

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

August 24, 1999

**NRC INFORMATION NOTICE 99-26: SAFETY AND ECONOMIC CONSEQUENCES OF
MISLEADING MARKETING INFORMATION**

Addressees:

All Distributors and/or Manufacturers of Generally Licensed Products.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice to alert addressees to a possible threat to public safety caused by misleading marketing information and lack of end-user understanding of the regulatory requirements. It is anticipated that recipients of this notice will review this information for applicability to their marketing, sales literature, and management practices. Distributors and/or manufacturers of generally licensed products should provide information to the customers so that they are fully aware before acquisition of products, of regulatory responsibilities associated with use, transfer and disposal of radioactive products. Suggestions, contained in this information notice, are not new NRC requirements, therefore, no specific action nor written response is required.

Description of Circumstances:

Radioisotopes may be used for measuring industrial-process parameters, physical properties of materials, or diagnostic or beneficial therapeutic medical applications. Thousands of industrial and consumer products contain radioactive materials. Some products have small quantities of authorized radioactive materials incorporated into them for functional purposes. Examples of such products are self-luminous exit signs, precision balances, thickness and density gauges. Other products may incorporate radioactive gas (such as in watch dials, hands or faces), which allow watches, clocks, and other products to be read or to be manipulated reliably in the dark, twilight, or on failure of normal lighting.

Radioactive products to be distributed under a general license are required to be inherently safe so that they can be used by untrained people. However, licensed devices containing radioactive materials have not always been disposed of, nor handled properly, particularly those authorized by general licenses. This has, on some occasions, resulted in radiation exposure to the public and subsequent costly decontamination of property. NRC's routine inspections of licensees indicate that some distributors and manufacturers appear not to completely understand these regulations and their responsibilities. For example:

On routine inspection vendors have been found to be marketing and distributing products to specific and general licensees not in accordance with their commitments made in support of the application for safety evaluation and registration of the product.

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updated on 8/25/99

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Some manufacturers are unclear as to what changes should be identified or what differences between the registration certificate and current design should be brought to the attention of licensees through marketing literature updates and mass distributions or other forms of communications.

Some manufacturers have failed to notify users that deviations from the stated marketing literature, approved design, and processes may cause the product to fail prematurely or be unable to survive its intended conditions of use, or harsh environment or may cause the radiation safety features of the product to be ineffective.

Many times the manufacturers and distributors of these types of radioactive products portray them to prospective customers as non-maintenance items that can be readily bought off the shelf, installed without any consideration given to special circumstances or safe location, and forgotten about. Product-related literature may provide misleading information, or information that can easily be misconstrued by omission or commission. An example of such literature, (*italics added for emphasis*) that has been brought to NRC's attention is:

"...the easiest to install, zero-maintenance building exit signs in existence. They can literally be screwed into place and forgotten for up to 20 years. The low installed cost is the last cost for the guaranteed life of the sign."

This type of language in an advertisement may suggest to the end-user that its responsibilities are over after the installation of the device. However, the user as a General Licensee is responsible for the device until it is safely returned or disposed off according to regulatory requirements.

During 1997, within a 6-month period, two separate incidents occurred in New Jersey, where damaged exit signs caused significant contamination. The incidents involved a private residence and a housing cottage at a school for emotionally impaired children. In one incident, a young boy found three exit signs powered by radioactive material at a building demolition site near his home. The boy brought home and broke one of the exit signs to examine it and thereby contaminated some portions of his home and the contents. In another accident a mentally impaired boy shattered an exit sign at an adolescence psychiatric hospital run by the State of New Jersey. Each of these accidents resulted in temporary relocation of the residents while the facilities were being decontaminated at a cost in excess of \$ 200,000 per incident to resolve. Exit signs, powered with radioactive material, that are forgotten and/or unattended for a long time, often are direct results of misleading information and contribute to increased risk of accidents which may result in substantial decontamination costs.

DISCUSSION:

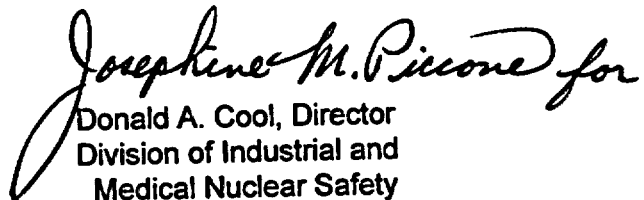
It is not the intent of this information notice to encourage or discourage the use of radioactive products. However, manufacturers and distributors are reminded of the problems that may arise when radioactive products sold through misleading or inexact marketing lead to improper control, transfer, damage, disposal, or discarding. Section 20.2001 of 10 CFR Part 20 specifies general requirements for disposal of licensed material. Because of the nature of the licensed material contained in a device, currently one of the options for disposal of licensed material is to transfer products containing radioactive material to an authorized recipient, as specified in 10 CFR 20.2001(a).

As a manufacturer/distributor of products licensed to 10 CFR Part 32 or by an Agreement State, you should inform the end-user that disposal of radioactive products will be by transfer to an authorized licensee. Authorized recipients of the used products for disposal are the original suppliers of the device, or a commercial firm, licensed by NRC or an Agreement State, to accept radioactive waste from another person.

Clear understanding of regulations and availability of accurate and complete information is the key to ensuring the safety and security of the public. The general licensees that possess these types of products have responsibilities, but many times do not clearly understand them until an accident forces them to do so. Often the chemical form of the source is mentioned by name, but the advertising text fails to mention that the source is radioactive and that owners of these types of devices are licensed to possess them. Accidents resulting from lapses in responsibilities and accountability may cause substantial and avoidable burdens on the agencies having jurisdiction over radioactive materials or members of the public and result in avoidable financial costs involved in dealing with such accidents.

A need for corrective action has been perceived for a long time. In a recent proposed rule (July 26, 1999; Volume 64 of Federal Register, page 40295), the Commission would require licensees that distribute products containing radioactive material to provide information to their customers prior to purchase and/or transfer of such products. The proposed rule would include a list of services that must be offered to users, information on disposal options including a cost estimate, and if transferred to an Agreement State, the name, address and the phone number for the appropriate Agreement State contact. The intent of this proposed requirement is to ensure that distributors of generally licensed products provide adequate radioactive product related information to their customers prior to purchase and/or transfer. All manufacturers and distributors are encouraged to examine the proposed rule and provide their comments. For more information on the rulemaking, please contact Catherine R. Mattsen, at (301)415-6264.

This Information Notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed or the appropriate regional office.


Josephine M. Piccone for

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

Attachments:

1. List of recently issued NMSS Information Notices
2. List of recently issued NRC Information Notices

Technical Contact: Ujagar S. Bhachu, NMSS
(301)415-7894
E-mail usb@nrc.gov

**LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES**

Information Notice No.	Subject	Date of Issuance	Issued to
99-24	Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices	7/12/99	All medical licensees' of broad-scope and master materials licensees
99-23	Safety Concerns Related To Repeated Control Unit Failures of the Nucletron Classic Model High-Dose-Rate Remote Afterloading Brachytherapy Devices	7/6/99	All U.S. NRC medical licensees authorized to use brachytherapy sources in Nucletron Classic Model high-dose-rate (HDR) remote afterloaders
99-22	10 CFR 34.43(a)(1): Effective Date for Radiographer Certification and Plans for Enforcement Discretion	6/25/99	Industrial Radiography Licensees
99-20	Contingency Planning for the Year 2000 Computer Problem	6/25/99	All material and fuel cycle licensees and certificate holders
99-18	Update on NRC's Year 2000 Activities for Materials Licensees and Fuel Cycle Licensees and Certificate Holders	6/14/99	All material and fuel cycle licensees and certificate holders
99-16-	Federal Bureau of Investigation's Nuclear Site Security Program	5/28	All U.S. Nuclear Regulatory Commission fuel cycle, power reactor, and non-power reactor licensees
99-11	Incident Involving the Use of Radioactive Iodine-131	4/16/99	All medical use licensees
99-09	Problems Encountered When Manually Editing treatment Data on the Nucletron Microselectron-HDR (New) Model 105-999	3/24/99	All medical licensees authorized to conduct high-dose-rate (HDR) remote after loading brachytherapy treatments
99-06	1998 Enforcement Sanctions as a Result of Deliberate Violations of NRC Employee Protection Requirements	3/19/99	All U. S. Nuclear Regulatory Commission licensees

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Information Notice No.	Subject	Date of Issuance	Issued to
99-25	Year 2000 Contingency Planning Activities	8/10/99	All holders of operating licenses for nuclear power plants and fuel cycle facilities
99-24	Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices	7/12/99	All medical licensees of broad-scope and master materials licensees
99-23	Safety Concerns Related To Repeated Control Unit Failures of the Nucletron Classic Model High-Dose-Rate Remote Afterloading Brachytherapy Devices	7/6/99	All U.S. NRC medical licensees authorized to use brachytherapy sources in Nucletron Classic Model high-dose-rate (HDR) remote afterloaders
99-22	10 CFR 34.43(a)(1); Effective Date for Radiographer Certification and Plans for Enforcement Discretion	7/6/99	Industrial Radiography Licensees
99-21	Recent Plant Events Caused By Human Performance Errors	6/25/99	All holders of licenses for nuclear power, test, and research reactors
99-20	Contingency Planning for the Year 200 Computer Problem	6/25/99	All material and fuel cycle licensees and certificate holders
99-19	Rupture of the Shell Side of a Feedwater Heater at the Point Beach Nuclear Plant	6/23/99	All holders of operating licenses or construction permits for nuclear power reactors
99-18	Update on NRC's Year 2000 Activities for Materials Licensees and Fuel Cycle Licensees and Certificate Holders	6/14/99	All material and fuel cycle licensees and certificate holders

OL = Operating License
 CP = Construction Permit

As a manufacturer/distributor of products licensed to 10 CFR Part 32 or by an Agreement State, you should inform the end-user that disposal of radioactive products will be by transfer to an authorized licensee. Authorized recipients of the used products for disposal are the original suppliers of the device, or a commercial firm, licensed by NRC or an Agreement State, to accept radioactive waste from another person.

Clear understanding of regulations and availability of accurate and complete information is the key to ensuring the safety and security of the public. The general licensees that possess these types of products have responsibilities, but many times do not clearly understand them until an accident forces them to do so. Often the chemical form of the source is mentioned by name, but the advertising text fails to mention that the source is radioactive and that owners of these types of devices are licensed to possess them. Accidents resulting from lapses in responsibilities and accountability may cause substantial and avoidable burdens on the agencies having jurisdiction over radioactive materials or members of the public and result in avoidable financial costs involved in dealing with such accidents.

A need for corrective action has been perceived for a long time. In a recent proposed rule (July 26, 1999; Volume 64 of Federal Register, page 40295), the Commission would require licensees that distribute products containing radioactive material to provide information to their customers prior to purchase and/or transfer of such products. The proposed rule would include a list of services that must be offered to users, information on disposal options including a cost estimate, and if transferred to an Agreement State, the name, address and the phone number for the appropriate Agreement State contact. The intent of this proposed requirement is to ensure that distributors of generally licensed products provide adequate radioactive product related information to their customers prior to purchase and/or transfer. All manufacturers and distributors are encouraged to examine the proposed rule and provide their comments. For more information on the rulemaking, please contact Catherine R. Mattsen, at (301)415-6264.

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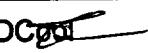
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 (301)415-7894

E-mail: usb@nrc.gov *See previous concurrence g:\bhachu\info5.wpd

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OFFICE	MSIB*		NMSS*		MSIB*		MSIB*	
NAME	UBhachu/Lucy		EKraus		JTelford		LCamper	
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Incidents resulting from lapses in responsibilities, accountability, or control of the devices may cause substantial and avoidable burdens for members of the public or the agencies having jurisdiction over the radioactive material. These incidents may also result in unwarranted and avoidable financial costs for clean-up of contamination.

Distributors and manufacturers should review the requirements of their licenses and should take any appropriate actions to prevent loss of control of the radioactive material once it has been transferred to the General Licensee. Specifically, the distributors and manufacturers should take appropriately conscientious actions to ensure that the purchasers are encouraged to return the device to them at its end-of-life or when it is no longer needed by the General Licensee.

Although this Information Notice requires no specific action nor written response, we do appreciate your help in avoiding these types of incidents. If you have any questions about the information in this notice, please address them to the technical contact listed below or the appropriate regional office.

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no local objection

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DATE	1/4/99	03/02/99	3/3/99	03/9/99	3/10/99	3/11/99	3/18/99
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These aforementioned types of problems can be confusing and misleading to the end-user. The general licensees that possess these types of products have responsibilities, but many times do not understand them until accidents forces them to try to understand them. Often a source chemical form is mentioned by name, but the advertising text fails to mention that source material is radioactive and that owners of these types of devices are licensed to possess them.

Accidents resulting from lapses in responsibilities and accountability may cause substantial and avoidable burdens on the agencies having jurisdiction over radioactive materials or members of the public and result in avoidable financial costs involved in dealing with such accidents.

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Accidents resulting from lapses in responsibilities and accountability may cause substantial and avoidable additional burdens on the agencies and personnel having jurisdiction over radioactive materials, as well as cause the various stresses and financial costs involved in dealing with such accidents.

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