

September 29, 1999

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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ATTN: Rulemakings and Adjudications Staff

To Whom It May Concern:

COMMENTS ON GENERALLY LICENSED DEVICES PROPOSED RULE

I am pleased to comment on the proposed rules published in the Federal Register on July 26, 1999 titled "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material." I am a health physicist who has been the radiation safety officer (RSO) at a medical facility holding a specific license of limited-scope from the NRC for the past three plus years, with six plus years of experience in health physics. The facility I work at possesses many generally licensed devices, although none of these devices would be included in the proposed registration rules. Below are my comments and concerns regarding the proposed rules:

31.5(c)(12): I agree with the proposed requirement to have each general licensee have an individual assigned to the day-to-day compliance duties. I do not agree with using the term "responsible individual" since the licensee is ultimately responsible for the devices, not this individual. Although the proposed rule states that the general licensee is responsible, there may be some confusion regarding these responsibilities. I am against assigning a backup responsible individual (BRI). The NRC does not require, by regulation, that specific licensees assign a backup RSO, which I think would be equivalent to a BRI. The concept that general licenses present a lower risk than specific licenses would not be implemented if a BRI is required, by regulation, for general licensees but not a backup RSO for specific licensees. The application of risk assessment needs to apply equally to all the different types of licenses. One question: If a licensee holds both a general license and a specific license, can the "responsible individual" be someone other than the RSO listed on the specific license?

31.5(c)(13): It is my opinion that once a registration policy and annual fees are implemented for certain general licensees that these licenses should be changed to a new category of specific licensees for these devices (a device specific license). This would be consistent with other license types that present a potential higher risk and are assessed an annual fee. The idea that some general licensees would be regulated differently than other could potentially cause more problems than it solves. One problem would be additional work for the NRC from general licensees submitting registrations for devices that are not required to be registered under the proposed rule. This is illustrated by the fact that at least one person that commented on the NRC rulemaking web site mistakenly thought that tritium "EXIT" signs would have to be registered. A few questions: If a licensee possesses devices that need registration along with devices that do not need registration, do all the devices need to be registered? Would specific

September 29, 1999


license holders have to pay the registration fee? 31.5(c)(13)(iii)(E) and (F) require "certification by the responsible representative of the general licensee." Do 31.5(c)(13)(iii)(E) and (F) require this "certification" by the licensee's management or the "responsible individual"? The NRC requires specific licensee's management to review and sign all licensing actions. It is not clear to me who is responsible for doing the certifying in these paragraphs.

32.51a(a): The manufacturer should be required to provide the required information to the "responsible individual" not "to each person that to whom a device is to be transferred." The NRC should supply, upon request, the manufacturer with the name of the "responsible individual" for a general licensee. This would assure that the responsible individual is aware of all new generally licensed devices that are purchased. This would also help the NRC maintain licensee accountability.

Other areas that are of a concern to me are as follows: 1.) Can the past inspection and enforcement history of a specific license be used to escalate the enforcement actions against the general license and vice versa? If so, is there precedence set for such actions? 2.) What criteria will be used to amend 30.5(c)(13)(i) to add additional devices to the list of devices that require registration? These criteria should be specified so that knee jerk reactions by the NRC to improper management, use or disposal of certain generally licensed devices does not occur. 3.) Is there a way for general licensee's to request a list of devices that should be in their possession? This would be a great benefit to the "responsible individual" once these proposed rules are implemented.

Thank you for the opportunity to comment on the proposed regulations. Should you have any questions regarding these comments, please do not hesitate to contact me at (414) 681-9329.

Sincerely,



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