

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

November 19, 2010

NRC INFORMATION NOTICE 2010-24: NOTICE OF POSSIBLE SOURCE LEAKAGE
DURING NON-ROUTINE MAINTENANCE ON A
GAMMACELL 40 IRRADIATOR

ADDRESSEES

All academic Type A broad scope licensees; all medical institutions; all self shielded irradiators less than or equal to 10,000 Curies licensees; all Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to alert addressees of a contamination event that occurred during a non-routine maintenance operation on a Gammacell 40 blood irradiator. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar incidents. However, the suggestions contained in this IN are not new NRC requirements; therefore, no specific action, or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

The NRC received an event notification from the New York State Department of Health on November 6, 2009, involving a Gammacell 40 irradiator being serviced for a non-routine security upgrade. While the manufacturer's, Best Theratronics, service technicians were dismantling the device, one of the technicians noted that one of the two pneumatic source drive mechanisms was moving noticeably slower. After removing the pneumatic drive assemblies and source drive rod end caps, and manually moving the source drive rods, the technician noted excessive resistance to movement and corrosion behind the source retaining ring. The technician noted that the amount of corrosion found behind the retaining ring was noticeably more than observed in servicing other units. The technician performed a wipe test to check for removable contamination on the source drive rods behind the source retaining ring. The result was removable Cs-137 contamination with an activity of 3.4 KBq (92 nCi) exceeding the leak test limits on both source drive rods. The contamination was limited to an area close to the source that is typically not accessed in normal use, routine maintenance, and leak testing.

The manufacturer reassembled the irradiator and the licensee suspended the use of the irradiator. The Gammacell 40 irradiator contained two Cs-137, Model C-161 Type 8 sources, manufactured at the Oak Ridge National Laboratory (ORNL) with an original activity of 132 TBq (3582 Ci) on November 11, 1975.

ML10280027

The New York State Department of Health has issued a notice to its licensees, dated November 23, 2009, regarding this event. It is attached for your reference. Best Theratronics issued a safety bulletin to its customers dated December 2, 2009. Please contact the manufacturer through their website at <http://www.theratronics.com> or at 866-792-8598 if you wish to obtain a copy.

DISCUSSION

The Gammacell 40 manufacturer was advised of the situation and followed-up by inspecting four other units that were scheduled for preventive maintenance. No contamination exceeding the acceptable limits was found. The contamination in this case may have been caused by leaching of the source over an extended period of time (15-20 years), as opposed to contamination which can occasionally occur as a result of the manufacturing process (i.e. hot cell manipulation and/or welding).

In this case, the source may have been leaching, as opposed to be leaking, because the radioactive material apparently diffused through the surface of the source encapsulation and there is no evidence of cracks or damage on the structure or weld. A source is considered to be leaking source if the radioactive material is coming out of the source encapsulation from the inside through a crack or damage to the source surface or weld. Leaching was also observed on a Cs-137 source, Model RAMCO 50, which was removed from a Gammacell 1000 irradiator. However, the provisions of 10 CFR 34.27(d) require that the observance of 185 Bq (0.005 μ Ci) or more of radioactive material must be considered evidence that the source is leaking regardless of the physical phenomena. Licensees who encounter such phenomena are expected to comply with the provisions of 10 CFR 34.27(d).

As described above, the contamination was found by the manufacturer during the performance of a non-routine task in areas that are usually inaccessible. The NRC believes it is possible that other licensees may encounter this issue, although NRC is not aware of other incidents. The NRC has determined that these devices can continue to be used safely, and incidents such as the one described above do not constitute a hazard to the user and/or general public. Nevertheless, the NRC is distributing this IN for awareness, and recommends that licensees limit non-routine maintenance on these devices to qualified persons. It is also recommended that licensees contact the manufacturer for guidance if dismantling work is planned. Licensees should also ensure that all routine maintenance operations (e.g., wipe tests) are done in accordance with standard operating procedures and all radiation safety precautions, and ensure that any contamination found above the 185 Bq (0.005 μ Ci) limit is reported to the NRC in accordance with 10 CFR 34.27(d).

CONTACTS

This IN requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

/RA/

Robert J. Lewis, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Programs

Technical Contacts: Lymari Sepulveda; FSME
(301) 415-5619
E-mail: Lymari.Sepulveda@nrc.gov

John Jankovich; FSME
(301) 415-7904
E-mail: John.Jankovich@nrc.gov

Enclosures:

1. New York State Department of Health
Notice, November 23, 2009
2. List of Recently Issued FSME Generic
Communications

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OFC	MSSA/LB	MSSA/LB	MSSA/RMSB
NAME	LSepulveda: sxx6	JJankovich	AMcIntosh
DATE	08/ 26 /10	08/ 26 /10	08/ 27 /10
OFC	MSSA/LB	MSSA	
NAME	JFoster	RJLewis	
DATE	08/ 26 /10	11/19/10	

OFFICIAL RECORD COPY

New York State Department of Health Notice



Flanigan Square 547 River Street Troy, New York 12180-2216

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

Notice to Licensees – BERP 2009-02

TO: Licensees that Possess Gammacell 40 Irradiators, and Irradiator Service Licensees
FROM: Bureau of Environmental Radiation Protection
SUBJECT: Gammacell 40 – Leaking Sources
DATE: November 23, 2009

The purpose of this notice is to inform Gammacell 40 unit licensees of the recent occurrence of leaking sources in an older (circa 1975) unit.

On November 3, 2009, Best Theratronics engineers/service personnel were “hardening” an irradiator. After removal of the cabinet, pneumatic drive cylinders and end caps to the source drive, rust/corrosion was noted on the source drive rods. A wipe/leak test of those areas (both upper and lower source drives) identified presence of cesium-137 in quantities that exceed the leak test limit. Contamination was limited to the internal areas of the unit. No persons, equipment/tools or the room were contaminated. The unit was reassembled and taken out of service by the licensee, with concurrence for such action by the Department and Best Theratronics.

Please note that the areas where the contamination was found are not accessible during routine use and are not typically accessible during routine preventive maintenance (PM) service. Therefore, it is unlikely that such areas have been measured for contamination (leak test) on most Gammacell 40 units.

Best Theratronics has implemented a program to inspect a number of units that are due for routine PM. The inspection involves disassembly to access the same areas where contamination was found on the subject unit in order to conduct leak testing. Two units were inspected on November 15, 2009, and contamination was not found. Additional inspections, which include older models, have been scheduled. We anticipate that Best Theratronics will issue a service bulletin in regard to this situation.

The Department is not requiring its licensees to take any action at this time. However, it is strongly recommended that those who possess older units contact Best Theratronics and/or a licensed/qualified irradiator service provider to schedule an inspection of your irradiator(s). If you are unsure of your unit’s vintage, please contact Douglas Beatty at Best Theratronics, 613-591-2100, ext. 2177, or doug.beatty@theratronics.ca. Please note that the Department may provide additional recommendations or implement new requirements based on the outcome and data from Best’s inspections.

If you have any questions, please contact us at 518/402-7550, berp@health.state.ny.us or write to:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Room 530
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Assistant Director

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
11/13/09	IN-2009-27	Revised International Nuclear and Radiological Event Scale User's Manual	All holders of an operating license or construction permit for a power reactor, test reactor or research reactor issued under 10 CFR Part 50; holders of or applicants for an early site permit, standard design certification, standard design approval, manufacturing license, or combined license issued under 10 CFR Part 52; holders of a materials license, certificate, approval, or registration issued under 10 CFR Parts 30, 31 through 36, 39, 40, 61, 70, 71, 72, and 76; Agreement State Radiation Control Program Directors and State Liaison Officers.
11/06/09	IN-2009-30	Findings from the NRC Initiative to Assess Materials Licensees' Compliance with the NRC Decommissioning Requirements	All U.S. Nuclear Regulatory Commission materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
12/03/09	RIS-2009-15	National Source Tracking System Annual Inventory Reconciliation	All licensees possessing Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.
01/21/10	RIS-2010-02	The Global Threat Reduction Initiative (GTRI) Federally Funded Voluntary Security Enhancements for High-Risk Radiological Material	All holders of operating licenses for nuclear power reactors and research and test reactors under the provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have ceased operations and have certified that fuel has been permanently removed from the reactor vessel and have no spent fuel stored on-site. All U.S. Nuclear Regulatory Commission (NRC) fuel cycle facilities licensed under 10 CFR Part 40, "Domestic Licensing of Source Material" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" and gaseous diffusion plants certified under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." All holders of site-specific licenses for independent spent fuel storage installations (ISFSIs) under the provisions of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater than Class C Waste," and all holders of 10 CFR Part 50 licenses with ISFSIs under the general license provisions of 10 CFR Part 72. All NRC materials licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, under the provisions of 10 CFR Parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, and 70.

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
05/25/10	RIS-2010-04	Monitoring the Status of Regulated Activities During a Pandemic	All holders of operating licenses for nuclear power reactors and research and test reactors under the provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have ceased operations and have certified that fuel has been permanently removed from the reactor vessel and have no spent fuel stored on-site. All U.S. Nuclear Regulatory Commission (NRC) fuel cycle facilities licensed under 10 CFR Part 40, "Domestic Licensing of Source Material" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" and gaseous diffusion plants certified under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." All holders of site-specific licenses for independent spent fuel storage installations (ISFSIs) under the provisions of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater than Class C Waste," and all holders of 10 CFR Part 50 licenses with ISFSIs under the general license provisions of 10 CFR Part 72. All NRC materials licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, under the provisions of 10 CFR Parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, and 70.
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p>			