U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Information Notice No. 84-27: Recent Serious Violations of NRC Requirements by Medical Licensees

SSINS No.: 6835
IN 84-27

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

April 17, 1984

Information Notice No. 84-27: RECENT SERIOUS VIOLATIONS OF NRC REQUIREMENTS BY MEDICAL LICENSEES

Addressees:

All byproduct materials licensees authorized to possess and use byproduct materials in institutional medical programs.

Purpose:

To bring to the attention of medical licensees the large number of recent cases involving serious violations of NRC license conditions, to point out the common causes of these violations, and to describe their consequences.

Discussion:

From January 1 to December 1, 1983 there have been 26 cases in which the NRC has taken escalated enforcement action against byproduct materials licensees. Nineteen of these cases involved a civil penalty, six involved Orders, to suspend the license or to show cause why the license should not be revoked, and one involved both a suspension Order and a civil penalty. These escalated enforcement actions were taken because various serious violations of NRC license requirements occurred. These violations included employees being overexposed to radiation, members of the public being unnecessarily exposed to radiation, and public property being contaminated with radioactive material. In addition, the financial consequences to the affected licensees have been significant because of the loss of income from the payment of civil penalties, the cost of decontaminating property, and the suspension or revocation of the license.

An analysis of the causes of these escalated enforcement cases shows that there were three common causes for the serious violations and their consequences. These causes were:

(1) Failure to read and understand the conditions of the license.
(2) Failure to train employees in the conditions of the license including the radiation safety procedures that are incorporated into the license.
(3) Failure to control operations including failure of licensee employees

to follow approved radiation safety procedures.

.

Attached are summaries of three medical licensee cases. They illustrate the causes and consequences of the serious violations that the NRC has found during inspections of this class of byproduct materials licensees.

One of the principal causes of violations is the fact that some licensees are not cognizant of all the conditions of their license. NRC has found during inspections that some licensees have never read the license or have little understanding of its conditions. Conditions and commitments in the license form the basis for the issuance of the license, and are necessary to protect the health and safety of the public. NRC, therefore, expects licen-sees to abide with all the conditions and commitments of their license.

Two other principal causes of violations are the failure to properly train the workforce and the failure to control the radiation-safety aspects of the licensee's operation. Licensee management is responsible for ensuring that employees receive proper training, that the proper radiation monitoring instrumentation and personnel dosimetry is available and used, and that employees comply fully with all the provisions of the license and associated radiation safety procedures.

The licensee's responsibility for control of its operations also extends to consultants and contractors. In certain circumstances the NRC encourages licensees to seek qualified assistance when the licensee does not possess the necessary experience, training, equipment, or personal dosimetry to perform particular activities; e.g., to handle problems arising from an accident ur unusual occurrence. However, the responsibility for the safety of the operations and compliance with NRC requirements remains with the licensee.

Licensees should review the conditions of their license to ensure that they understand their responsibilities under the license. This should include an examination of the details of their radiation safety program to verify that the program complies with all requirements. As a result, licensees can avoid the serious consequences to their employees and the public and the significant financial costs that can result from failure to follow NRC requirements.

No response to this information notice is required. If you have any questions regarding this matter, please contact the Administrator of the appropriate Regional Office or this office.

J. Nelson Grace, Director
Division of Quality Assurance,
Safeguards, and Inspection Programs
Office of Inspection and Enforcement

Technical Contacts: J. R. Metzger, IE (301) 492-4947

E. D. Flack, IE (301) 492-9823

Attachments:
1. Selected Cases Involving Serious Violations of NRC Requirements
2. List of Recently Issued IE Information Notices

.

CASE A

Twelve violations were found at a hospital including five that were similar to violations that had been found during the previous inspection. The most significant violations are listed below.

Violations

1. Therapeutic sealed sources were used on patients over a three-year period without authorization.

2. Unauthorized physicians were using radioactive materials.

3. Patients were not surveyed after sources were implanted.

4. Nurses assigned to brachytherapy patients were not issued film badges or thermoluminescent dosimeters.

Causes

1. Licensee management and employees did not read and understand the conditions of the license.

2. Licensee management and employees did not adequately control the licensed activities of the hospital.

Consequence

1. Potential overexposure to patients and the hospital staff because of failure to observe necessary safety procedures.

Enforcement

NRC imposed a civil penalty of $2,500 which the licensee paid.

.

CASE B

Twelve violations were found at a hospital including two that were similar to violations that had been found during a previous inspection. The most significant violations are listed below:

Violations

1. The licensee failed to perform surveys for releases of Xenon-133 to unrestricted areas.

2. Trash containing 70 microcuries of iodine-125 was released to a sanitary landfill.

3. The licensee failed to report a diagnostic misadministration to the NRC.

4. The licensee failed to leak test brachytherapy sources at six month intervals.

5. Some workers failed to wear disposable gloves while handling radiopharmaceuticals.

6. A student did not wear TLD finger rings while preparing radiopharmaceuticals.

7. An individual admitted pipetting by mouth radiopharmaceuticals containing phosphorous-32.

Causes

1. Licensee management and employees did not adequately control licensed activities at the hospital.

2. Workers were not adequately trained in the conditions of the license.

Consequence

1. Potential for unnecessary exposure and contamination spread to hospital workers and members of the general public.

Enforcement

NRC imposed a civil penalty of $2,500 which the licensee paid.

.

CASE C

Seven violations were found at a hospital during a routine inspection. The most significant violations are listed below.

Violations

1. For over a month, two 50 millicurie cesium-137 brachytherapy sources were left in unlocked shields on a transport cart. The unlocked shields containing at least one of the sources were left unsecured in patients' rooms for three days.

2. Cesium-137 sources that had,been removed from a patient were left in unlocked shields on an unattended cart in an unlocked patient's room. No one had been assigned responsibility for the sources.

Causes

1. Management and employees of the hospital did not adequately control the licensed material and follow required procedures.

Consequence

1. A 50 millicurie Cesium-137 source was lost or stolen resulting in potential unnecessary radiation exposures to patients, hospital personnel, and members of the public.

Enforcement

NRC imposed a civil penalty of $2,000 which the licensee paid.

Page Last Reviewed/Updated Tuesday, November 12, 2013