

May 24, 2005

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

**TEMPORARY INSTRUCTION, "SAFETY PROCEDURES FOR PANORAMIC IRRADIATORS"
(STP-05-040)**

On May 5, 2005, the U. S. Nuclear Regulatory Commission's (NRC), Office of Nuclear Material Safety and Safeguards (NMSS), issued additional directions to inspectors relating to safe operation of panoramic irradiators. Temporary Instruction (TI) 2800/037, "Safety Procedures for Panoramic Irradiators," provides instructions to determine the extent to which irradiator operators may need to defeat, or have defeated, interlocks for any reason including to effect repairs of the irradiator.

This TI is being provided, as a result of the panoramic irradiator event that occurred on April 21, 2004 at Baxter Healthcare Corporation (Baxter) of Aibonito, Puerto Rico. During that event two employees at the facility were exposed to radiation when they entered the panoramic irradiator facility without knowing that a source rack, containing a large amount of cobalt-60 in sealed sources, was stuck in an unshielded position. Because of the high safety significance of the event at Baxter (two individuals could have received near lethal exposures had they continued on their intended path) and because approximately 80 percent of panoramic irradiators in the United States are in Agreement States, we request that you implement and incorporate the TI into your routine inspection program for irradiators within your State over the next two years.

We also request you provide a report* describing the results of your inspections using the TI (see Section 2800/037-05, "Reporting Requirements" of the Enclosure). Copies of your reports should be sent to Sami Sherbini, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NMSS, Mail Stop T8F3. This TI remains in effect two years from the date of issuance.

If you have any questions regarding this correspondence, please contact me or the individuals named below.

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/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure: As stated

*This information request has been approved by OMB 3150-0029, expiration 06/30/07. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0029), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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TEMPORARY INSTRUCTION 2800/037

SAFETY PROCEDURES FOR PANORAMIC IRRADIATORS

CORNERSTONE: RADIATION SAFETY

APPLICABILITY: This TI applies to the inspectors responsible for implementing the Focus Elements of Inspection Procedure 87122, "Irradiator Programs."

2800/037-01 OBJECTIVES

- 01.01 To determine if activities authorized pursuant to 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators" are conducted safely.
- 01.02 To determine the extent to which irradiator operators may need to defeat, or have defeated, interlocks for any reason, including to effect repairs of the irradiator.
- 01.03 To determine if licensees have procedures or practices for the defeat of interlocks and enter the irradiator. If so, to determine if such procedures are adequate to protect workers from radiation exposure.
- 01.04 To determine irradiator operators' knowledge and understanding of functions and limitations of equipment, particularly the safety interlocks and the methods to verify radiation levels inside the irradiator.
- 01.05 To determine irradiator operators' knowledge and understanding of events that would require them to implement emergency response procedures, and to determine if there is a clear link between normal operating procedures and emergency/abnormal operating procedures.

2800/037-02 BACKGROUND

This Temporary Instruction provides additional direction to inspectors in implementing the Focus Elements of Inspection Procedures 87122, "Irradiator Programs", during the next cycle of inspections of panoramic irradiators.

As a result of an event at a panoramic irradiator on April 21, 2004, the NRC learned that, under certain conditions, an irradiator licensee has defeated safety interlocks in order to enter the irradiator to effect repairs. In the case of the irradiator involved in the April 21, 2004, event, the programmable logic controller [PLC] verifies that the source rack is in its safe storage position by confirming that all the source-rack-down indicator switches are properly activated. This should occur when the source rack reaches its fully descended position and comes in contact with the source-rack-down indicator switches. If the PLC cannot confirm that the source-rack-down indicator switches are all properly activated, it is assumed the source rack is NOT in its safe storage positions and the PLC prevents entry into the cell and activates alarms and indicators to identify that a fault has occurred. If the source rack is actually in its safe storage position, then there is a problem with the source-rack-down indicator switches (or the signals from them). In this irradiator facility, it then becomes necessary to defeat the interlocks in order to gain entry into the irradiator to repair the switches. In the April 2004 event, the licensee did not consider this type of problem to require implementation of emergency procedures. The licensee in this case used an informal, unwritten practice that did not include redundant verification of the radiation levels inside the irradiator or verification of the position of source racks prior to entry; instead, it relied only on use of a portable survey instrument to identify unusual radiation levels during entry procedures.

On April 21, 2004, two such problems occurred in which the irradiator PLC system could not verify that the source racks were in a safe storage position, and therefore caused the interlocks to prevent entry. During the first occurrence on that day, the source racks were, in fact, in the safe storage position, and an irradiator operator defeated the interlocks, entered the irradiator, and repaired switches. In the second occurrence, however, one of the source racks was stuck in an unshielded position but employees did not know this. After defeating the interlocks, an irradiator operator and an assistant walked a short way into the irradiator prior to noticing elevated radiation levels on a portable survey instrument. They received doses of 4.4 rem and 2.8 rem, respectively, by the time they turned around and exited the irradiator. NRC inspectors estimated that, if the two workers had continued on their intended path through the irradiation room, each worker would have received a dose of about 450 rads, which is potentially lethal.

The NRC was unaware of any circumstances at an irradiator which required defeat of interlocks in order to effect repair of the operation of the irradiator. Regulations in 10 CFR 36.23 require access controls to prevent inadvertent entry of personnel if sources are not in a shielded position, but does not address deliberate defeat of interlocks in order to effect repair of systems inside the irradiator causing the interlocks to prevent entry. Regulations in 10 CFR 36.67 require the use of a survey meter when entering the irradiator room after an irradiation to determine that sources are returned to a shielded position, but does not address use of survey meters after raising and lowering the source rack for testing purposes.

Regulations in 10 CFR 36.53 require, in part, that licensees perform a drill of one of the emergency procedures each year, but does not specify that drills should vary the emergency procedure from year to year. In this case, licensee personnel practiced the same emergency drill each year, and never practiced their response to a stuck source event.

The source rack was prevented from returning to its safe storage position because a

ladder, left in the irradiator room following repair activities, lodged under the source rack when it descended again after being raised to test repairs of the switches. There are no NRC regulations or guidance which direct licensees to ensure that no obstructions remain in the source rack path prior to raising the source rack.

2800/037-03 INSPECTION REQUIREMENTS

- 03.01 Inspectors should perform a routine inspection in accordance with Manual Chapter 2800 and Inspection Procedure 87122 to determine if activities authorized pursuant to 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators" are conducted safely. This inspection should include interviews with as many operators, maintenance staff, and others involved in the operation of the irradiator as possible, as well as licensee management,
- 03.02 inspectors should determine the extent to which irradiator operators may need to defeat interlocks, or have defeated interlocks, for any reason such as to effect repairs of the irradiator. Inspectors should determine if there is potential for such an event at the irradiator facility. If such event(s) have occurred, inspectors should review when the event(s) occurred, how often, and the licensee's actions during such event(s).
- 03.03 Inspectors should determine if licensees have procedures or practices for the defeat of interlocks and entry of the irradiator. If so, inspectors should review the circumstances under which the licensee has, or would, defeat interlocks, and the inspector should review the procedures or practices to determine if they are adequate to protect workers from radiation exposure.
- 03.04 Inspectors should determine irradiator operators' knowledge and understanding of the functions and limitations of equipment, particularly the safety interlocks and the methods to verify radiation levels inside the irradiator. Inspectors should determine if the operators have a method of determining the position of the source rack and the radiation levels inside the irradiator other than use of a portable survey meter during entry.
- 03.05 Inspectors should interview irradiator operators to determine their level of knowledge and understanding of events that would require them to implement emergency response procedures, and to determine if there is a clear link between normal operating procedures and emergency/abnormal operating procedures.

2800/037-04 GUIDANCE

Inspection Procedure 87122, "Irradiator Programs"

NUREG-1556, Volume 6, "Consolidated Guidance About Materials Licensees, Program Specific Guidance About 10 CFR Part 36 Irradiator Licenses"

2800/037-05 REPORTING REQUIREMENTS

Inspectors should provide a separate summary report briefly describing the results of the inspections of Items 0.03.01 through 03.05. The summary report should include the name, license number, docket number and address of the licensee; the date of the inspection; the inspector's name, and the results of the items listed in this TI. Summary reports should be submitted within 30 days of the completion of the inspection. The summary reports should be sent to Sami Sherbini, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NMSS, Mail Stop T8F3.

2800/037-06 COMPLETION SCHEDULE

Irradiator facilities are normally inspected at two-year intervals. The expected completion schedule for this TI is 24 months from the date of issuance, to ensure that most irradiators are included in the implementation of the TI.

2800/037-07 EXPIRATION

This TI remains in effect two years from the date of issuance.

2800/037-08 CONTACT

Questions regarding this TI should be addressed to Sami Sherbini, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NMSS, at 310-415-7853.

2800/037-09 STATISTICAL DATA REPORTING

No change in entering/charging staff hour expenditures or administrative effort to the is required for the implementation of this TI during the two-year period.

2800/037-10 ORIGINATING ORGANIZATION INFORMATION

10.1 Organizational Responsibility. The Materials Safety and Inspection Branch, IMNS, NMSS initiated this TI.

10.2 Resource Estimate. Inspections conducted under this TI are not expected to require staff hour expenditures exceeding those required for inspections of these licensees using the current inspection procedure.

2800/037-11 REFERENCES

NRC Inspection Manual, Inspection Procedure 87122, "Irradiator Programs"
NUREG-1556, Volume 6, "Consolidated Guidance About Materials Licensees, Program
Specific Guidance About 10 CFR Part 36 Irradiator Licenses"

END