

PR 31
(74FR38372)

Yale University

46

DOROTHY K. ROBINSON
Vice President and General Counsel
P.O. Box 208255
New Haven, Connecticut 06520-8255

Telephone: 203 432-4949
Fax: 203 432-7960

October 16, 2009

DOCKETED
USNRC

Secretary
U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

October 20, 2009 (10:50am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Re: Limiting the Quantity of Byproduct
Material in a Generally Licensed Device
Docket ID NRC-2008-0272

Dear Sir or Madam:

I am pleased to comment on behalf of Yale University on the proposed revision to the Nuclear Regulatory Commission's standards for generally licensed devices (74 FR 38372). We understand the rationale for limiting the quantity of byproduct material in generally licensed devices, and we believe the proposed revisions to 10 CFR 31.5(b)(3) would not hinder the conduct of research or medical care on university campuses.

However, one aspect of the NRC's proposal would be highly impractical and we urge that the NRC reconsider it. The NRC states that it is considering an additional requirement to prohibit specific licensees (SL) from possessing a device under a general license. This is described as follows in Section C of the Proposed Rule's preamble on pages 38377-8 of the *Federal Register*:

The Commission is also considering and may include in the final rule an additional change concerning generally licensed devices held by specific licensees. The proposal would *prohibit* [emphasis added] specific licensees from possessing generally licensed devices under 10 CFR 31.5 at the same site. Any specific licensee possessing a device generally licensed under 10 CFR 31.5 at a site for which an SL is in place would be required to transfer the device to the authority of their SL.

Yale opposes this change.

Yale possesses a variety of devices under a general license. We use them for many purposes at many locations. All of the generally licensed sources at Yale contain less than 1/100th of IAEA Category 2 activity limits. We manage these smaller sources safely and effectively outside of the requirements of our NRC Broadscope license. This approach adjusts the level of oversight to reflect the level of risk from the device; it provides a high level of safety and security and promotes an efficient use of Yale resources for protection of health and safety in Yale laboratories and clinical settings.

Yale has not found it problematic or confusing to comply with two sets of requirements for the different classes of devices because of the reduced requirements for these generally licensed devices. In fact, contrary to the NRC's suggestions in the *Federal Register*, requiring institutions with a Broadscope

Template = SECY-067

DS10

Yale University
page 2

license to manage all devices, including devices that usually fall under a general license, under the special license would neither promote safety nor facilitate compliance.

Transferring these small sources to our specific license would not have a material effect on health and safety. For example, much of the biomedical and basic science research performed on our campus utilizes a liquid scintillation counter. Each counter contains a very small activity, internally installed generally licensed source that is not "handled" by the researcher. The NRC notes in the Proposed Rule that these devices present a "relatively low security risk"; it is therefore unclear why the NRC wishes to make them subject to the more stringent requirements of a Broadscope license.

Placing generally licensed devices and sources under the control of our Broadscope academic license would be a significant administrative burden. Acquisition and disposal of sources may require a license amendment. Depending on the device, acquisition may impact our license limits and associated financial assurance requirements.

It would be very difficult to meet the requirements of a special license for generally licensed devices. For example, Yale has been able to establish controls to manage the procurement of specifically licensed radioactive materials because the NRC imposes certain rules on vendors of specially licensed devices. However, there are no comparable requirements for vendors of generally licensed devices, which makes it difficult for any institution to track purchases or receipt at the level required by a Broadscope license. Meeting the terms of the Broadscope license for generally licensed devices and sources would require significant changes to business processes on the part of both the vendors (if they cooperate) and the buyers. That is, it would be necessary for vendors to adopt practices similar to those used for specifically licensed devices. The University has and will continue to assure the safe use of generally licensed devices on campus, but we simply cannot manage these devices in the same manner as specifically licensed material under our Broadscope license.

The NRC also asked for comments on the question, "Would it be preferable to maintain the applicability of 10 CFR 31.5, but to apply some or all of the terms and conditions of the SLs?" (page 38378) While this alternative would provide some relief, ensuring compliance with the terms and conditions of our Broadscope license for these devices would present the same problems we describe in this letter.

In conclusion, Yale does not object to the proposed changes in the limits for generally licensed devices. However, we hope the NRC will not proceed with the proposal to prohibit the possession of generally licensed devices and sources at specifically licensed sites. Such a change would not improve safety or security, which is a stated purpose of this rulemaking. Moreover, compliance with the proposed change would be very difficult without significant changes in the practices of vendors. We have discussed the NRC proposal with Radiation Safety Officers at other universities, and we know they share our situation and concerns.

Thank you for the opportunity to provide comments on this proposed rule.

Respectfully submitted,



Dorothy K. Robinson
Vice President and General Counsel

Yale University

Office of the Vice President and General Counsel
P.O. Box 209255
New Haven, CT 06520-8255
Tel. (203) 432-4949 • Fax (203) 432-7960

Campus Address:
Whitney Grove Square
2 Whitney Avenue, 6th Floor
New Haven, CT 06510

FAX TRANSMISSION

Date: October 19, 2009

To: Secretary, US Nuclear Regulatory Commission

Fax Number: 301-415-1101

From: Dorothy K. Robinson, Vice-President & General Counsel

Number of Pages - 3 pages
(including fax cover)

CONFIDENTIALITY NOTICE: This facsimile contains legally PRIVILEGED AND CONFIDENTIAL information intended only for the use of the addressee(s) named above. If you are not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this facsimile is strictly prohibited. If you have received this facsimile in error, please immediately notify us by telephone at (203) 432-4949 and return the original facsimile to us at the above address via U.S. Postal Service. Thank you.