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

July 10, 1997

NRC INFORMATION NOTICE 97-50: CONTAMINATED LEAD PRODUCTS

Addressees

All U.S. Nuclear Regulatory Commission licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to the potential for some shielding products containing lead to be contaminated with small amounts of naturally occurring radioactive material. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid unnecessary exposure to radioactive material. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

NRC recently was notified of the distribution of contaminated lead and lead products, including medical shielding devices. The contaminants are lead-210 and its daughter nuclides bismuth-210 and polonium-210. Based on current information, it appears that the contaminated products were manufactured from lead processed by one supplier between November 1996 and May 1997.

The contaminated lead was used to manufacture a variety of products consisting of lead-vinyl or lead-plastic products used to make radiation shielding materials for x-ray machine drapes, aprons, gonad shields, and sheet shielding. The contaminated lead may also have been incorporated into other commercially distributed products, such as brushes for electric motors, bullets, lead shot, lead roof flashing, and galvanizing compounds. Radiation from these products does not appear to represent a public health and safety hazard and there is little possibility of persons being exposed to radiation from any of these products except the radiation shielding products (vinyl-lead and plastic-lead).

Although NRC does not regulate the radioactive contaminants and the products do not appear to represent a threat to public health and safety, we are issuing this notice because of the use of many of the contaminated lead products as medical devices and temporary shielding and that users may not be aware of the contamination.

Discussion

This information has been coordinated with the Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and the Conference of Radiation Control Program Directors (CRCPD). The FDA has distributed a Public Health Notice to health care professionals advising them of this issue and requesting a report if any contaminated lead products are identified (see attachment). Some medical device firms and distributors have initiated a voluntary recall. The EPA and CRCPD have provided relevant information, respectively, to regional offices and all members.

If you discover that you possess a product that contains this contaminated lead, please contact the appropriate EPA regional office and State radiation regulatory agency.

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 or the appropriate regional office.

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

Technical contact: Brian W. Smith, NMSS
301-415-5723
E-mail: bws1@nrc.gov

Attachments:
1. FDA Public Health 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

June 13, 1997

FDA PUBLIC HEALTH NOTICE
Radioactivity in Radiation Protection Devices

TO: Health Care Professionals

FDA is notifying you that some shielding products used for radiation protection contain lead contaminated with small amounts of naturally occurring radionuclides. The contaminants are lead-210 (Pb-210) and its daughter nuclides bismuth-210 (Bi-210) and polonium-210 (Po-210). Initial FDA and state evaluations indicate that there is only a very small exposure to radioactivity from the affected products, and the contaminants are not transferable to patients, personnel or equipment by ordinary use. The products identified to date include medical devices used for radiation protection such as lead aprons, gonad shields, and thyroid shields manufactured after October 1, 1996.

Standard radiation safety practice is to avoid unnecessary exposure to radiation. Therefore the use of contaminated products should be discontinued. However, in cases where no alternative shielding is available, continued use of the contaminated products will be likely to provide greater protection during therapeutic and diagnostic procedures than using no shielding. Facilities which have no alternative protective devices available should consider continued use of the contaminated items until replacements are obtained.

Investigations are underway to identify all firms that received contaminated lead. FDA and state radiation control program officials have determined that a shipment of contaminated tin-lead alloy was imported from Brazil and then processed by MIDCO Industries of St. Louis, MO. MIDCO sold contaminated lead to Taracorp Industries of Granite City, IL. Taracorp then manufactured contaminated lead powder which was sold to 19 firms. Some of these 19 firms manufactured or distributed contaminated lead or lead products to a number of companies, including medical device manufacturers.

Recalls are being initiated by medical device firms and distributors. To date, E-Z-EM of Portchester, NY, and Picker Corporation of Cleveland, OH, are voluntarily recalling contaminated products. Other manufacturer recalls are likely to follow. If you have purchased affected products, you should receive notice from your supplier. The notice should provide instructions for disposition or return of the devices, and may include replacement information. As affected product lists are available, they will be provided to the Conference of Radiation Program Control Directors and posted on the FDA's internet site (http://www.fda.gov/cdrh/safety.html).

FDA recommends radiation protection medical devices containing lead purchased after October 1, 1996 be surveyed for radionuclide contamination. This should be done by

qualified personnel with a suitable survey meter, such as a thin window Geiger Mueller (G-M) instrument in contact with the product. The 1.16 MeV beta from the Bi-210 is easily detected with this type of instrument.

- If the survey results indicate contamination, contact your supplier for further instructions.
- If you don't have the capability to survey, contact the supplier of your devices purchased after October 1, 1996, to determine if their products are affected by this problem.
- If you receive a notice or a customer letter from a manufacturer or supplier concerning this matter, follow the instructions which should include information on disposition of affected products.

FDA is working with state radiation control program officials to identify all contaminated lead products that have been introduced into commercial distribution and to facilitate effective recalls of all contaminated devices. As additional information becomes available, FDA will issue updated notices.

FDA requests users who discover shielding products with contaminated lead to report this information directly to MedWatch, the FDA's voluntary reporting program. Submit these reports to MedWatch by telephone at 1-800-FDA-1088, by FAX at 1-800-FDA-0178, or by mail to:

MedWatch
Food and Drug Administration, HF-2
5600 Fishers Lane
Rockville, MD 20857

Contact Sherry Purvis-Wynn of FDA's Center for Devices and Radiological Health by E-mail slp@cdrh.fda.gov or by fax 301-594-2968 if you have any questions about this notice.

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
97-47	Inadequate Puncture Tests for Type B Packages Under 10 CFR 71.73(c)(3)	06/27/97	All "users and fabricators" of type B transportation packages [as defined in 10 CFR 171.16(10(B)]
97-42	Management Weaknesses Resulting in Failure to Comply with Shipping Requirements for Special Nuclear Material	06/27/97	All fuel cycle conversion, enrichment, and fabrication facilities
97-39	Inadequate 10 CFR 72.48 Safety Evaluations of Independent Spent Fuel Storage Installations	06/26/97	All holders of OLs or CPs for nuclear power reactors. All holders of licenses for independent spent fuel storage installations
96-53, Supp. 1	Retrofit to Amersham 660 Posilock Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility	06/23/97	All industrial radiography licensees
97-35	Retrofit to Industrial Nuclear Company (INC) IR100 Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility	06/18/97	All industrial radiography licensees
97-30	Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises	06/03/97	All material and fuel cycle licensees

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-49	B&W Once-Through Steam Generator Tube Inspection Findings	07/10/97	All holders of OLs or CPs for nuclear power reactors
97-48	Inadequate or Inappropriate Interim Fire Protection Compensatory Measures	07/09/97	All holders of OLs or CPs for nuclear power reactors
97-47	Inadequate Puncture Tests for Type B Packages Under 10 CFR 71.73(c)(3)	06/27/97	All "users and fabricators" of type B transportation packages [as defined in 10 CFR 171.16(10)(B)]
97-46	Unisolable Crack in High-Pressure Injection Piping	07/09/97	All holders of OLs or CPs for nuclear power reactors
96-44, Supp. 1	Failure of Reactor Trip Breaker from Cracking of Phenolic Material in Secondary Contact Assembly	07/02/97	All holders of OL permits for nuclear power reactors
97-45	Environmental Qualification Deficiency for Cables and Containment Penetration Pigtails	07/02/97	All holders of OLs or CPs for nuclear power reactors
97-44	Failures of Gamma Metrics Wide-Range Linear Neutron Flux Channels	07/01/97	All holders of OLs or CPs for test and research reactors

OL = Operating License
CP = Construction Permit

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COORDINATED WITH EPA C. CONKLIN 6/13/97
CRCPD

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OFC	IMOB	Tech Editor	IMOB	OSP	FCSS
NAME	BSmith	EKraus	JPiccone	RLBangart	LETenEYCK
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OFC	NRR	IMNS			
NAME	AChaffee	DCool			
DATE	6/ /97	6/3/97			

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