

§ 150.3 Definitions.

*****

Fuel recycling facility means a facility designed or used for recycling and its associated activities conducted on a contiguous site such as, but not limited to, spent fuel storage, vitrification, plutonium and/or minor actinides processing, and fuel fabrication, waste storage and processing, and storage of new fuel to the extent such associated activities are included in the application and or license for the fuel recycling facility.

*****

Production facility means:

(1) Any equipment or device determined by rule of the Commission to be capable of the production of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public, including a uranium enrichment facility and a fuel recycling facility; or

(2) *****

47) In § 150.15, paragraph (a)(7) is changed as follows:

§ 150.15 Persons not exempt.

(a) ***

(7) The storage of:

(i) Spent fuel in an independent spent fuel storage installation (ISFSI) licensed under part 72 of this chapter,

(ii) Spent fuel and high-level radioactive waste in a monitored retrievable storage installation (MRS) licensed under part 72 of this chapter, ~~or~~

(iii) Greater than Class C waste, as defined in part 72 of this chapter, in an ISFSI or an MRS licensed under part 72 of this chapter; the GTCC waste must originate in, or be used by, a facility licensed under part 50 of this chapter, or

(iv) Spent fuel and high and low-level waste including GTCC waste at a fuel recycling facility licensed under part 7x of this chapter.

*****