

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF WASTE, AIR AND RADIATION MANAGEMENT
BUREAU OF RADIATION PROTECTION
HARRISBURG, PA 17101

January 7, 2011

BRP INFORMATION NOTICE 2011-01

NOTICE OF POSSIBLE SOURCE LEAKAGE
DURING NON-ROUTINE MAINTENANCE
ON A GAMMACELL 40 IRRADIATOR

ADDRESSEES

All Pennsylvania irradiator licensees and irradiator service providers.

PURPOSE

The purpose of this information notice (IN) is 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 DEP requirements; therefore, no specific action or written response is required.

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. A wipe test was performed to check for removable contamination on the source drive rods behind the source retaining ring. Removable Cs-137 contamination with an activity of 3.4 kBq (0.092 μ Ci) exceeding the leak test limits was found on both source drive rods. However, 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.

The New York State Department of Health has issued a notice to its licensees, dated November 23, 2009, regarding this event. A copy is enclosed 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. The U.S. Nuclear Regulatory Commission (NRC) issued an information notice NRC IN # 2010-24 to Agreement States on November 19, 2010 suggesting that they advise their licensees of this event.

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 activity from the source leaching 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 activity because the radioactive material apparently diffused through the surface of the source encapsulation as there was no evidence of cracks or damage on the structure or weld. A source is considered to be leaking 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 has also been 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, in late 2010, the NRC requested Agreement States to distribute this IN for awareness, and recommends that licensees limit non-routine maintenance on these devices to qualified persons. Licensees should contact the manufacturer for device dismantling work which is not specifically authorized as a license condition. 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 Department in accordance with Title 25 § 219.61 and 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.

David J. Allard, CHP
Director,
Bureau of Radiation Protection

Technical Contacts: Joseph Melnic
John Chipppo
(717) 787-3720

Enclosure: New York State Department of Health Notice November 23, 2009



STATE OF NEW YORK DEPARTMENT OF HEALTH

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

