Jim McKnight

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

March 5, 1998

NRC INFORMATION NOTICE 98-09: COLLAPSE OF AN ISOCAM II, DUAL-HEADED NUCLEAR MEDICINE GAMMA CAMERA

Addressees:

All medical licensees.

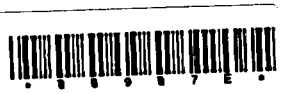
Purpose:

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to the occurrence of an incident involving an Isocam II, dual-headed nuclear medicine gamma camera, manufactured by Park Medical Systems of Quebec, Canada. The reported failure mode under investigation poses a potential for a serious crushing injury to the patient or the technicians using the camera. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to ensure safety. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

The Food and Drug Administration (FDA) issued a Safety Notice on February 13, 1998, to alert users of Isocam I single-head and Isocam II dual-headed nuclear medicine gamma camera systems of a possible design or manufacturing defect that could, cause structured failure and result in serious injury to the patient undergoing testing, or to other personnel using or servicing the camera. The FDA Notice is attached for your information. As indicated in that notice, Park Medical Systems of Quebec, Canada, is no longer in business and, for this reason, owners of such cameras are asked to report any malfunctions that could cause injury directly to the FDA. Owners are also urged to notify FDA of their possession of such a camera so that FDA may forward additional information on the camera as it becomes available.

The device is a radiation detector used to take images of patients injected with radiopharmaceuticals. It contains no radioactive material. The hazard involves physical injury from falling components, not radiation exposure.



NMSS

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact listed below.

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

Technical Contact: Steven Baggett, NMSS
301-415-7273
E-mail: slb@nrc.gov

Attachments:
1. Food and Drug Administration Safety Notice
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

FDA Safety Notice
Failure of Isocam II, Dual-Headed Nuclear Medicine Gamma Camera

TO: Nuclear Medicine Imaging Facilities

FDA has recently become aware of a malfunction, with potential for serious injury, involving an **Isocam II, dual-headed nuclear medicine gamma camera** (also available as a single-head system), manufactured by Park Medical Systems of Quebec, Canada. A stainless steel plate from a harmonic drive motor failed, causing an arm of the system to fall into the gantry housing of the device. No collimator was on the camera at the time and no patient or operator was injured.

The cause of this incident is under investigation by the U.K., Medical Devices Agency and Park U.K. We will report the findings once they become known; but we are unable to offer any recommendation at this time.

Adverse event reports related to device malfunctions that could cause or contribute to a serious injury are usually submitted to the device manufacturer. As Park Medical Systems is no longer in business, adverse event reports on the Isocam II camera should be submitted to FDA. In addition, if you own or operate one of these systems, please notify the FDA, at the address below, so that we can forward new information to you.

Please also be advised that the Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious illnesses and injuries associated with the use of medical devices. Practitioners should follow the procedures established by their facility for such mandatory reporting

We encourage you to report directly to MedWatch, FDA's voluntary reporting program, those problems and malfunctions not required to be reported under SMDA. You may report to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20857.

If you own or operate one of these systems or if you have questions about the content of this letter, please contact Paula Simenauer, CDRH, HFZ-510, 1350 Piccard Drive, Rockville, MD 20850, FAX 301-594-2968, or e-mail pzs@cdrh.fda.gov.

Sincerely yours,

D B Burlington

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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
97-86	Additional Controls for Transport of the Amersham Model No. 660 Series Radiographic Exposure Devices	12/12/97	Registered users of the Model No. 660 series packages, and Nuclear Regulatory Commission industrial radiography licensees
97-75	Enforcement Sanctions Issued as a Result of Deliberate Violations of NRC Requirements	09/24/97	All U.S. Nuclear Regulatory Commission licensees

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
98-07	Offsite Power Reliability Challenges from Industry Deregulation	2/27/98	All holders of operating licensees for nuclear power reactors
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 material
97-45, Supp. 1	Environmental Qualification Deficiency for Cables and Containment Penetration Pigtails	2/17/98	All holders of operating licenses for nuclear power reactors except those licensees who have permanently ceased operations and have certified that the fuel has been permanently removed from the reactor vessel
98-05	Criminal History Record Information	2/11/98	All holders of operating licenses for power reactors
98-04	1997 Enforcement Sanctions for deliberate Violations of NRC Employee Protection requirements	2/9/98	All U.S. Nuclear Regulatory Commission licensees
98-03	Inadequate Verification of Overcurrent Trip Setpoints in Metal-Clad, Low-Voltage Circuit Breakers	1/21/98	All holders of operating licenses for nuclear power reactors
98-02	Nuclear Power Plant Cold Weather Problems and Protective Measures	1/21/98	All holders of operating licenses for nuclear power reactors
98-01	Thefts of Portable Gauges	1/15/98	All portable gauge licensees

OL = Operating License
CP = Construction Permit

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Original signed by Donald A. Cool

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

Technical Contact: Steven Baggett, NMSS
301-415-7273
E-mail: slb@nrc.gov

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DATE	2/25/98		2/25/98		2/25/98		2/25/98		2/26/98	

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