DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(22)

FEB 28 1997

Secretary
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Docketing and Service Branch

DOCKET NUMBER
PROPOSED RULE PR 33
(61FR58346)

Dear Sir or Madam:

The Radiation Safety Branch (RSB) of the National Institutes of Health (NIH) has reviewed the Proposed Rulemaking for "10 CFR 33: Specific Domestic Licenses of Broad Scope for Byproduct Material" dated November 6, 1996, and wishes to offer the following comments.

The RSB is concerned that the NRC is taking hasty action to initiate changes to regulations which would impact all licensees when the problems identified in the "Background" discussion as precursors to the proposed rulemaking were the result of failures at only a small number of facilities. In fact, the NRC acknowledges this by stating "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" (Federal Register Vol.61, No.221, p. 58347). The NRC has provided little or no evidence of real damage or harm to persons or property to justify these proposed changes. Rather than providing specific examples of events that directly threaten the public as a result of weak controls by the RSO or RSC, the NRC vaguely indicates that "these types of events, which could ***potentially*** [italics added] result in doses to the public from radioactive material in unrestricted areas, are ***often*** [italics added] the result of weak controls by either the RSO or RSC"(Federal Register Vol. 61, No.221, p. 58347). In fact, later in the "Background" discussion, the NRC only provides evidence of one event in which weak management oversight was linked to an internal contamination incident. And yet, even in this case, the weak management oversight was characterized as a "contributing factor" and not the cause of the incident.

It appears that the NRC is attempting to control individual human behavior which will always remain beyond the control of any governing agency. What the NRC is proposing is simply a paperwork exercise, which will not significantly improve the fine performance that the majority of broad scope licensees exhibit. The level of management oversight necessary to provide for the safe use of byproduct material is entirely dependent upon the people doing the managing and those being managed. It is not appropriate for regulatory agencies to stipulate how licensees must manage their radiation safety programs. Rather, the role of regulatory agencies is to review the results achieved by the regulated community and determine whether or not the results achieved are satisfactory. When the results are not satisfactory, the regulators are required to take action to bring the licensee into compliance. Recent NRC action to extend from 5 to 10 years the period that licenses are effective would appear to support that, contrary to the implications in the proposed rulemaking, broad scope licensees exhibit excellent compliance with and understanding of existing regulations.

DS10

In addition, it is our opinion that the NRC should do more to provide licensees with official positions or statements regarding licensing and operational expectations. The NRC frequently relies on draft guidance to mold their regulatory program, as evidenced by the fact that Draft NUREG 1516 (published in **January 1995**) and Draft Regulatory Guide DG-0005 (published in **October 1994**) are referenced in this advance notice of proposed rulemaking as examples of information that licensees should consider in preparing these comments. Also, it is common for the NRC to ask licensees to use draft regulatory guidance (such as DG-0005) in preparing licenses for submittal. This places the potential licensee in the position of using dated materials which do not have any final official status. Licensees would be best served if the NRC would finalize draft guidance documents in a timely manner and publish them as official positions.

The NIH Radiation Safety Program has complete management support from NIH officials, including involvement in the day to day operations. Therefore, we feel qualified to address the following questions presented by the NRC:

1. *Should the Responsibilities of Licensee Management for the Radiation Safety Program be Specified in Part 33?*

   We do not believe that additional regulations specifying the responsibilities of the licensee management are necessary. It would be more beneficial to issue regulatory guidance which combines the Draft Regulatory Guide NUREG 1516 with Draft Regulatory Guide DG-005. While these two documents address the needs of a medical licensee, the concepts could be developed and finalized to accommodate other types of broad scope licenses.

   Each licensee should be afforded the flexibility to design a radiation safety program that keeps health and safety in the forefront of operations while maintaining control over the program activities. The RSO and RSC should maintain the flexibility to operate within the management structure and mechanisms for control as they see fit, without the need to seek NRC approval. The final mechanism for evaluating the effectiveness of the guidance should be a compliant radiation safety program, not a checklist regulation where the licensee loses the flexibility of controlling its own radiation safety program.

2. *Should the NRC Incorporate Requirements for the Duties and Responsibilities of the RSO and the RSC?*

   The RSB agrees that there should be some guidance concerning the roles and responsibilities of the RSO and the RSC. However, this guidance should not be in the form of regulation as proposed in 10 CFR 33.23(b). The authority, duty, and responsibilities of these entities change throughout the course of a radiation safety program. Consequently, the licensee needs flexibility in a program in order to adjust to changes in the program over time.

In the proposed 10 CFR 33.21(b), the NRC is prescribing specific expectations for the training and experience of an RSO. Requiring the RSO to have a degree may place an additional, unnecessary burden on a licensee. An individual without a degree may be better qualified if he/she has extensive, relevant experience through employment at similar licensed facilities. For example, small companies may not have the funding to meet the additional salary demands from an individual with a degree, as opposed to an individual without a degree, but with extensive experience.

Moreover, there is a concern that NRC may eventually require the RSO to be a Certified Health Physicist and/or to possess a Ph.D. in related fields. The RSB urges the NRC to retain the specifications of an RSO as outlined in the current 10 CFR 33.13(c)(2) and 10 CFR 33.14(b)(1).

3. *Should Specific Minimum Training and Experience Criteria for Authorized Users be Incorporated Into Part 33?*

Specific minimum training and experience criteria for authorized users should definitely NOT be incorporated into Part 33. The NRC needs to recognize that each license is unique and that personnel qualifications and experience vary among institutions. Placing specific criteria into the regulations forces a standard that may not be feasible or appropriate for all licensees. For example, an authorized user at the NIH may be a laboratory technician, laboratory chief, or even a Scientific Director. Some of our most effective authorized users do not meet the expectations of the current 10 CFR 33.15(b)(1), but instead have only received training as outlined in 10 CFR 33.15(b)(2).

The criteria for authorized users should only be addressed in guidance documents. At a minimum, the guidance for authorized users should stipulate the training and experience as detailed in the current 10 CFR 33.15(b)(2). The RSO and the RSC should retain the authority to judge the credentials/criteria for proposed authorized users based on the needs of the program. Otherwise, the licensee may lose some of the best authorized users and strong advocates of the radiation safety program due to a simple regulatory clause that automatically excludes them from consideration.

4. *Should the NRC Incorporate Specific Requirements for Inventory and Accountability of Byproduct Material in Use or Modify Its Existing Guidance?*

The current 10 CFR 33.13 (c) requires that "the applicant has established administrative controls and provisions relating to . . . material control . . . ." The same requirement is outlined for Type B and C licensees. This may be interpreted as requiring licensees to have an inventory and accountability program in place to control the byproduct material received. Existing and draft regulatory guidance documents address material inventory and accountability (see DG-0005, section 10.3, and Regulatory Guide 8.23, section 1.16.2). The NRC should expand upon the existing requirements through guidance

documents which provide more detailed information as to examples of inventory and accountability programs the NRC would deem acceptable. Using guidance documents to present this information affords licensees the flexibility to tailor their individual programs to meet the intent of the regulations. During license application reviews and on-site inspections, the NRC can determine whether or not the proposed or existing inventory and accountability program is adequate.

5. *Should the NRC Consider the Risks Associated With Internal Exposure Pathways (e.g., Ingestion, Inhalation, Absorption) Separate From Those Associated With External Radiation?*

The NRC made great strides in 1994 with the revised 10 CFR 20 by incorporating the concept of the "Total Effective Dose Equivalent" (TEDE) which is consistent with the philosophy of the ICRP and NCRP. The NRC should not reverse itself. The NRC already has methods to adequately manage radiation exposures, as detailed in each licensee's ALARA program.

The RSB is concerned that if the NRC is proposing to consider risks from internal and external exposures separately, then there is an implication that the risk from internal is worse than the risk from external exposure or vice versa. Additional perceived risks lead to additional precautions and regulations. However, additional precautions and regulations would not have prevented either of the two P-32 incidents referred to by the NRC. Neither was associated with routine use of radioactive materials or caused by faulty procedures within the lab environment. Rather they resulted from deliberate, malicious misuse of radioactive material.

The Federal Register states "Although the Commission recognizes that there may be greater uncertainties with the estimation of internal exposure, the revision of 10 CFR 20 assumes that internal and external exposure are equivalent in terms of risk." While there may be uncertainty in calculating the dose estimates from internal uptakes, this does not mean that the associated risks from internal/external doses should be treated separately. There is no perfect situation which patterns Reference Man. However, with competent bioassay programs in place and the ability to adjust dosimetry models to fit specific cases, accurate doses can be obtained with valid statistical precision.

6. *Are There Other Specific Aspects of the Draft Regulatory Guide DG-0005 That Should be Codified in Part 33?*

The NRC states that "There are currently no specific requirements in 10 CFR 33 addressing these topics . . . . " The "topics" referred to by the NRC include "administrative procedures, material inventory and accountability, audits and appraisals, safety evaluations and exposure control." The NRC has adequately addressed these topics in the current 10 CFR 33.13(c), 33.13(c)(3)(i-iii), 33.14(b), 33.14(b)(2)(i-iii), and in 33.15(c), and they are specific enough. The NRC can provide more specific

"guidance" in the Draft Regulatory Guide DG-0005, but should not place any additional specifications in the regulations. No other aspects of the Draft Regulatory Guide DG-0005 should be codified.

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 10 CFR 50.59?*

The NRC should permit the licensees to make changes in their radiation safety programs without the interference of the NRC, as long as safety is not compromised in the process. Allowing changes to the radiation safety program to be approved by the RSC rather than the NRC provides flexibility for licensees and avoids long delays before implementation of programmatic improvements. For example, in January 1996, the NIH submitted a license amendment to the NRC pertaining to security policy changes. To date, the NRC has not acted on this amendment. Consequently, the NIH has been forced to administer an antiquated policy which has cost the NIH significantly in terms of person-hours and supplies and equipment which may become obsolete if the NRC approves the amendment.

In the proposed 10 CFR 33.59(a), the NRC states that "the holder of a specific license of broad scope for byproduct material may make changes in the facility or procedures as described in the license application, after review and approval by the Radiation Safety Committee, without prior Commission approval unless the proposed change involves a change in a specific license condition or is less restrictive than the regulations." The NRC needs to clarify "unless the proposed change involves a change in a specific license condition." For example, the NIH was forced to submit a license amendment to computerize our radioactive material ordering system. The NRC insisted upon the license amendment because they interpreted the change from paper to computer to be a change in a specific license condition. The NRC may want to provide examples of changes they deem acceptable under the proposed regulation.

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?*

The NRC should not condense the three types of broad licenses into a single type. It appears that the NRC is attempting to pigeonhole varying degrees of regulatory oversight into one category, and this is not practical for the NRC or the licensee. Currently, Type B and C licensees do not require an RSC because these programs involve possession of limited quantities of radioactive materials and may be indicative of small operations. If the NRC were to combine all types of licenses into one, then everyone would be expected to have an RSC as stipulated in the proposed 10 CFR 33.22. This may present an unreasonable and unnecessary financial and managerial burden on small programs.

Based on the proposed Part 33 regulations, the specific expectations outlined in 10 CFR 33.12 "Applications for license amendments, or renewal," 10 CFR 33.17 "Requirements of specific licenses of broad scope," 10 CFR 33.21 "Radiation Safety Officer," and 10 CFR 33.22 "Radiation Safety Committee," are too prescriptive for some of the smaller Type B and C licensees. For example, if the NRC were to eliminate the three types of licensees, there would be an increased cost to the Type C licensees to ensure compliance with the single type license. The Type C licensee would have to institute an RSC, hire or appoint an RSO, and modify the program to conform with the expectations outlined in the proposed 10 CFR 33. This is over-regulation based on no apparent safety issue.

11. *What Balance Should Be Maintained Between a Performance-Based and a Prescriptive Approach to Regulating Broad Scope Licensees?*

There needs to be more flexibility within the regulations to permit licensees to tailor each program to meet the specific needs of the facility. The NRC can suggest plans to assist in implementing a sound and safe program, but they must recognize that one answer, i.e., prescriptive regulations cannot be applied to all situations. The NRC must use the licensing and inspection programs to evaluate the adequacy of the licensees' programs and the risk associated with the type of materials in use.

The RSB would like to see the NRC take a performance-based approach to assess compliance with the regulations. However, this will not have an impact on the licensees unless the inspection/enforcement programs are similarly performance-based. Currently, the inspection/enforcement programs are not focused on the true safety aspect of radiation protection. Instead, the inspections in many cases focus on a prescriptive approach such as a signature on a piece of paper.

The RSB is encouraged by the four key elements identified by the NRC staff and wishes to comment on each:

(1) *There are measurable or calculable parameters to monitor licensee performance*

The RSB is concerned with the concept of measurable or calculable parameters. During recent inspections by the NRC, it became clear that the NRC is looking for 100% compliance. This may not be achievable in all situations, particularly where human behavior is involved. The NRC should establish parameters which permit a certain percentage of compliance taking into consideration the size of a facility. Certainly a licensee that has 100 labs, 15 of which have failed to comply with contamination survey requirements is more of a problem than a licensee that has 3500 labs, 15 of which have failed to comply. The NRC recognized this when revising its enforcement policy on June 30, 1995. In Federal Register Vol. 60, No. 126, p. 34385, the Commission states that "there are other violations of minor safety or environmental concern which are below the level of significance

of Severity Level IV violations. These minor violations are not the subject of formal enforcement action."

(2) *objective criteria are established to assess performance*

These objective criteria should be made available to the licensees so that they know what they are being judged upon. Based on many years of inspection experience, it appears that the NRC inspectors have a specific agenda or focus for each inspection, but that agenda or focus changes each time. The NRC's current top priority appears to be the security of radioactive materials, whereas a few years ago it was "hot" particles and skin contamination. Before that, it was radioactive releases to the environment. Thus, licensees continually must guess as to what the NRC's latest focus will be and what new interpretations of existing regulations will be used to assess compliance.

(3) *licensee has the flexibility to determine how to meet established performance criteria*

It is important to recognize that each licensed facility has different operating parameters. By establishing guidelines and allowing the licensees to develop specific procedures to guarantee compliance, the NRC provides the licensee with much needed flexibility to operate a successful radiation safety program. Note that the licensee should be permitted to change the written policies and procedures used to maintain compliance without NRC involvement or second-guessing.

(4) *failure to meet a performance criterion will not have an intolerable outcome*

In the event that the licensee has written policies and procedures in effect and an active enforcement program, the NRC must recognize that errors and violations occur due to individual human behavior. Consequently, self-identified violations are a sign of a successful program with reviews and audits that work! Therefore, the licensee should not be further penalized for self-identified violations where corrective actions have been taken and proven successful.

We hope that these comments are useful in your review of the proposed revision to 10 CFR 33. Please feel free to contact me at (301) 496-2254 if you have any questions regarding these comments.

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