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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30303

JAN 12 1979

CORNELL UNIVERSITY
RADIATION SAFETY OFFICE
512 E. STATE STREET
ITHACA NY 14850

Gentlemen:

The enclosed IE Circular 79-01, is forwarded to you for information. If there are any questions related to your understanding of the suggested actions, please contact this office.

James P. O'Reilly
Director

Enclosures:
1. IE Circular No. 79-01
2. List of IE Circulars Issued in 1978

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

January 12, 1979

IE Circular No. 79-01

ADMINISTRATION OF UNAUTHORIZED BYPRODUCT MATERIAL TO HUMANS

Description of Circumstances:

Recently the U. S. Nuclear Regulatory Commission (NRC) has investigated two incidents in which reagent grade compounds containing byproduct material were administered as intravenous radiopharmaceuticals to humans. These compounds had neither been manufactured for use as radiopharmaceuticals nor undergone testing for human use.

In these incidents the byproduct materials were in chemical forms other that the forms used in diagnostic studies and should not have been shipped by the supplier. In one case Selenium-75 labeled selenious acid was shipped instead of Selenium-75 labeled selenomethionine. In the other case Ytterbium-169 labeled chloride was shipped instead of Ytterbium-169 labeled diethylenetriaminepentaacetic acid (DTPA).

The hospitals which received these materials should not have accepted them since they were not authorized to possess them by their NRC license. In addition, the hospital personnel preparing the patient doses should not have prepared these materials for administration to a patient since the labels, leaflets, and brochures in each case identified the radioisotope and chemical form and included a warning that the radioactive material was not for use in humans or clinical diagnosis.

Notice to Medical Licensees:

Medical licensees should have procedures to be followed by persons preparing radiopharmaceuticals for administration to humans. The procedures should include the following steps:

a. confirmation that the compound is a radiopharmaceutical intended for human use,

b verification that the type, chemical form and quantity of byproduct material is the correct one for the particular patient and the medical procedure being used, and

c. verification that the radiopharmaceutical was manufactured and distributed under a license issued by the NRC or and Agreement State.

These confirmations and verifications can be accomplished by reviewing the labels, leaflets, and brochures enclosed in the package.

Medical licensees should instruct and require personnel to follow these procedures in preparing and administering radiopharmaceuticals to patients.

The contents of this Circular should be brought to the attention of all personnel who prepare and administer licensed radiopharmaceuticals to human patients.

No written response to this Circular is required. If you require additional information regarding this subject, please contact the Director of the appropriate NRC Regional Office.

IE Circular No. 79-01
January 12, 1979

LISTING OF IE CIRCULARS ISSUED IN 1978

Circular No.	Subject	Date of Issue	Issued To
78-01	Loss of Well Logging Source	4/5/78	All Holders of Well Logging Source Licenses
78-02	Proper Lubricating Oil for Terry Turbines	4/20/78	All Holders of Reactor OLs or CPs
78-03	Packaging Greater Than Type A Quantities of Low Specific Activity Radioactive Material for Transport	5/12/78	All Holders of Reactor OLs, CPs, Fuel Cycle, Priority I Material and Waste Disposal Licenses
78-04	Installation Error That Could Prevent Closing of Fire Doors	5/15/78	All Holders of Reactor OLs or CPs
78-05	Inadvertent Safety Injection During Cooldown	5/23/78	All Holders of Reactor OLs or CPs
78-06	Potential Common Mode Flooding of ECCS Equipment Rooms at BWR Facilities	5/23/78	All Holders of Reactor OLs or CPs
78-07	Damaged Components of a Bergen-Paterson Series 25000 Hydraulic Test Stand	5/31/78	All Holders of Reactor OLs or CPs
78-08	Environmental Qualification of Safety Related Equipment at Nuclear Power Plants	5/31/78	All Holders of Reactor OLs or CPs
78-09	Arcing of General Electric Company Size 2 Contactors	6/5/78	All Holders of CPs

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January 12, 1979

LISTING OF IE CIRCULARS ISSUED IN 1978

Circular No.	Subject	Date of Issue	Issued to
78-10	Control of Sealed Sources Used in Radiation Therapy	6/14/78	All Medical Licensees in Categories G and G1
78-11	Recirculation M-G Set Overspeed Stops	6/15/78	All Holders of BWR OLs or CPs
78-12	HPCI Turbine Control Valve Lift Rod Bending	6/30/78	All Holders of BWR OLs or CPs for plants with HPCI Terry Turbine
78-13	Inoperability of Multiple Service Water Pumps	7/10/78	All Holders of Reactor OLs and CPs except for plants located in: AL, AK, CA, FL, GA, LA, MS, SC
78-14	HPCI Turbine Reversing Chamber Hold Down Bolting	7/12/78	All Holders of BWR OLs or CPs for plants with a HPCI Terry Turbine excepting Duane Arnold and Monticello
78-15	Checkvalves Fail to Close In Vertical Position	7/20/78	All Holders of Reactor OLs or CPs
78-16	Limitorque Valve Actuators	7/26/78	All Holders of Reactor OLs or CPs
78-17	Inadequate Guard Training/ Qualification and Falsified Training Records	10/13/78	All Holders of and applicants for Reactor OLs.

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January 12, 1979

LISTING OF IE CIRCULARS ISSUED IN 1978

Circular No.	Subject	Date of Issue	Issued To
78-18	UL Fire Test	11/6/78	All Holders of Reactor OLs or CPs
78-19	Manual Override (bypass) of Safety Actuation Signals	12/29/78	All Holders of Reactor CPs