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DOCKETED  
USNRC  
UCSF  
97 FEB 14 P4:01

DOCKET NUMBER  
PROPOSED RULE PR 33  
(61FR58346)

OFFICE OF SECRETARY  
DOCKETING & SERVICE  
BRANCH

December 29, 1996

Docketing and Services Branch  
Secretary  
Nuclear Regulatory Commission  
Washington, DC 20555-0001

This is with reference to the Commissions notice for revising the rules for Broad Scope Type A Licensees, which includes establishment of specific duties of RSO and RSC.

It appears that the main reason for this rule making are two:

1. Some licensees have not performed in accordance with their license criteria, or regulatory requirements.
2. There were two incidents which resulted in internal contamination.

I would like to comment on the applicability of each reason to establishment of additional regulatory burdens for licensees.

Point 1.

Current NRC and Agreement State regulations and requirements have substantial requirements for a description of the roles and responsibilities of the RSO and RSC, as well as an inventory control program. These include detailed requirements for maintaining records of receipt, usage and disposal of the radionuclides authorized. In addition licensees are required to establish a system of record keeping to verify that the total quantities of radionuclides on hand do not exceed the licensed quantities.

Usually the roles and responsibilities are clearly defined in the Radiation Safety Manuals and application submittals. An organization chart is also included (at least for Agreement States) describing the line of authority.

The exact procedures for maintaining these records are included in the license application and reviewed at the time of approval, or renewal. Presumably these details meet the standards of NRC or the Agreement State reviewers, otherwise the license will not be granted.

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In addition, each Broad Scope Type A licensee is inspected every two years. During these inspections the record keeping procedures are scrutinized in detail and their efficacy verified. Another item of inspection is the effectiveness of the Radiation Safety Program as a whole. The latter is an indicator of the overall control mechanism by which an inspector judges if the adequate management controls exist.

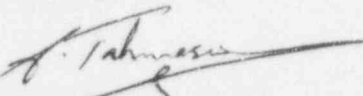
Point 2.

Presumably the two incidents are those occurring at the NIH and MIT. If this is the case, then their correlation to any management lapse in control of radioactive materials is irrelevant. As reported by the NRC investigators: *in both instances, the incidents happened as a result of the deliberate act of person or persons unknown*. Both individuals were contaminated in an approved laboratory, were approved users and were using an approved radionuclide. No matter how detailed any procedures are, or management responsibilities are codified, deliberate acts will be almost impossible to stop.

The current licensing and inspection structure provide adequate details for proper management of radioactive materials used under a Broad Scope Type A License. This is evident by the description in the "Notice for Proposed Rule Making" that there have only been a few instances of loss of radionuclides. During a typical year hundreds of thousands (most institutions will receive 10,000 - 15,000 vials per year) of packages are delivered to licensees. A few instances of loss of material, although undesirable, does not constitute a problem of lack of management control.

Broad Scope licensees operate under varied management schemes. It will be impossible to develop a "one-size-fits-all" package which will not force undue burdens on the institutions. The current systems in place are adequate and provide an appropriate degree of flexibility. If inspections by NRC or Agreement States identify a lack of appropriate management controls by a licensee, it is appropriate to force specific additional requirements on that licensee. However, it is not necessary to introduce another layer of bureaucratic requirements which will not contribute to any real health and safety.

Sincerely,



Ara Tahmassian, Ph.D.

Director, Office of Environmental Health and Safety

Radiation Safety Officer