MANUAL CHAPTER 2815

CONSTRUCTION AND PREOPERATIONAL INSPECTION OF PANORAMIC, WET-SOURCE-STORAGE GAMMA IRRADIATORS

2815-01 PURPOSE

To determine whether panoramic, wet-source-storage gamma irradiators (large irradiators) are constructed and equipped and can be operated in accordance with: (a) the license application, including any modifications made in response to U.S. Nuclear Regulatory Commission (NRC) findings; and (b) NRC regulations, with special emphasis on 10 CFR Part 36.

2815-02 BACKGROUND

The Food and Drug Administration expanded authorizations for gamma irradiation for the preservation of foodstuffs. This, along with other market and economic factors, has increased interest in large irradiators. In some cases licensees are having custom-made facilities designed and constructed for or by the firm instead of purchasing "turn-key" facilities from established irradiator manufacturers. Thus, there are needs to ensure that systems and procedures important to safety at large irradiator facilities are adequate when operations begin and will continue to be adequate over years of operation. The NRC Office of Nuclear Material Safety and Safeguards (NMSS) and the Regions will evaluate the initial assurance of worker and public health and safety at large irradiators by conducting construction and pre-operational inspections.

With the issuance of Part 36, large irradiator construction can not begin before a license application and the associated fee required by 10 CFR 170.31 are received. Although this is a change from the one-step licensing process under 10 CFR Part 30, which allowed construction before an application was received, it is still necessary for licensing and engineering management and staff to work together as soon as a license application is received. A critical part of this effort is the engineering staff's early preconstruction examination of license applications to identify potential engineering and inspection problems that might be averted by the licensing staff's interaction with the applicant.

2815-03 DEFINITIONS

The following lists the systems that are important to safety and defines the related engineering and safety concerns associated with each:

Access Control: Adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23. For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before to operational testing.

Site: Potential need for protection against flooding and earth slides.

Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement, liquefaction, ground water, soil compaction.

Footers and Foundations for the Pool and Shielding Structures: Strength and reinforcement, alignment with pool and shielding structures.

Pool and Shielding Structures: Strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding.

Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.

Pool Plumbing: Makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems.

Penetrations Through Shielding: Any significant effect on structural strength, shielding, or both.

Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming.

Source-Rack Movement and Position-Sensing System: Structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system.

Source-Rack Electrical Control System: Adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms.

Source-Leak Detection: Adequacy of systems for detecting and isolating leaking sources.

Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair.

Uninterruptable Electrical Power Supply: Adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system.

Fire Protection System: Adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool.

Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered.

Ozone Ventilation System: Capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components.

System for Transferring Sources from and to Transport Vehicles: Adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the roof-shield plug and its supports for its removal and replacement; structural and mechanical adequacy of systems for moving shipping containers into and out of the pool area.

Other Potential Technical Safety and Operational Problems: Potential safety and operational problems not specifically covered by this instruction, but which are identified by regional licensing and engineering staff.

2815-04 RESPONSIBILITIES AND AUTHORITIES

Before initial operation of a large irradiator, NMSS and regional inspection and licensing management and staff will conduct construction and pre-operational inspections in a joint cooperative effort to accomplish the purpose of this Chapter.

04.01 Director, Division of Industrial and Medical Nuclear Safety (IMNS) Approves the inspection program.

04.02 Chief, Materials Safety and Inspection Branch (MSIB). Develops, implements, and assesses the effectiveness of the inspection program.

04.03 Regional Administrator. Ensures that regional inspection and licensing management and staff cooperate in implementing this instruction.

04.04 Director, Regional Division of Reactor Safety (DRS)

a. Provides engineering inspectors to perform reviews and inspections as required by this instruction and as requested by the regional materials staff.

b. Ensures that regional materials licensing management is made aware of any construction or preoperational problems as soon as possible.

04.05 Director, Regional Division of Nuclear Material Safety (DNMS). Has project management responsibility and ensures coordination between the engineering inspection and materials licensing staffs so that the objectives of the program are accomplished.

04.06 Chief, Regional Nuclear Materials Safety (Inspection) Branch. Ensures that inspections are planned and conducted by appropriately qualified inspectors and coordinated with the licensing staff, and that inspection reports are prepared, approved, and a copy forwarded to the Chief of the MSIB.

2815-05 BASIC REQUIREMENTS

Basic requirements apply only to systems that are important to safety and their attendant engineering and safety concerns (see 2815-03, Definitions).

The engineering staff should: (a) execute the instructions for preconstruction activities (05.01); (b) perform the construction inspections (05.02); (c) document any inadequacies or uncertainties in systems that are important to safety; and (d) recommend to the licensing staff what should be done before a license is granted or denied.

05.01 Preconstruction Activities (Engineering)

a. Examine the license application to determine whether there are apparent or potential structural, seismic, construction, or operational engineering problems with systems that are important to safety. Document any problems and discuss them with the licensing staff. (The licensing staff will calculate the radiological adequacy of shielding.)

b. Examine the license application to determine whether systems important for safety are engineered to adequately meet the design and performance requirements of Part 36 Subpart C.

c. Examine the license application to determine whether the applicant has provided a construction plan and a schedule that will allow NRC to keep informed of construction progress and make inspections at appropriate points. If a plan and a schedule have not been submitted or are inadequate to cover construction activities, recommend to the licensing staff that this information is needed if construction is to be properly inspected.

d. Examine the license application to determine whether the applicant has made adequate arrangements to ensure (independently of its construction and equipment contractors) that its facility is constructed according to design requirements. If the applicant has not provided adequate information, recommend to the licensing staff that this information is needed. Independent construction inspections are adequate only if inspections are conducted at critical points during construction. Inspection of only finished foundation and structural work is unacceptable.

e. If local building inspectors or independent engineering firms are involved, examine their construction inspection procedures, holdpoints, and documentation requirements to determine to what extent their inspections would be adequate to ensure that the facility is constructed as designed. Ask the licensing staff to request the applicant to provide this information if it is not included with the application.

f. The activities and results of preconstruction activities are to be documented as memoranda from engineering management to licensing management, with copies to MSIB.

05.02 Construction Inspections (Engineering)

a. If the engineering staff decides that the applicant has made adequate arrangements to determine (independently of its construction and equipment contractors) whether its facility is constructed as designed, the NRC inspection requirements are to:

(1) Inspect the facility once during construction, preferably when construction is being inspected by the applicant's inspectors;

(2) Determine whether the applicant's inspections are adequately conducted and documented;

(3) Review inspection documentation to determine whether all systems important to safety thus far constructed were inspected and if the construction was as designed; and

(4) Complete the review initiated in (3),above, after construction is completed.

b. If the engineering staff decides that the applicant cannot, by its choice or by necessity, arrange for adequate independent construction inspections, the requirements are to:

(1) Take advantage of any independent construction inspections that are conducted by following the requirements of 06.02a, where applicable;

(2) Inspect the facility at least twice during construction to determine whether all systems important to safety are constructed as designed;

(3) Report any deviations and the need for corrective actions to the regional licensing staff; and

(4) Inspect the adequacy of any corrective actions.

c. If construction deviations are detected by the applicant's or NRC's inspectors, the NRC engineering staff is to determine the need for and the adequacy of any corrective actions proposed by the applicant and is to inspect the results of the corrective actions.

d. The activities and results of construction inspections are to be documented as Inspection Reports.

05.03 Preoperational Inspections (Engineering and Radiation Safety)

a. Before Sources Are Installed. The requirement is to have the licensee and its trained, qualified personnel successfully exercise all operational systems that are important to safety. Here, "successful" means that any equipment, control, personnel, or procedural problems are corrected, and that the exercise is repeated successfully, with reasonable assurance that the operational system will continue to be satisfactory.

The detailed inspection should be conducted before the applicant has received sources, to ensure that the following criteria for acceptance testing, required by 10 CFR 36.41, are met:

Shielding - verify construction met design.

Foundations - verify construction met design.

Pool Integrity - verify construction met design and that the pool integrity has been tested.

Water-Handling System - verify that water purification system, conductivity meter, and water-level indicator systems operate properly.

Source-Rack - verify movement of source racks for proper operation, including source-rack lowering because of simulated loss of power; verify that the conveyor system movement meets the requirements of 10 CFR 36.35; and verify testing of any limit switches and interlocks used to protect the source-rack and mechanism that moves the source rack from moving product carriers.

Access Control - verify that the complete access control functions as designed and ensure that all alarms, controls, and interlocks work properly. If the emergency exit relies on power, or involves a time delay, notify the licensing reviewer and headquarters for further review.

Fire Protection System - verify ability of heat and smoke detectors to detect a fire, activate alarms, and cause the source rack to become fully shielded.

Source Return - verify licensee’s ability to return source racks to fully shielded position on loss of offsite power.

Computer Systems - for access-control systems that are computer-controlled, verify that access control will work with loss of offsite power and that the computer has security features which prevent operators from overriding the access-control system when it is required to be operable.

Wiring - verify construction met design.

Systems for Transferring Sources from and to Transport Vehicles - verify construction met design.

b. When First Sources Are Installed. The first requirement is to witness:

(1) Unloading of a simulated and then an actual source- shipping container from the transport vehicle, and radiological monitoring for contamination;

(2) Transferal (by crane or other means) of a simulated and then an actual source into the pool area; and

(3) Transferal of sources into pool racks from shipping containers, and attendant radiological monitoring to determine whether the operations are successfully conducted and comply with all license conditions and pertinent NRC regulations.

The second requirement is, with the facility now equipped with radioactive sources, to repeat the requirements of 05.03(a) above, and to determine whether radiation levels outside of the shielding (sources raised) are within requirements.

c. Other Preoperational Requirements

(1) Determine whether enough operators are trained in accordance with the NRC-approved training requirements in the application to be able to safely operate the irradiator in accordance with the applicant's plan for initial operation.

(2) Determine whether the NRC-approved radiation safety program has been implemented at the irradiator site.

05.04 The results of construction and preoperational inspections should be documented in formal inspection reports and distributed in accordance with the standard distribution list, including copies to the MSIB.

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