



State of New Jersey

Department of Environmental Protection

Christine Todd Whitman
Governor

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REGION 1

Robert C. Shinn, Jr.
Commissioner

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Q-4

November 14, 2000

Mr. Thomas Thompson, Senior Health Physicist
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Mr. Thompson:

This is a follow up to our telephone conversation of October 31, 2000, regarding relabeling companies (RC). These are companies that place their names on products that contain radioactive materials which are manufactured and/or distributed by a company (M/D) that is specifically licensed by either the U.S. Nuclear Regulatory Commission (NRC) for byproduct materials or the States for naturally occurring and accelerator produced radioactive materials (NARM).

Three recent incidents involving a RC labeled product made us aware that there appears to be a gap in notifying regulatory agencies about radiation-related problems with products containing radioactive materials. Specifically, the New Jersey Department of Environmental Protection (NJDEP) was not notified by either the RC or the M/D of incidents involving radiation contamination from products sold by the RC.

The NJDEP's concerns are the following:

1. RCs, while not in possession of the product, enter into contracts with purchasers of the products. Essentially, NJDEP believes that the RCs own or have title to the products, which are sold to the end users.

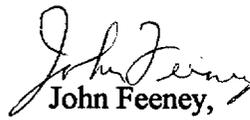
2. Since the radioactive materials are sold by the RC's, it is the RCs who direct the distribution of the radioactive products.
3. When there are problems of a radiological nature with the products, customers call the RCs for recourse.
4. RCs do not appear to be regulated by the NRC for byproduct materials or the States for NARM.
5. How does the NRC learn of product defects or other radiation-related problems with RC labeled products containing byproduct materials, if the RCs are not regulated by the NRC?
6. Would the NRC learn of problems with RC labeled products containing byproduct materials from the M/D of the product? If so, would the M/D be required to report such problems or simply to retain records for viewing during inspection? What sections of the NRC's regulations require reporting and what sections require retaining records of product problems?
7. Should the M/D go bankrupt, or should the contract between the RC and the M/D no longer exist, who is responsible for the products if they are owned by the RC?

One RC with which we are concerned is BRACCO Diagnostics, Inc., 107 College Rd. East, Princeton, New Jersey 08543. BRACCO Diagnostics has placed their labels on strontium-82/ribidium-82 generators which the NJDEP regulates as well as iodine-131 therapeutic capsules which NRC regulates.

Since New Jersey is considering becoming an agreement state, we would like to know of NRC's policies and procedures regarding dealing with RCs, so that we might possibly establish consistent policies and procedures for NARM.

Should you have any questions regarding the above, please feel free to contact me (609) 984-5555.

Sincerely,


John Feeney,
License Administrator

cc: Alyssia Wolf, DAG
Patricia Gardner, Chief, BER
Bill Cszasz, BER