UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
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January 24, 2001

John Feeney
License Administrator
New Jersey Department of Environmental Protection
Division of Environmental Safety, Health & Analytical Programs
Bureau of Radiation Protection
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415

SUBJECT: DISTRIBUTION OF LABELED PRODUCTS

Dear Mr. Feeney:

This is in response to your November 14, 2000 letter to Thomas Thompson of this office regarding NRC policies and procedures relating to relabeling companies (RC). This issue was also discussed further between you and Duncan White of this office during a telephone conversation on November 29, 2000.

In your letter and during your conversation with Mr. White, you raise a number of issues regarding the policies and procedures with regard to relabeling companies.

The principal regulatory mechanism in which the NRC will learn of product defects or other radiation related hazards is found in 10 CFR Part 21. 10 CFR 21.21 requires the individual, director or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended or the Energy Reorganization Act of 1974 to evaluate, document and report all defects or failures that are associated with, or could lead to a substantial safety hazard. A substantial safety hazard is defined as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or licensed activities as defined in Parts 30, 40, 50, 60, 61, 70, 71 or 72.

From a radiological perspective, a substantial radiation safety hazard exists if there is a potential for a moderate exposure to, or release of licensed material. As outlined in Section 14 of NUREG-1556, Volume 3, *Applications for Sealed Source and Device Evaluation and Registration*, moderate exposure or release of licensed material would be a 250 mSv (25 rem) whole body exposure to occupationally exposed workers, 5 mSv (0.5 rem) to an individual in an unrestricted area, or release of materials in amounts reportable under the provisions of 10 CFR 20.2202(b)(2).

The reporting of product defects by others not covered by the regulations in 10 CFR 21 is encouraged. 10 CFR 21.2(d) states that "Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure."

Additional reporting requirements for events in which equipment is disabled or fails to function as designed can be found 10 CFR 30.50(b)(2).

10 CFR 21.21 also includes requirements for written reports to the NRC and maintenance of auditable records. In addition, distribution licensees are routinely inspected by the NRC to determine compliance with NRC requirements and license conditions.

Responsibility for the proper disposition of licensed material if the manufacturer goes bankrupt or the contractual relationship between the manufacturer and the relabeling company no longer exists falls to the general or specific licensee who possesses the material. 10 CFR 30.35 requires that specific licensees maintain financial assurance to fund decommissioning of their facility based on the isotope, quantity, and half-life of licensed material authorized on their license.

Since New Jersey is considering becoming an Agreement State, you should note that the adoption of 10 CFR Part 21 is not required for compatibility. The requirements in 10 CFR 30.3 are a matter of compatibility and needed for the common understanding regarding activities requiring a license. The compatibility category for this part of the regulations (category C) would require New Jersey to adopt the essential objectives to avoid duplications, conflicts or gaps with the NRC and other Agreement States. The manner in which New Jersey addresses the essential objectives need not be the same as NRC provided the essential objectives are met. For example, New Jersey would be compatible with regard to 10 CFR 30.3 if the State requires that persons take actions in addition to those required to satisfy the NRC-equivalent regulation. For additional information on capability, please see State and Tribal Programs (STP) Procedures SA-200 *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements* and SA-201 *Review of State Regulations* located on the STP web site at http://www.hsrd.ornl.gov/nrc/home.html.

If you any additional question regarding this matter, please feel free to contact me at (610) 337-5031 or Duncan White, Regional State Agreements Officer at (610) 337-5042.

Sincerely,

Original signed by J. Bradley Fewell

J. Bradley Fewell
Regional Counsel

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