Jim McKnight

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

April 3, 1998

NRC INFORMATION NOTICE 98-12: LICENSEES' RESPONSIBILITIES REGARDING REPORTING AND FOLLOW-UP REQUIREMENTS FOR NUCLEAR-POWERED PACEMAKERS

Addressees:

All U.S. Nuclear Regulatory Commission nuclear pacemaker licensees.

Purpose:

The U.S. Nuclear Regulatory Commission is issuing this information notice to remind the addressees of their responsibilities regarding the reporting and follow-up requirements for nuclear-powered pacemakers. The requirements involve tracking the patients until explantation and return of the explanted nuclear-powered pacemakers to the manufacturer.

It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

Recently, a patient with a nuclear-powered pacemaker (pacemaker) expired in a different hospital from where the pacemaker was implanted. This hospital, not licensed by NRC, explanted the pacemaker and contacted the licensed hospital. The licensee made arrangements to return the pacemaker to the manufacturer. The manufacturer never received the pacemaker and informed the Radiation Safety Officer (RSO) at the licensed facility of the fact. The licensee contacted NRC to report the lost pacemaker. Six weeks had passed between the explantation of the pacemaker and the reporting to NRC. The pacemaker's 178,000 MBq (4.8 curie) plutonium-238 sealed source has not been recovered.

Discussion:

The event described above might have been avoided had the licensee addressed the possibility of the patient dying at a hospital other than the licensee's hospital. A standard materials license condition places the responsibility on the licensee (the implanting hospital) for the follow-up, explantation, and return of the pacemakers to the manufacturer, for proper disposal.

The loss of a pacemaker has an important regulatory and safety significance. The lack of control and security of the licensed material can lead to unnecessary exposures to the public. In recognition of the hazards associated with the event of a lost pacemaker or the improper

disposal of a pacemaker, NRC is reminding licensees of their commitment and responsibility to follow-up on each pacemaker patient, to remove pacemakers when patients no longer need them or die, and to return explanted pacemakers to the manufacturers for proper disposal. It is critical that the licensees make every reasonable effort to maintain contact with the pacemaker patient in accordance with their licensing commitments and the manufacturer's protocol. Licensees are responsible for the pacemaker from receipt, until return to the manufacturer.

NRC has been licensing pacemakers for approximately 25 years. Specifically, Section 20.2201, Title 10 of the U.S. Code of Federal Regulations, requires licensees to report to NRC immediately after it is known when any material is lost, stolen, or missing. When obtaining a nuclear pacemaker license, applicants must make certain commitments to ensure compliance with the above regulations, as well as other commitments to ensure public health and safety. These commitments are included in the license as license conditions. Under the direction of license conditions, the following occurrences also require a report to NRC, within 24 hours: the death of a pacemaker patient, and any adverse reaction to the pacemaker, and/or any malfunction involving the pacemaker system, including the leads. Additionally, a report to NRC is required within 10 days of loss of contact with a pacemaker patient.

With regard to the proper disposal of explanted pacemakers, licensees may wish to consider making prior contract arrangements with a carrier for the delivery of explanted pacemakers from their facilities to the manufacturer before the need for such service arises. NRC recognizes that not all carriers will deliver packages containing radioactive materials such as plutonium. However, the licensee, working with the manufacturer, may find a carrier to transport this radioactive material safely to the manufacturer for proper disposal.

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Torre Taylor, NMSS
(301) 415-7900
E-mail: tmt@nrc.gov

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

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# LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

| Information Notice No. | Subject | Date of Issuance | Issued to |
|---|---|---|---|
| 98-10 | Probable Misadministrations Occurring During Intravascular Brachytherapy With The Novoste Beta-Cath System | 4/3/98 | All Medical Licensees |
| 98-09 | Collapse of an Isocam II, Dual-Headed Nuclear Medicine Gamma Camera | 3/5/98 | All medical licensees |
| 98-08 | Information Likely to be Requested if an Emergency is Declared | 3/3/98 | All parts 30, 40, 70, 72 and 76 licensees and certificate holders required to have a Nuclear Regulatory Commission approved Emergency plan. |
| 98-06 | Unauthorized use of License to Obtain Radioactive Materials, and its Implications Under The Expanded Title 18 of the U.S. Code | 2/19/98 | All NRC Licensees authorized to Possess Licensed Materials |
| 98-04 | 1997 Enforcement Sanctions for Deliberate Violations of NRC Employee Protection Requirements | 2/9/98 | All U.S. Nuclear Regulatory Commission licensees. |
| 98-01 | Thefts of Portable Gauges | 1/15/98 | All portable gauge licensees |
| 97-91 | Recent Failures of Control Cables Used on Amersham Model 660 Posilock Radiography Systems | 12/31/97 | All industrial radiography licensees |
| 97-89 | Distribution of Sources and Devices Without Authorization | 12/29/97 | All sealed source and device manufacturers and distributors |
| 97-87 | Second Retrofit to Industrial Nuclear Company IR100 Radiography Camera, to Correct Inconsistency in 10 CFR Part 34 Compatibility | 12/12/97 | All industrial radiography licensees |

# LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

| Information Notice No. | Subject | Date of Issuance | Issued to |
|---|---|---|---|
| 98-11 | Cracking of Reactor Vessel Internal Baffle Former Bolts in Foreign Plants | 3/25/98 | All holders of operating licensing for pressurized-water reactors (PWRs) except those who have ceased operation and have certified that fuel has been permanently removed from the reactor vessel. |
| 95-52, Supp.1 | Fire Endurance Test Results for Electrical Raceway Fire Barrier Systems Constructed From 3M Company Interam Fire Barrier Materials | 3/17/98 | All holders of operating licenses for nuclear power reactors except those who have permanently ceased operation and have certified that fuel has been permanently removed from the reactor vessel. |
| 98-10 | Probable Misadministrations Occurring During Intravascular Brachytherapy With The Novoste Beta-Cath System | 3/9/98 | All Medical Licensees |
| 98-09 | Collapse Of An Isocam II Dual-Headed Nuclear Medicine Gamma Camera | 3/5/98 | All Medical Licensees |
| 98-08 | Information Likely To Be Requested If An Emergency Is Declared | 3/2/98 | All Parts 30, 40, 70, 72, and 76 licensees and certificate holders required to have a Nuclear Regulatory Commission-approved Emergency Plan. |
| 98-07 | Offsite Power Reliability Challenges from Industry Deregulation | 2/27/98 | All holders of operating licensees for nuclear power reactors |

OL = Operating License
CP = Construction Permit

disposal of a pacemaker, NRC is reminding licensees of their commitment and responsibility to follow-up on each pacemaker patient, to remove pacemakers when patients no longer need them or die, and to return explanted pacemakers to the manufacturers for proper disposal. It is critical that the licensees make every reasonable effort to maintain contact with the pacemaker patient in accordance with their licensing commitments and the manufacturer's protocol. Licensees are responsible for the pacemaker from receipt, until return to the manufacturer.

NRC has been licensing pacemakers for approximately 25 years. Specifically, Section 20.2201, Title 10 of the U.S. Code of Federal Regulations, requires licensees to report to NRC immediately after it is known when any material is lost, stolen, or missing. When obtaining a nuclear pacemaker license, applicants must make certain commitments to ensure compliance with the above regulations, as well as other commitments to ensure public health and safety. These commitments are included in the license as license conditions. Under the direction of license conditions, the following occurrences also require a report to NRC, within 24 hours: the death of a pacemaker patient, and any adverse reaction to the pacemaker, and/or any malfunction involving the pacemaker system, including the leads. Additionally, a report to NRC is required within 10 days of loss of contact with a pacemaker patient.

With regard to the proper disposal of explanted pacemakers, licensees may wish to consider making prior contract arrangements with a carrier for the delivery of explanted pacemakers from their facilities to the manufacturer before the need for such service arises. NRC recognizes that not all carriers will deliver packages containing radioactive materials such as plutonium. However, the licensee, working with the manufacturer, may find a carrier to transport this radioactive material safely to the manufacturer for proper disposal.

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| Date | 3/24/98 | | 3\9\98 | | 3/11/98 | | 3/18/98 | | 3/26/98 | |

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The loss of a pacemaker has an important regulatory and safety significance. The lack of control and security of the licensed material can lead to unnecessary exposures to the public. In recognition of the hazards associated with the event of a lost pacemaker or the improper disposal of a pacemaker, NRC is reminding licensees of their commitment and responsibility to follow-up on each pacemaker patient, to remove pacemakers when patients no longer need them or die, and to return explanted pacemakers to the manufacturers for proper disposal. It is critical that the licensees make every reasonable effort to maintain contact with the pacemaker patient in accordance with their licensing commitments and the manufacturer's protocol. Licensees are responsible for the pacemaker from receipt, until return to the manufacturer.

NRC has been licensing pacemakers for approximately 25 years. Specifically, Section 20.2201, Title 10 of the U.S. Code of Federal Regulations, requires licensees to report to NRC immediately after it is known when any material is lost, stolen, or missing. When obtaining a nuclear pacemaker license, applicants must make certain commitments to ensure compliance with the above regulations, as well as other commitments to ensure public health and safety. These commitments are included in the license as license conditions. Under the direction of license conditions, the following occurrences also require a report to NRC, within 24 hours: the death of a pacemaker patient, and any adverse reaction to the pacemaker, and/or any malfunction involving the pacemaker system, including the leads. Additionally, a report to NRC is required within 10 days of loss of contact with a pacemaker patient.

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licensee for the follow-up, explantation, and return of the pacemakers to the manufacturer for proper disposal.

The loss of a pacemaker has an important regulatory and safety significance. The lack of control and security of the licensed material can lead to unnecessary exposures to the public. The plutonium used in these pacemakers is highly toxic in addition to being radioactive.

In recognition of the hazards associated with the event of a lost pacemaker or the improper disposal of a pacemaker, the NRC is reminding the licensees of their commitment and responsibility to follow-up on the pacemaker patient and to return the explanted pacemaker to the manufacturer for proper disposal. It is critical that the licensees make every reasonable effort to maintain contact with the pacemaker patient in accordance with their licensing commitments and the manufacturer's protocol. Licensees are responsible for the pacemaker from receipt, until ultimate disposal.

Pursuant to the Code of Federal Regulations, Title 10, Section 20.2201, licensees are also required to immediately report to the NRC, any event involving licensed material, such as an unplanned contamination or equipment malfunction. Under the direction of standard license conditions, the following occurrences would require a report to the NRC: the death of a pacemaker patient, any adverse reaction to the pacemaker, and any malfunction involving the pacemaker. In addition, standard license conditions require that the licensees submit a written report, within 30 days, to the NRC detailing any adverse reaction to the pacemaker or any malfunction involving the pacemaker system.

With regard to the proper disposal of explanted pacemakers, licensees may wish to consider contracting a carrier for the delivery of explanted pacemakers from their facilities to the manufacturer. The NRC recognizes that not all carriers will deliver packages containing radioactive materials such as plutonium. However, the licensee, working with the manufacturer, may find a carrier to transport this radioactive material safely to the manufacturer for proper disposal.

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