PR 31
(74FR38372)

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Public Health Service
National Institutes of Health

October 15, 2009

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

RE: Public Comments on the proposed rule change *Limiting the Quantity of Byproduct Material in a Generally Licensed Device* (Docket ID NRC-2008-0272)

Dear Sir/Madam:

In response to the Request for Comments by the Nuclear Regulatory Commission on the proposed rule change to 10 CFR 31, the National Institutes of Health (NIH) wishes to submit the following comments:

In this proposal, the NRC intends to amend 10 CFR 31.5 to include paragraph 31.5(b)(3) which will state that all terms and conditions of a licensee's specific license will apply to devices at the site which have traditionally been authorized to be used under a general license. It is suggested that this is needed to reduce confusion by standardizing requirements and that this will lead to increased compliance. It is also suggested that this is needed to reduce the number of generally licensed devices that the NRC tracks.

If this proposal is enacted as is being considered, it will require that all generally licensed devices at locations where a specific license is in place be transferred under the authority of the specific license; in other words, a specific license will be prohibited from possessing generally licensed devices under 10 CFR 31.5 at the same site. The NIH is adamantly opposed to such a requirement. As 10 CFR 31.5 is currently worded, the transfer of a generally licensed device to a specific license (and all of its terms and conditions) is an *option* of the licensee. There are many instances where adopting that option is in the best interests of the licensee, but there are also many instances where it is not. To *require* the option be adopted would eliminate the ability of the licensee to weigh its own cost/benefit analysis of the particular instance.

This approach does not align with the Commission's own risk-based approach to regulation, given that the generally licensed devices in question are acknowledged to be designed with inherent radiation safety features so that:

- they can be used by individuals with no radiation training or experience,
- it is unlikely that any individual will receive a dose in excess of 10% of the annual occupational dose limit in one year,
- under ordinary conditions of handling, storage and use, the byproduct material contained in the device will not be released or inadvertently removed,
- under accident conditions of handling, storage and use, it is unlikely that any individual will receive an external radiation dose or dose commitment in excess of applicable limits.

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Especially regarding generally licensed devices containing IAEA Category 4 and 5 quantities of radioactive material, the required adoption of these devices under a specific license already in place runs counter to the NRC's logic in determining to not require a specific license (in places where a specific license does not currently exist) for devices containing less than 1/10 of Category 3 quantities.

The logic for requiring a specific license in lieu of a general license (in places where a specific license does not currently exist) for devices containing greater than 1/10 of Category 3 quantities is understood to be a better awareness of applicable requirements for proper recordkeeping, handling and disposal, thereby leading to improved compliance. The NIH has no real argument with this logic and concurs that public health and safety will likely be enhanced as a result.

However, in places where a specific license already exists, requiring all generally licensed devices to be transferred under the umbrella of the specific license requirements and commitments does not make good sense. At best, the parallel rationale should be to propose the requirement only for devices containing greater than 1/10 of Category 3 quantities. Even better, the decision on whether to transfer regulation of a device under general license or specific license conditions should be that of the licensee and not the NRC.

As it is currently written in the proposed rulemaking, paragraph 31.5(b)(3) and the prohibition of a specific licensee to possess any source under a general license will significantly burden licensees with the requirements to verify that the specific license authorizes the possession and use of each device, remove existing labels and re-label each device such that it is in compliance with 10 CFR 20.1904, report the transfer under 10 CFR 31.5(c)(8)(ii), and apply all of the requirements and commitments for package receipt, inventory, security, radiation surveys and disposal as specified in the specific license. Given the enormous number of such devices (many if not most at less than 1/10 of Category 3 quantities) in healthcare and research environments, this would be an immense undertaking.

While the proposed change may reduce regulatory confusion, it will be only on the part of the NRC, Agreement States, and (resignedly) specific licensees' Radiation Safety offices. The proposed change will only serve to *increase* regulatory confusion on the part of end users, shippers and vendors, who currently understand that generally licensed devices may be purchased "off the shelf" and delivered directly to the workplace. Many, if not most, generally licensed device users are not radiation workers and thus have little to no interaction with the facility's radiation safety office, or even an awareness of such an office. This will cause a need for a constant outreach effort on the part of the radiation safety office to the user community, and this significant level of effort is simply not commensurate with the risk posed by the vast majority of generally licensed devices, for example those recognized to be of low security concern.

By way of additional detail, at the NIH there are 114 individual buildings on the grounds and leased space locations which are under the control of the specific license. These buildings contain nearly 8.5 million square feet of research space, and another 4.6 million square feet of administrative and support space. Extending the specific license commitments for package receipt, inventory, security, posting, surveys, and disposal to all of this space would be excessively burdensome; especially for devices that are of very low security risk such as liquid scintillation counters and gas chromatographs.

There is no gain in public health and safety. In fact, the only advantage to such a proposal would be to the benefit of the NRC: reduced tracking of generally licensed sources in the GLTS. For specific licensees, the only outcomes of such a proposal are a vastly increased regulatory burden, increased confusion among procurement agents and end users, and a significantly increased workload to apply radiation safety controls to devices that are by their very nature designed to be used by non-radiation workers. At present, the NIH possesses over 250 generally licensed devices subject to 10 CFR 31.5, including chemical agent detectors (15 mCi Ni-63 ea), aerosol neutralizers (up to 10 mCi Kr-85 ea), XRF analyzers (up to 30 mCi Am-241 or 20 mCi Fe-55 or 40 mCi Cd-109 ea), liquid scintillation counters (up to 40 uCi Cs-137 or 12 uCi Eu-152 or 20 uCi Ba-133 ea), gas chromatographs (15 mCi Ni-63 ea), blot analyzers (100 uCi Fe-55 ea), and exit signs (up to 20 Ci H-3 ea).

The NIH intends to follow this initiative very closely, and we appreciate the opportunity to provide these comments to you. Basic research needs are currently being met using generally licensed devices and it would be a grave disservice to over-regulate these low-hazard devices. Attached to this letter is the NIH response to your specific questions for comment.

Sincerely,

Robert Zoon, M.E., M.S.,
Radiation Safety Officer, NIH

Catherine Ribaudo, M.S.,
Chief, Materials Control and Analysis Branch, DRS

cc: Dr. Ira Levin, Chair, Radiation Safety Committee, NIH

Attachment:

NRC Specific questions for comment:

A. How should this change be applied in the case of devices used by a specific licensee at different locations? Would there be difficulties in determining which devices used by a given entity must be under the specific license, if the applicability of 10 CFR 31.5 were to be determined by the location of use, as suggested?

   This question is not applicable to NIH, as only a single specific license applies to a single (albeit broad) location of use.

B. How much time should be allowed for the specific licensees to transfer their currently held generally licensed GL devices to their SLs? Should devices currently held under the GL only be added to the SL only at the time of license renewal or amendment?

   At a facility such as the NIH, a significant amount of time would be needed to conduct a walk-through of all space, locate each device and provide radiation safety training to each user, re-educate all procurement agents and general staff on new receipt and storage requirements, and tailor the surveillance activity of the radiation safety program to include the addition of all formerly generally licensed devices. Possibly the specific license would require an amendment of possession amounts, emergency plan for responding to a release, and/or financial assurance for decommissioning. Only then would the actual transfer of licensing be able to be accomplished. It is unknown how long to estimate this workload will require, although an absolute minimum of twelve months is expected.

C. Should the details of the voluntary transfer process in 10 CFR 31.5(c)(8)(iii) become mandatory and be maintained in the regulation to assist the process?

   The NIH advocates that 10 CFR 31.5(c)(8) remain as a voluntary option for specific licensees. If, however, the NRC decides to apply the draft prohibition of a specific licensee to possess any source under a general license, then it is assumed that 10 CFR 31.5 would no longer be applicable at all, for licensees such as the NIH. In the event the NRC decides to go with a tiered system for application of the requirement to transfer all generally licensed devices to a specific license, (i.e., less than or greater than 1/10 Category 3 sources) then 10 CFR 31.5(c)(8)(iii) may remain in the regulations without undue hardship to NIH.

D. Would there be a significant impact from the applicability of reciprocity requirements in 10 CFR 150.20 for portable gauges currently licensed under 10 CFR 31.5 and equivalent Agreement State regulations that are used in more than one jurisdiction? How would this proposal affect servicers of devices currently operating under the reciprocity provision of 10 CFR 31.6 and equivalent provisions of Agreement States?

   This question is not applicable to NIH as no portable gauges are possessed within the grounds or leased space locations.

E. 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, e.g. by removing the exemptions in 10 CFR 31.5(c)(10) for those holding an SL?

Unequivocally this approach is preferable. Furthermore, the NIH contends that the licensee should be able to state which terms and conditions of its specific license shall be applicable to devices regulated by 10 CFR 31.5, and may elect to retain the general license possession entirely.

F. How much impact would there be to 10 CFR 32.51 licensees and Agreement State equivalent licensees to ensure that they are transferring these devices to entities without an SL?

The vendors of generally licensed devices (i.e. 10 CFR 32.51 licensees) will be required to contact each recipient of its product(s) and verify whether a specific license is in place which covers that proposed location of receipt/use. The dialogue must take place at the time the product is ordered, so that – if a specific license is determined to prevail – proper documentation for assuring compliance with appropriate possession limits and a correct shipping location will be arranged before the delivery occurs. There is much uncertainty and a lack of confidence that the vendor will be able to ascertain this information from a dialogue with an end user who may not even be aware that a radiation safety program exists which covers the product. Still, compliance with a proposal to require the transfer all generally licensed devices to a specific license for entities where a specific license already exists will best be achieved by requiring the vendor to initiate the process, and not assume that the specific licensee has the means to know when a generally licensed device is received at its site. Furthermore, the NRC will also need to consider the many small businesses that specialize in refurbishment of scientific equipment, some of which may be generally-licensed devices, operating outside the bounds of 10 CFR 32.51 and their supply (transfer) of these products to end users.

G. Should the sealed source and device registration certificates authorizing devices for use under 10 CFR 31.5 and equivalent Agreement State regulations be required to address transfers to both general and specific licensees?

The NIH feels that the only appropriate point of compliance will be on the 10 CFR 32.51 licensees and not the specific licensees to whom the transfer is made. Separately addressing transfers of 10 CFR 31.5 products to general and specific licensees will result in two separate sets of regulation for the same product; one with only 31.5 requirements in place, and the other with the full set of commitments to Parts 19, 20, 21 and any specific license conditions. The sealed source and device registration certificates should only need to address the transfer of the device to specific licensees if the device contains greater than 1/10 of Category 3 quantities.

Rulemaking Comments

From: Ribaudo, Cathy (NIH/OD/ORS) [E] [ribaudoc@ors.od.nih.gov]
Sent: Thursday, October 15, 2009 4:54 PM
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Cc: Ribaudo, Cathy (NIH/OD/ORS) [E]
Subject: Docket ID NRC-2008-0272
Attachments: 20091015125216642.pdf

Comments on proposed rulemaking to 10 CFR Part 31: "Limiting the Quantity of Byproduct Material in a Generally Licensed Device"

Thank you,
Cathy

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