UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76012

July 13, 1979

License No. 05-00046-13

Department of the Army
Fitzsimons Army Medical Center
Denver, Colorado 80240

Gentlemen:

The enclosed IE Circular 79-14, is forwarded to you for information. If there are any questions related to your understanding of the suggested actions, please contact this office.

Sincerely,

Karl V. Seyfrit
Director

Enclosures:
1. IE Circular No. 79-14
2. List of IE Circulars
   Issued in 1979

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

IE Circular No. 79-14
July 13, 1979

UNAUTHORIZED PROCUREMENT AND DISTRIBUTION OF XENON-133

Description of Circumstances:

Recently the U.S. Nuclear Regulatory Commission (NRC) and the State of Texas have investigated several incidents in which a nuclear pharmacy procured bulk shipments of Xenon-133 gas labeled "Not For Human Use"; partitioned the material into unit doses, relabeled and packaged the material, and distributed it as a prepared radiopharmaceutical for human use. Some bulk shipments of Xenon-133 were procured by the nuclear pharmacy and transferred to medical institutions not authorized to receive the material.

The above actions by the nuclear pharmacy are contrary to both NRC and the Food and Drug Administration (FDA) regulatory requirements. The nuclear pharmacy procured the Xenon-133 gas from a supplier whose product was not intended for human use. This was in noncompliance with the nuclear pharmacy's NRC license which requires that "radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug and Cosmetic Act." Also, contrary to NRC regulations (10 CFR 30.41(b)(5) and 10 CFR 30.41(c)), the nuclear pharmacy transferred Xenon-133 "Not For Human Use" to medical institutions who were only authorized to receive Xenon-133 in a form suitable for human use.

The NRC only licenses nuclear pharmacies to distribute radioactive drugs that have been approved or accepted by FDA. This includes those radioactive drugs: (a) subject to an FDA-approved "New Drug Application" (NDA) or (b) for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND). The nuclear pharmacy in this case violated FDA regulations since it did not possess an NDA or IND which is required to process "chemical grade" radioactive material into "pharmaceutical grade" radioactive drugs. As part of its approval of NDAs and INDs, FDA requires that certain tests (i.e., total activity, radionuclide purity, etc.) be performed to ensure that the material is safe and effective for human use. The nuclear pharmacy in this case also did not test either the unit doses or the bulk shipments of Xenon-133.

Notice to Licensees Who Procure, Distribute, and Use Radiopharmaceuticals:

All licensees who procure, process, and distribute radiopharmaceuticals for human use or who administer radiopharmaceuticals to humans should be aware of NRC's and FDA's regulations. Licensees who receive Xenon-133 and other radiopharmaceuticals for human use should review the labels, leaflets, and brochures

enclosed in radiopharmaceutical packages to verify that the radioactive material is a radiopharmaceutical intended for human use. Chemical grade radioactive materials are typically labeled as follows: "Caution: For Manufacturing, Processing or Repacking. Pharmaceutically Unrefined. Not Tested for Sterility or Freedom From Pyrogens. Not for Human Use in Present Form."

Most NRC licensees who distribute and use radioactive materials for human use have a license condition, as stated in the Description of Circumstances part of this Circular, which requires that radioactive gases for human use be procured only from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug and Cosmetic Act. Distributors and users should review their NRC licenses and procedures to ensure against the use of unauthorized radioactive material.

The contents of this Circular should be brought to the attention of all personnel in your organization who procure, prepare, and use radiopharmaceuticals for human use. Appropriate instructions should be included in your procedures for procurement, receipt, preparation and use of radiopharmaceuticals.

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.

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July 13, 1979

LISTING OF IE CIRCULARS ISSUED IN
LAST TWELVE MONTHS

78-12	HPCI Turbine Control Valve Lift Rod Bending	6/30/78	All Holders of BWR Operating Licenses (OL) or Construction Permits (CP) with Similar HPCI Design
78-13	Inoperability of Service Water Pumps	7/10/78	All Holders of Reactor Operating Licenses (OL) or Construction Permits (CP) 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 Operating Licenses (OL) or Construction Permits (CP) for plants with a HPCI Terry Turbine excepting Duane Arnold and Monticello
78-15	Tilting Disc Check Valves Fail to Close With Gravity in Vertical Position	7/20/78	All Holders of Reactor Operating Licenses (OL) or Construction Permits (CP)

78-16	Limitorque Valve Actuators	7/26/78	All Holders of Reactor Operating Licenses (OL) or Construction Permits (CP)
78-17	Inadequate Guard Training/Qualification and Falsified Training Records	10/13/78	All Holders of and applicants for Reactor Operating Licenses (OL)
78-18	Underwriters Laboratory Fire Test	11/6/78	All Holders of Reactor Operating Licenses (OL) or Construction Permits (CP)
78-19	Manual Override (Bypass) of Safety Actuation Signals	12/29/78	All Holders of Reactor Construction Permits (CP)
79-01	Administration of Unauthorized Byproduct Material to Humans	1/12/79	All Medical Licensees except Teletherapy Medical Licensees and each Radiopharmaceutical Suppliers
79-02	Failure of 120 Volt Vital AC Power Supplies	1/16/79	All Holders of Reactor Operating License (OL) and Construction Permits (CP)
79-03	Inadequate Guard Training - Qualification and Falsified Training Records	2/23/79	All Holders of and applicants for Special Nuclear Material Licenses in Safeguards Group I
79-04	Loose Locking Nut On Limitorque Valve Operators	3/16/79	All Holders of Reactor Operating License (OL) or Construction Permits (CP)

79-05	Moisture Leakage in Stranded Wire Conductors	3/20/79	All Holders of Reactor Operating License (OL) or Construction Permits (CP)
79-06	Failure to Use Syringe and Battle Shields in Nuclear Medicine	4/19/79	All Holders of Medical Licensees except teletherapy licensees
79-07	Unexpected Speed Increase of Reactor Recirculation MG Set Resulted in Reactor Power Increase	5/2/79	All Holders of BWR Operating Licenses (OLs) or Construction Permits (CPs)
79-08	Attempted Extortion - Low Enriched Uranium	5/18/79	All Fuel Facilities and Reactors Licensed by NRC
79-09	Occurrences of Split or Punctured Regulator Diaphragms In Certain Self Contained Breathing Apparatus	6/22/79	All Materials Priority I, Fuel Cycle and Operating Reactor Licenses (OL)
79-10	Pipefittings Manufactured from Unacceptable Material	6/26/79	All Power Reactor Licensees with a Construction Permit and/or Operating License (OL)
79-11	Design/Construction Interface Problem		All Holders of and Applicants for Power Reactor Construction Permits (CP)
79-12	Potential Diesel Generator Turbocharger Problem	6/28/79	All Power Reactor Licensee with a Construction Permit (CP) and/or Operating License (OL)
79-13	Replacement of Diesel Fire Pump Starting Contactors	7/13/79	All Power Reactor Licensee with a Construction Permit (CP) and/or Operating Licensee (OL)