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

December 29, 1997

NRC INFORMATION NOTICE 97-89: DISTRIBUTION OF SOURCES AND DEVICES WITHOUT AUTHORIZATION

Addressees

All sealed source and device manufacturers and distributors.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to the situation of unauthorized sources and devices being distributed to specific and general licensees, and the breakdown of the vendor's regulatory program that allowed such distribution. This notice provides information that vendors of sources and devices may consider to avoid distribution of products that have not been authorized. It is expected that recipients will review the information for applicability to their licensed activities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

A routine inspection of a vendor authorized to distribute products to specific and general licensees revealed that the vendor distributed products that had not been distributed in accordance with its license or certain commitments made in support of its application for safety evaluation and registration of the products. After the inspection, a Confirmatory Action Letter was issued, to the vendor, indicating the vendor's commitment to review all past distributions of sources and devices to determine if the products were in accordance with its license and the registration certificate, and to verify whether commitments made in support of its application for safety evaluation and registration had been met. The vendor's investigation identified that: (a) there were several hundred instances where products were distributed contrary to the conditions in the registration certificate; and (b) certain of the vendor's commitments had not been met. The deviations from the registration certificate identified by the licensee varied from minor modifications to essentially complete redesigns. In addition, a number of the deviations indicated potential health and safety concerns that required further review.

Several factors contributed to the improper distributions and commitments not being met. These included: (a) the vendor's not having and maintaining a program sufficient to identify and prevent distribution of products containing deviations from the registration certificate;

(b) uncertainty as to interpretations of information contained in the registration certificate and the information submitted in support of the safety evaluation and registration of the product; and (c) a lack of oversight and communication between the vendor and the manufacturer of the products. The root cause of these factors seems to be not implementing an effective quality assurance and quality control (QA/QC) program.

The vendor's QA/QC program failed to ensure that products were distributed in accordance with the approved designs, for several reasons. These included: (1) the vendor failed to verify the validity of design information, submitted by former distributors, vis a vis the current design of the products; (2) the vendor's audits of the manufacturer were not sufficiently in-depth to identify changes in product design; and (3) the vendor relied on the manufacturer to compare the actual design of the product being distributed with the design contained in the registration certificate. As a result, the vendor committed to designs that, in some cases, did not accurately reflect the current designs of the products. In addition, the manufacturer based its reviews on the current designs of the products and not on the designs contained in the registration certificates, and was unclear about the types of changes that should be identified to the licensee. Therefore, the manufacturer did not identify differences between the previous designs and the current designs and did not notify the vendor of all design changes that should have been identified.

Subsequent to the inspection of the vendor, that identified the improper distributions, several similar inspections of other vendors were performed. These inspections concentrated on the QA/QC programs of the vendors and whether the vendors had distributed products that were not authorized. Several of these inspections identified similar problems where a lack of an effective QA/QC program or not following the QA/QC program led to a vendor distributing products not in accordance with its license and/or the registration certificate for the product.

Discussion

Persons who distribute products that have been issued registration certificates must ensure that distributed products are in accordance with the statements and representations contained in their applications, as well as the provisions of the registration certificates for the products. This requirement is codified in 10 CFR 32.210. Specifically, 10 CFR 32.210 requires, in part, that applicants submit information concerning their quality control programs to the regulatory authorities for review. This information must provide reasonable assurance to the reviewer that the quality control programs are sufficient to ensure that distributed products are in accordance with the approved designs. To this extent, a vendor's QA/QC program should ensure that all changes to the product are reviewed for safety implications, before implementing the change; that changes which require amendment to the registration certificate are submitted to the regulatory authority for review; and that the changes submitted to the regulatory authority are approved and included in the registration certificate before distribution of products that include the change. Deviations from the approved design and processes may cause the product to be unable to survive its intended conditions of use or may cause the radiation safety features of the product to be ineffective.

When establishing QA/QC programs, manufacturers and distributors should be certain that they contain the essential elements needed to ensure that products are distributed in accordance

with the approved designs. In addition, QA/QC programs should periodically be reviewed, to determine their effectiveness and to identify needed modifications or updates to reflect changes such as new technology, manufacturing processes, and corporate reorganizations. Examples of elements that are considered critical to an adequate QA/QC program include: design control; a process to identify and address deviations; inspection and testing programs (performed on a continuous or periodic basis); and periodic audits of the QA/QC program and the programs and processes of suppliers, to ensure they remain effective. Additional guidance on what are considered essential elements necessary for the establishment of an adequate QA/QC program is contained in Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material."

It should be noted that vendors who do not have QA/QC programs that are adequate to ensure that products are manufactured and distributed in accordance with the design and processes approved by the regulatory authority, or that fail to follow their approved QA/QC programs, may be subject to enforcement actions, including revocation of the approvals contained in their registration certificates.

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: Douglas Broaddus, NMSS
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E-mail: dab@nrc.gov

Attachments: Attachments filed in Jacket
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

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LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-87	Second Retrofit to Industrial Nuclear Company IR100 Radiography Camera, to Correct Inconsistency in 10 CFR Part 34 Compatibility	12/12/97	All industrial radiography licensees
97-86	Additional Controls for Transport of the Amersham Model No. 660 Series Radiographic Exposure Devices	12/12/97	Registered users of the Model No. 660 series packages, and Nuclear Regulatory Commission industrial radiography licensees
97-75	Enforcement Sanctions Issued as a Result of Deliberate Violations of NRC Requirements	09/24/97	All U.S. Nuclear Regulatory Commission licensees
97-72	Potential for Failure of the Omega Series Sprinkler Heads	09/22/97	All holders of OLs or CPs for nuclear power reactors and fuel cycle facilities
97-65	Failures of High-Dose-Rate Remote Afterloading Device Source Guide Tubes, Catheters, and Applicators	08/15/97	All high-dose-rate remote afterloader licensees
97-64	Potential Problems Associated with Loss of Electrical Power in Certain Teletherapy Units	08/13/97	All U.S. Nuclear Regulatory Commission medical tele-therapy licensees
97-61	U.S. Department of Health and Human Services Letter, to Medical Device Manu-facturers, on the Year 2000 Problem	08/06/97	All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, and manufacturers/distri-butors of medical devices
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-88	Experiences During Recent Steam Generator Inspections	12/16/97	All holders of OLs for pressurized-water reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor
97-87	Second Retrofit to Industrial Nuclear Company IR 100 Radiography Camera, to Correct Inconsistency in 10 CFR Part 34 Compatibility	12/12/97	All industrial radiography licensees
97-86	Additional Controls for Transport of the Amersham Model No. 660 Series Radiographic Exposure Devices	12/12/97	Registered users of the Model No. 660 series packages, and Nuclear Regulatory Commission industrial radiography licensees
97-85	Effects of Crud Buildup and Boron Deposition on Power Distribution and Shutdown Margin	12/11/97	All holders of OLs for pressurized-water reactors, except those licensees who have permanently ceased operations and have certified that the fuel has been permanently removed from the reactor vessel
97-84	Rupture in Extraction Steam Piping as a Result of Flow-Accelerated Corrosion	12/11/97	All holders of OLs for nuclear power reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel
95-49, Sup. 1	Seismic Adequacy of Thermo-Lag Panels	12/10/97	All holders of OLs for nuclear power reactors

OL = Operating License
CP = Construction Permit