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ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

DOCKETED
USNRC

'97 APR -7 P3:15

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

April 3, 1997

DOCKET NUMBER
PROPOSED RULE PR 33
(61FR58346)

John C. Hoyle, Secretary
Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attn: Docketing and Service Branch

RE: Advance Notice of Proposed Rulemaking, Specific Domestic Licenses of Broad Scope for Byproduct Material; 61 FR 58346, November 14, 1996.

Dear Secretary Hoyle:

The American College of Nuclear Physicians and the Society of Nuclear Medicine would like to provide the following comments on the above referenced document for your consideration.[1] We would caveat these comments however, by pointing out that any meaningful reform of the broad scope licensing process should take place only after the Commission implements any regulatory reform initiatives for the medical program. This would allow those changes to be reflected in the approach taken towards broad scope licensees. We believe a scaling back of the medical program under 10 CFR 35 could also result in similar changes to medical conduct under 10 CFR 33.

General Comments:

The ACNP/SNM generally opposes the concept of codifying the nearly endless number of Specific Domestic Licenses of Broad Scope (SLBS) license conditions. Such a move would most certainly result in a highly prescriptive chapter of regulation. Instead, ACNP/SNM supports performance based regulations, but only when they set a standard, and allow the licensee to fulfill the standard through multiple mechanisms as applicable to the scope and nature of the licensee's program. ACNP/SNM want to stress that any revisions to part 33 must be performance based. Unfortunately, in the past the NRC has labeled regulations as performance based, when in reality they were quite prescriptive (e.g., Quality Management Program).

[1] ACNP and SNM represent over 14,000 physicians, technologists, pharmacists, and scientists who provide quality nuclear medicine diagnostic and therapeutic services to patients and perform research and development in this specialty. Each year over 10 million nuclear medicine procedures are performed in the United States.

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Some of the topics the NRC is concerned with are: the roles of the Radiation Safety Officer (RSO), Radiation Safety Committee (RSC), Authorized User (AU), and the types, quantities, uses, inventory, security, control, storage, and disposal of byproduct material. While some of these topics clearly need amplification in the regulations, many do not. The subjects of inventory, security, and control are all closely interrelated, and subject to independent review by the NRC. Any action taken on these subjects should apply across the board to all licensees. Storage and disposal regulations suffice in their current form and require no additional amplification by the NRC.

Types, quantities, and uses of byproduct material are closely related to the subjects of RSC and AU. The credentials of the members of the RSC, and the qualifications of the AU should be commensurate with the proposed types, quantities, and uses of material for that specific license. Some SLBS will be research (bench and human subject) and medical, some SLBS will be non-human subject research only. Obviously the qualifications of AU's (and those of the members of the RSC) will have to be dependent on the proposed uses. However, there are some basic common qualifications that all AU's should possess. Again, depending on the extent of the types, quantities, and uses of byproduct material at a SLBS, the qualifications, and duties of the RSO will vary.

AU: AUs in a SLBS will typically be professionals, either researchers or scientists, using byproduct material in specific applied fashions. The RSC should be able to determine whether or not its own AU is qualified, because the RSC is intimately familiar with the uses of byproduct material at its facility. In a research setting, most researchers (AUs) use only a few isotopes, and use them in very specific amounts and methods. In these cases the RSC could certify each AU for as many isotopes and techniques as the AU can present credentials for.

AU as supervisor: Provided that the AU only supervises workers operating with in the scope of authorization for that AU, a simple performance based rule would suffice: "An AU may supervise the work of others within the scope of the AU's authorization from the RSC. The licensee (RSC and RSO) shall determine the scope of authorization granted to the AU in the licensee's license."

Requirements for AU: A successful candidate for AU will at a minimum:

- demonstrate proficiency with 10 CFR part 20;
- understand the basics of radiobiology;
- have knowledge of laboratory techniques associated with safe handling of radioactive material;
- know the basics of dosimetry;
- be proficient in the basics of radiation safety (time, distance, and shielding);
- have knowledge of basic radiation physics;
- be proficient in the use of radiation detection and survey instruments;

Traditionally SLBS are designed to have maximum flexibility, as such a setting demands it. Prescriptive regulations for SLBS would have serious detrimental effects. It would be far more productive to have basic performance guidance for these licenses. For example, part 33 could state that the licensee (and its management) is responsible for:

- radiation safety audits;
- inventory;
- security and control;

(However, all three of these issues are covered in part 20 as they apply specifically to SLBS.)

Additionally, the licensee should be able to make changes in its Radiation Safety program that allow it to function at the same or at an improved (improved includes economic improvements) level provided that the RSO and RSC approve. The NRC should be notified of such changes in a timely manner (e.g. on an annual basis). Such changes would include changing members of the RSC, dosimetry providers, calibration vendors, etc. ACNP/SNM supports a provision similar to § 50.59 being added to part 33.

ACNP/SNM is concerned that the NRC in this ANPR is relying on the two internal contamination problems which occurred last year to imply all SLBS have a similar problem. In both of these cases, the internal contamination appeared to have been the deliberate work of a knowledgeable individual, e.g. criminal action. The ACNP/SNM agrees with the NRC when it stated: "Generally, the current program governing the regulation of specific licenses of broad scope for byproduct material has worked well to provide for public health and safety from these licensed activities. For the three year period from 1993-96 there were only 38 events involving these licenses that resulted in some enforcement action." On the issue of security and control (the underlying issue in the two internal contamination cases) the NRC is working to resolve the incomplete and conflicting guidance currently existing. ACNP/SNM believes that this is the appropriate mechanism for solving this problem, and that it should not be handled separately in the revision of part 33.

Draft NUREG 1516, Management of Radioactive Material Safety Programs at Medical Facilities (RSO NUREG) is referenced in this ANPR numerous times. ACNP/SNM believe the RSO NUREG, although a draft, is far from being a suitable document for management. It contains factual errors, is excessive in length (repetitive), is highly prescriptive, and tends to reflect the ideas of its primary author (i.e., this is not a consensus document). Additionally, it offers little advice on today's topics of interest which include inventory, security, and control.

Specific Questions in ANPR:

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

Answer 1: No, by signing the license and providing the financial assurance documents management is aware of the responsibility. Generally management does not possess radiation safety expertise, and to make a list for them would be a waste of resources. It would be far more productive to ensure that management hires a competent RSO, appoints a qualified RSC, and mandates that they ensure that the license and regulations are not violated.

Question 2: *Should the NRC incorporate requirements for the duties and responsibilities of the RSO and the RSC?*

Answer 2: No, nothing more than a simple statement for the RSO like: "to ensure that NRC regulations and license conditions are followed." For the RSC: "to review the workers and work to ensure that the regulations and license conditions are followed."

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

Answer 3: Yes, but the training must be so generic as to allow a wide variety of AU's to be appointed. For instance, there is a wide difference in education, training, and experience between a MD/Ph.D. doing biomedical research on human subjects, and a chemist using tritiated compounds to determine chemical stability. It is the areas of commonality that must be described in the minimum training and experience criteria. (See our previous suggestions.)

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

Answer 4: No, do not incorporate specific requirements, simply modify the existing guidance. SLBS are quite varied, any specific requirements will merely limit flexibility. SLBS need flexibility to solve complex problems created by the extreme variety and amounts of byproduct material used by their AU. Additionally, the requirements for inventory and accountability apply to all NRC licenses, and the NRC is revisiting this issue separately. ACNP/SNM support this review, part 33 should not be the site of an attempted solution.

Question 5: *Should the NRC consider the risks associated with internal exposure pathways (e.g., ingestion, inhalation, absorption) separate from those associated with external radiation?*

Answer 5: No, ACNP/SNM feel that absorbed dose is absorbed dose. There is no need to place any quality factors on dose simply based on its route of administration.

Question 6: *Are there other specific aspects of the draft regulatory guide DG-0005 that should be codified in part 33?*

Answer 6: No.

Question 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 §50.59?*

Answer 7: Yes, ACNP/SNM supports such a move. See our previous detailed comments.

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

Answer 8: No, continue to maintain A, B, and C SLBS. Obviously there is an advantage for the 60 some B and C licensees, otherwise they would have converted to specific licenses of limited scope.

Question 9: *Should a category for Master Materials Licenses be incorporated into part 33 with the respective necessary requirements?*

Answer 9: Yes, this would facilitate corporate entities with multiple locations to obtain a master materials license. Corporate entities with multiple locations would apply for a multi-site license (vide infra). Master materials licenses are for entities such as the Uniformed Services or Federal Agencies. See discussion on this topic in the ACMUI minutes from the November 1996 meeting.

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

Answer 10: Yes, the minimum requirements should be codified in a manner analogous to the requirements for SLBS.

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

Answer 11: The balance between performance and prescriptive based approaches to regulating SLBS should be weighted heavily in favor of performance based standards.

Comments on the proposed rule language (p. 58350):

§33.2 Definitions: To AU add: "the authorization to use and the type of use are specific to the license." To management add: "management is responsible for compliance with the rules, regulations, and license conditions."

§33.5 Records: No Comment

§33.11 Type of specific licenses of broad scope: No Comment

§33.12 Applications for license, amendment, or renewal:
(A) No Comment
(B) NRC should have a clause allowing for application without this requirement - a new entity with the right professionals could do this...
(C) same comment as B above
(D) No Comment
(E) No Comment
(F) No Comment
(G) ACNP and SNM disagree with NRC; management would lack the expertise to perform a review. This would have to be contracted out, or done in-house using the radiation safety personnel.

§33.17 Requirements of specific licenses of broad scope: No Comment

§33.21 Radiation Safety Officer:
(A) No Comment
(B) Delete the words "in physical or biological science or engineering." This is too specific. Each RSO applying for such a position will need to have had specific training and experience, the actual degree title may be immaterial with respect to qualifications.

§33.22 Radiation Safety Committee: No Comment

§33.23 Statements of authority and responsibility:
(A)(1) No Comment
(A)(2) Replace "in which health and safety may be compromised to an unacceptable level" with "in which health and safety are compromised by exposure levels in violation of the regulatory limits." The remainder of §33.23 will suffice.

§33.25 Supervision: No Comment

§33.59 Radiation safety program changes: No Comment

The ACNP and SNM would like to work closely with the Commission as it contemplates making large scale changes such as these, but again must reiterate that the Commission would benefit from developing changes to other areas first. The reform of 10 CFR 35 may produce useful regulatory models that could then be applied to 10 CFR 33. For further information or questions, feel free to contact Mr. David Nichols at (703) 708-9773.

Sincerely,

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