

February 10, 1997

DOCKET NUMBER
PROPOSED RULE **PR 33**
(61FR58346)

Amersham Holdings, Inc.
2636 S. Clearbrook Drive
Arlington Heights, IL 60005
tel (847) 593-6300

Secretary
Nuclear Regulatory Commission
Washington, DC 20555-0001

Amersham
The Health Science Group

Attn: Docketing and Service Branch

RE: 10 CFR Part 33 Advance Notice of Proposed Rulemaking. Federal Register, Vol. 61, No. 221, Thursday, November 14, 1996.

These comments are submitted on behalf of Amersham Holdings, Inc. Amersham is a manufacturer and world-wide distributor of radiopharmaceuticals, life science research radiochemicals, and radioactive sealed sources used in medicine and quality and safety assurance. Amersham facilities as well as many of our customers will be affected by this proposed rule. We appreciate the opportunity to submit the following comments in response to the Advance Notice of Proposed Rulemaking published in the Federal Register on November 14, 1996.

General Comments

It is important to continually review and update regulations in order to ensure that standards are clearly communicated and are consistent with most recent recommendations of nationally and internationally recognized organizations. However, care must be taken to avoid wide sweeping changes solely resulting from reactions to relatively isolated circumstances, especially when those changes may present a significant burden to licensees who are already managing an effective program.

In general, we agree with NRC's proposal to amend 10 CFR Part 33 to clarify the regulations governing specific licenses of broad scope for byproduct material. Most broad scope licenses are very diverse in their use and management of byproduct material which is specific to the individual needs of the licensee. Therefore, it would be impracticable to present prescriptive requirements that would be applicable to all broad scope licensees. This diversity of individual licensees, combined with the fact that most broad scope licenses are issued to organizations who have the expertise and have already demonstrated the capability to effectively manage their radiation safety programs, necessitate that these regulations be more performance based and less prescriptive wherever possible. Performance based standards would empower the licensee to continually develop improved methods of managing their radiation safety programs based on their own needs.

9702130086 970210
PDR PR
33 61FR58346 PDR

DS10

The specific requirements of each licensee should continue to be reviewed when the license application is submitted, ensuring that the commitments made in the application are commensurate with the proposed licensed activity.

The training and experience requirements for the Radiation Safety Officer, qualification of authorized users, and the specific responsibilities of the management staff should also be reviewed taking into account the scope of the individual operation for each licensee.

To facilitate timely review of applications and lessen the burden on NRC Licensing staff, prescriptive requirements that are already acceptable to NRC staff could be presented in NRC Regulatory Guides. It would then be up to the individual licensee to decide to incorporate those requirements or develop their own for NRC review.

Comments on specific sections of the proposed rule document follow:

II. General Considerations

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

The overall responsibility of any licensee is to maintain an effective radiation safety program. Considering the variability of licensed activities covered under a broad scope license, each institution should have the flexibility to describe the responsibilities and commitments for the management of their specific program. A sample statement of responsibilities, already deemed acceptable to NRC, may be included in a regulatory guide for use by licensees.

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

NRC should avoid specific, prescriptive requirements for the duties and responsibilities of the RSO and RSC. These requirements, as well as minimum requirements for training and experience, will be dependent on the scope of the licensed activity. All RSO and RSC requirements, including minimum training and experience, should be commensurate with the licensed activity and reviewed during the application/approval process.

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

Training and experience requirements for authorized users will vary depending on the scope of the licensed activity and the individual authorized user's role within the facility (certain authorized users may only be permitted to use limited amounts of byproduct material within an organization). Minimum requirements could be addressed in guidance documents but, ultimately, the specific requirements for these users are better determined by the RSO and 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, particularly sealed sources, should be a fundamental requirement for any licensed operation. Existing guidance may be modified to clarify acceptable methods for assuring accountability of byproduct material, but care should be taken to incorporate flexibility to permit licensees to develop methods that are most suitable to their needs.

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 risks associated with *both* internal and external radiation and application of a Total Effective Dose Equivalent limit as is specified in 10 CFR 20 is consistent with ICRP recommendations and the overall philosophy of maintaining exposures and risk as low as reasonably achievable. It is unnecessary to consider the risks from internal pathways separately, and could be counterproductive if licensees are compelled to devote more of their resources toward minimizing one type of exposure at the expense of another. NRC should ensure that a licensee's program is adequate for determining dose from internally deposited radionuclides, but the management of the dose and associated limits should be consistent with those already specified in 10 CFR Part 20.

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

Regulatory guides should contain information, policy statements and procedures that are acceptable to NRC which may be utilized by licensees in the development of their license application. Codifying parts of the regulatory guide could significantly reduce the flexibility of a broad scope licensee to develop the most effective methods for maintaining their programs. Part 33 should only contain performance based standards to be met by licensees, with model procedures incorporated into the regulatory guide for consideration by an applicant.

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 Part 50.59?*

The level of expertise involved in maintaining a broad scope license should enable a significant amount of flexibility to make changes to their radiation safety program within the scope of their operation as long as licensed radionuclides, maximum possession limits and physical boundaries of the facility are not exceeded. The individual licensee's criteria for their review and approval of these changes can be specified in their license application, and their performance of these duties assessed during inspections.

Commensurate with the level of expertise demonstrated by broad scope licensees and the technical complexity of licensed operations, licensees should be empowered to make changes in accordance with approved QA and radiation protection programs.

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?*

Different types of broad scope licenses would not be necessary if NRC reviewed each application for requirements that are appropriate for the scope of the proposed operation. If maintaining different types of broad scope licenses somehow lessens the burden on NRC for reviewing these applications, then they could be maintained with little impact on the overall effectiveness of the regulations, as long as types B and C licenses are not expected to maintain as comprehensive a program as that required for Type A licenses.

9. *Should a Category for "Master Materials Licenses" Be Incorporated Into Part 33 With Respective Necessary Requirements?*

It would seem unnecessary to incorporate a "Master Materials License" into Part 33 considering the relatively few licenses of this type that would be needed. These licenses could continue to be issued on a case-by-case basis with the review of requirements based on the overall scope of the proposed activity.

10. *Should Requirements for "Multi-Site Facilities" Be Codified in Part 33 or Should This Be Defined Only in 10 CFR Part 30?*

Refer to comments in Item Number 9.

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

As stated previously, NRC should keep requirements for broad scope licenses as performance-based as possible. Prescriptive requirements related to ensuring safety are already incorporated into the standards set in other parts of the regulations such as 10 CFR 19, 20, and 71. Broad scope licensees should be provided with the flexibility to develop and establish their programs to meet these standards in the most effective manner considering the scope of the activity covered under the license. The establishment of a performance based approach should not necessarily be limited to those whose failure will not have an intolerable outcome since failure to meet a performance-based standard could be addressed the same as a failure to meet any other standard, prescriptive or otherwise.


IV. Specific Examples of Possible Regulatory Language

The following comments apply to specific sections of the proposed language.

- §33.21 (b) The minimum training requirements for the Radiation Safety Officer are good recommendations, but this section should include a provision for flexibility based on the scope of licensed activity. In addition, there should be some provision for accepting extensive work experience in lieu of an academic degree, even if it is to be approved on a case-by-case basis by NRC.
- §33.22 (a)(1) The RSC membership should include a provision for broad scope licensees with small management organizations in which all managers are authorized users.
- §33.22(a)(4) There should be a provision for the management's representative and RSO to send a qualified designee in their place if one or both are not available due to unforeseen circumstances.
- §33.59(b)(2) The requirement to submit a report within 30 days of any effective date of a change authorized in this section is unnecessarily burdensome. Changes that are authorized by the RSO and RSC under this section need only be maintained for review during an inspection or submitted as a specific request by the NRC. NRC notification and approval prior to implementation of significant changes are appropriately covered in §33.59(c).

Thank you for your consideration of these comments. We at Amersham look forward to NRC's development and implementation of effective broad scope license regulations.

Sincerely,



Wayne London, CHP
Manager, Nuclear Regulatory Affairs