Merck & Co., Inc.
West Point, PA 19486

(20)

'99 OCT 12 P3:30

October 11, 1999

MERCK
Research Laboratories

DOCKET NUMBER
PROPOSED RULE PR 30, 31, 32 170+171
(64FR40295)

Attn: Rulemakings and Adjudications Staff
Secretary
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Proposed Rule
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material
RIN 3150-AG03

Dear Sir/Madam:

Merck & Co., Inc. would like to provide the following comments concerning the Proposed Rule addressing the Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material.

Background

Merck & Co., Inc. is a large pharmaceutical company developing pharmaceutical products in all major therapeutic categories. As part of the research and manufacturing of new drugs, the Company needs to assure purity of the laboratory samples of compounds under study as well as the purity of pharmaceutical products which will be administered to humans. This purity is often achieved by the use of static elimination devices, and often these devices employ the use of generally licensed byproduct material.

Analysis

The Proposed Rule for the Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material is intended to provide greater control over generally licensed material. Specifically, the Proposed Rule is intended to help ensure that devices containing byproduct material are maintained and transferred properly and are not inadvertently discarded.

Merck & Co., Inc. agrees that is prudent to require the registration of generally licensed devices that have the potential, if not handled or disposed properly, to cause exposure of the general public or widespread contamination of property. The devices listed in the proposed 10 CFR 31.5(c)(13) have the potential to cause exposure of the general public or contaminate a steel mill and should be registered. Unfortunately, other parts of 10 CFR 31.5 are being revised that will apply to all generally licensed devices under 10 CFR 31.5 including static eliminators. These changes appear to be burdensome and impractical.

9910130170 991011
PDR PR
30 64FR40295 PDR

D510

Static eliminators containing polonium-210 are covered by 10 CFR 31.5. These devices are used in research labs, production areas, and print shops. When they are ordered, the individual placing the order may not know they are receiving a generally licensed device until it arrives. For a company such as Merck & Co., Inc. that has several thousand employees at each of its major sites, it would be almost impossible for one "responsible" individual at each site to ensure the "day-to-day compliance" for these devices as required by the proposed 10 CFR 31.5(c)(12). The static eliminators are not labeled with a serial number. To inventory the entirety of the static eliminators on each site would prove impossible. The proposed rule appears to disregard the obstacles which are presented by having many small devices without serial numbers which are collectively used by groups of people from three different divisions which are dispersed throughout a large company.

Proposed 10 CFR 31.5(c)(15) requires that a general licensee not hold devices that are not in use for longer than two years. Again, this would also prove burdensome. Generally licensed devices may placed in storage and not be used for a period of more than 2 years. The owner may intend to use the device at a later date. This proposed rule would preclude this activity and would require the general licensee to dispose and re-purchase the generally licensed device. In the case of a static eliminator, it would be very difficult for the responsible individual to determine when such a device has been held in storage for longer than 2 years.

The additional regulatory burden required by the Proposed Rule is not warranted in light of the following. Typically, the devices employed by the pharmaceutical industries, as with many other industries, are those which present a lower risk. These devices are sealed sources which are designed to be inherently safe with regard to radiation safety. These devices are manufactured and distributed without serial numbers. Therefore, to require a general licensee to inventory and assure that devices are not stored for more than two years poses an undue regulatory burden.

In addition, many of these devices, specifically those that present a lower risk, do not enter a site by coming through any single designated person, such as an RSO or the proposed Responsible Individual (RI). Consequently, there is no simple of fail-safe method of determining what sources have already come on site and are being used.

We suggest that the following changes be made to the proposed rule:

1. 31.5(c)(12)
   Any general licensee required to register devices in accordance with paragraphs (c)(13), shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of responsibility in this regard.

2. 31.5(15)(c)(i)
   May not hold devices that are not in use for longer than 5 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person and have not been tested within the required test interval, they must be tested for leakage before being put back into service.

3. 31.5(15)(c)(ii)
   For generally licensed devices distributed without an affixed serial number, 10 CFR 31.5(c)(15)(i) is not applicable.

I am sure that this comment will receive careful review and consideration before the final rule is promulgated. I would also welcome an opportunity to discuss this matter with a member of the Rulemakings and Adjudications Staff. I can be reached at 215-652-4890.

Sincerely,

John J. Mueller

Edwin A. Wurtz, Ph.D.
Director
Health Physics, Biosafety, and
Environmental Affairs

for