(7)

Comments on Advanced Notice of Proposed Rulemaking
Broad Scope Licensing for Byproduct Material

Comments on General Considerations

1. Should of the responsibilities of licensee management for the radiation safety program be specified in part 33?

It may be acceptable to spell out licensee management responsibilities in part 33; however, when a license application is submitted, the individual who signs said application is basically committing the licensee to following all NRC regulations, commitments made in the application, and any license conditions. The individual signing the application should have sufficient authority to make such commitments for the licensee. Reiterating licensee management's responsibility in part 33 may be unnecessarily redundant. If licensee management responsibilities are incorporated into part 33, they should be very general.

2. Should the NRC incorporate requirements for the duties and responsibilities of the RSO and the RSC?

Given the diversity of the types of broad scope licensees, any RSO duties and responsibilities incorporated into part 33 should be very general. Specifying minimum training and experience criteria for the RSO may be difficult, particularly if the different types of broad scope licenses (e.g., Type A, B, or C) are dissolved. Obviously, the RSO for a Type A license must have considerably more training and experience than the RSO for a Type C license. If the various types of broad scope licenses are eliminated, the "minimum" training requirements for the RSO of a broad scope license might be overkill for one license and inadequate for another.

3. Should specific minimum training and experience criteria for authorized users be incorporated into part 33?

Many broad scope licenses include a considerable diversity regarding radionuclide use. Some authorized users may be handling microcurie to millicurie quantities of radioactive materials. Others may be using self-contained irradiators. Training and experience criteria should be developed by the licensee and included as a part of the license application with appropriate justification. Licensees should also have the flexibility to adjust the training and experience requirements under certain circumstances provided that such adjustments are reviewed and approved by the RSC.

4. Should the NRC incorporate specific requirements for inventory and accountability of byproduct material in use, or modify its existing guidance?

Inventory and accountability of byproduct material should be a license specific requirement. Licensees should be required to describe their methods of inventory and accountability of

byproduct material during the licensing process. Codifying this requirement into the regulations would not appear to be advantageous over dealing with inventory and accountability during the licensing process.

5. Should the NRC consider the risks associated with internal exposure pathways separate from those associated with external radiation?

No.

6. Are there other specific aspects of the Draft Regulatory Guide DG-0005 that should be codified in part 33?

Codifying regulatory guide aspects into regulations should be done with considerable caution. Prescriptive regulations are not a substitute for "good" licensing. The last major revision of 10 CFR 35 involved the incorporation of guidance from the medical licensing guide (Regulatory Guide 10.8) into the regulations. This caused a considerable amount of confusion, particularly for broad medical licensees. The licensee should work with the NRC during the licensing process to assure that the radiation safety program meets the regulations and can be effectively administered by the licensee. Prescriptive regulations may reduce the flexibility which a broad scope license is intended to provide.

7. Should broad scope licensees be allowed to make changes in their radiation safety program similar to those authorized for production and utilization facilities in sec. 50.59?

This should be allowed for large broad scope licensees (e.g., Type A) that have a radiation safety committee and/or a full time radiation safety officer. Smaller broad scope licensees that do not utilize a radiation safety committee and/or a full time radiation safety officer may not have the expertise to fully evaluate the impact of such changes.

8. Should the different types of broad scope licenses currently in part 33 (Types A, B, & C) be deleted and replaced with a single type?

There are some advantages in retaining the various types of broad scope licenses. As mentioned in previous comments, various types of requirements (e.g., RSO qualifications, RSO duties and responsibilities, program changes, etc.) can be tied to the type of license. It might be possible to reduce the number of broad license types (e.g., "limited" broad scope and "extended" broad scope).

9. Should a category for "Master Materials Licenses" be incorporated into part 33 with the respective necessary requirements?

No comment.

10. Should requirements for "Multi-Site Facilities" be codified in part 33 or should this be defined only in 10 CFR 30?

No comment.

11. What balance should be maintained between a performance-based and a prescriptive approach to regulating broad scope licensees?

Regulations should be predominately performance-based for large, broad scope licensees. These types of licensees typically require professionally trained health physicists, adequate technical support staff, and some type of committee oversight to administer the radiation safety program. Prescriptive based regulations should be minimized for such licensees that include these key components. Furthermore, extensive prescriptive regulations may result in increased numbers of requests for exemptions to said regulations and may defeat the purpose of the broad scope license.

Comments on Proposed Part 33 Language

Sec. 33.2 Definitions - Add the following definition:

Radiation worker means an individual receiving, possessing, or using byproduct material under the supervision of an authorized user.

Sec. 33.11 Types of specific licenses of broad scope - Retain Type A, Type B, and Type C licenses with the current descriptions of each.

Sec. 33.12 Applications for license, amendment, or renewal - Items (b) and (c) under this section imply that a broad scope license will only be issued if the applicant has had a previous license of limited scope and based upon previous regulatory compliance. Although unlikely, it is possible that an applicant would apply for a broad scope license initially (i.e., would not have a limited scope license before the application). Items (b) and (c) should be deleted.

If the different types of licenses is retained (e.g., Type A, B, or C) as suggested above, item (e) would only apply to a Type A license. Item (e) should be changed accordingly.

Item (h)(10) implies that anyone working in or frequenting areas where byproduct material is used or stored would have to be trained. This is in direct conflict with the requirements of 10 CFR 19.12. The word *personnel* should be changed to *authorized user or radiation worker* in item (h)(10).

In item (h)(11), it appears that the words *users* and *uses* are reversed in the context of the sentence. It should be revised to read, *"(11) Conducting radiation safety evaluations of proposed authorized uses of byproduct material, including training and experience of proposed users;"*

Item (h)(12) is redundant with the first part of item (h)(11). The review of facilities and equipment should be incorporated into item (h)(11) or item (h)(12) should be revised to read, *"(12) Evaluating the facilities and equipment where byproduct material is to be utilized and stored;"*

Sec. 33.17 Requirements of specific licenses of broad scope - Item (b)(2) restricts the use of byproduct material in humans (medical use as defined in 10 CFR 35) to individuals who meet the training requirements of 10 CFR 35.900 through 10 CFR 35.981. There is no reason why physicians who do not necessarily meet the requirements of those sections cannot perform human use research studies with byproduct material. For example, human tracer studies utilizing microcurie quantities of a ^{14}C labeled compound could be done by a physician with specific training in such activities which may not be as restrictive as that referenced in 10 CFR 35. The following sentence should be added to (b)(2) of this section: *"Licensees who authorize the use of small quantities of byproduct material in humans for research purposes must submit training and experience criteria in the license application for physicians who wish to conduct such research if said physicians do not meet the training criteria in 10 CFR 35.900 through 10 CFR 35.981."*

Sec. 33.22 Radiation Safety Committee - The NRC typically requires licensees to list the names of their Radiation Safety Committee members in their license application which is incorporated into the license by reference. There are some circumstances where a committee member might not be able to attend a scheduled meeting (e.g., sickness, sabbatical leave, etc.). This may affect the ability of the committee to hold a scheduled meeting due to quorum or other attendance requirements. Rescheduling a meeting under such circumstances is unnecessarily cumbersome. To alleviate this problem, an additional item (e.g., item (a)(5)) should be added to this section as follows: *"(5) With the exception of the RSO or the committee chairman, any committee member may temporarily appoint a replacement to attend a scheduled committee meeting with the approval of the committee chairman. Such replacements shall be specifically noted in the committee meeting minutes.*

Sec. 33.25 Supervision - As noted in a previous comment, the term "radiation worker" was defined as an individual working under the supervision of an "authorized user". In this section, references to *"individuals"* or *"supervised individuals"* should be replaced with the term *"radiation worker"*.

Sec. 33.59 Radiation safety program changes - Item (b)(1) is too prescriptive with respect to the documentation of changes to the radiation safety program. For Type A licenses (assuming the different types are retained), any radiation safety program changes should be reviewed and approved by the Radiation Safety Committee (RSC). Documentation of such changes should be documented in the RSC meeting minutes. It is recommended item (b) of this section be changed as follows:

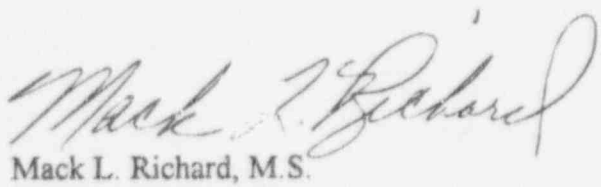
"(b) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section until the license has been renewed or terminated. Such records shall include:

> *(1) For broad scope licensees with a Radiation Safety Committee (RSC), the changes shall be documented in the RSC meeting minutes, signed by the RSC chairman. Such documentation shall be of sufficient detail to establish the nature of the change and the justification for same;*
>
> *(2) For broad scope licensees that are not required to establish a RSC, the changes shall be described in a written document, signed by the RSO and a management representative. The information shall be in sufficient detail to establish the nature of the change and the justification for same.*

Item (b)(2) of this section requires that a report be submitted within 30 days of making changes under this section. It does not specified to whom such a report is to be submitted. It appears that the report is supposed to be submitted to the NRC. If that is the case, this requirement is not consistent with the "ministerial" changes authorized under 10 CFR 35.31 (i.e., medical licensees are not required to report ministerial changes). Broad scope licensees are probably more qualified to make these changes; therefore, requiring reporting of such changes (at least those that are ministerial in nature) seems too restrictive. Perhaps the proposed rule needs to be expanded to include the types of changes for which a report to the NRC is required (or not required).

General Comments

It appears that one of the primary reasons for this proposed rule change is related to the recent incidents involving ingestion of byproduct material. Based upon a review of these incidents, there was some speculation that malicious intent was involved. It should be pointed out that no amount of regulation can eliminate malicious acts. Rather than change the regulations, a better approach may be to place additional emphasis on certain aspects of broad scope licensee programs during the licensing process. Broad scope licenses are designed to provide flexibility and minimize the administrative burdens on both the licensee and the NRC for licensees who can demonstrate adequate administrative and technical control of their radiation safety programs. Any changes in the regulations should certainly be performance based rather than prescriptive to prevent undermining the intent of the broad scope license.



Mack L. Richard, M.S.
Radiation Safety Officer
Indiana University Medical Center