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DOCKET NUMBER
PROPOSED RULE PR 33
(61FR 58346)

Attention: Docketing and Service Branch

References: Federal Register, Vol. 61, No. 221, November 14, 1996 Proposed Rule: Specific Domestic Licenses of Broad Scope for By-Product Material.

Federal Register, Vol. 59, No. 212, November 3, 1994
NRC Draft Regulatory Guide DG-0005
Applications for Licenses of Broad Scope.

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control. CORAR members are U.S. NRC or Agreement State broad scope licensees and are therefore affected by this proposed rule. The main concern here is that NRC is proposing to prescribe how licensees are to structure their organization and how to design duties and responsibilities within the organization. CORAR maintains that such suggestions should be presented in a Regulatory Guide, as examples of how to organize a radiation protection program, rather than in a regulation. CORAR has attached detailed comments on this proposed rule and has the following general comments:

1. Regulations for broad scope licensees should be performance based.

2. Prescriptive requirements should be avoided in the regulations, and when necessary, applied on a case by case basis as license conditions.

3. Most of the prescriptive requirements in this proposed rule would be more effectively conveyed to licensees in a Regulatory Guide if presented as examples of acceptable ways to structure a radiation protection program.

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4. It is impractical for any regulatory agency to prescribe organization structure and specific duties and responsibilities for the great range of broad scope licensee practices and conditions.

5. Broad scope licensees have access to sufficient expertise and resources to enable them to make their own decisions on developing and maintaining a radiation protection program and should be given the authority to do this to meet regulatory performance standards.

6. 10 CFR 33 should include a section that specifically permits licensees to define their own radiation protection program and related organization, responsibilities and duties in the license application to meet regulatory requirements.

7. Broad scope licensees should be allowed to make timely and appropriate improvements to their radiation protection program and related information described in license applications without the delays and burden of intensive documentation and NRC notifications and approvals.

8. CORAR is concerned that the proposed rule is: (1) too prescriptive and is often counterproductive for major manufacturing licensees, and (2) has content that would serve the licensee, the regulator and the public more effectively if reshaped and issued as guidance rather than regulation.

CORAR appreciates the opportunity to comment on this proposed rule and would be glad to provide further information or clarification.

Sincerely yours,

Leonard R. Smith,
CORAR Vice Chairman

2/4/97

CORAR COMMENTS ON PROPOSED RULE: SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL AND DRAFT REGULATORY GUIDE DG-0005.

1. **Page 58346, column 3, paragraph 1, SUMMARY:**

"Currently, the regulations do not contain a clear description of the duties and responsibilities of management, the Radiation Safety Officer (RSO) or the Radiation Safety Committee (RSC)."

CORAR agrees with the NRC intent that licensee management, RSO and RSC responsibilities and duties with respect to the control of licensed material should be clear. However, we maintain that it is impracticable for the NRC to prescribe these duties and responsibilities in the regulations. It is infeasible that a set of duties and responsibilities can be established that would be applicable to all broad scope licensees.

Instead of defining duties and responsibilities in the regulations, the NRC should require licensees to do this. The NRC should consider providing examples of acceptable ways to implement these responsibilities in a regulatory guide. By this approach NRC can avoid being prescriptive and licensees will have the flexibility to optimize their radiation protection programs.

2. **Page 58347, column 3, paragraph 3, lines 7 to 10:**

"...from 1993-96 there were only 38 events involving these licenses that resulted in some type of enforcement action."

An important point that was not stated is that actual doses to members of the public were negligible. It appears from this result that controls are adequate and that there is little need for further regulatory controls.

3. **Page 58348, column 1, paragraph 3, lines 9-14:**

"Although Part 33 requires the establishment of an RSC and the appointment of an RSO, it does not provide broad scope licensees with a clear description of the duties and responsibilities of the RSO or the RSC."

It is not necessary or even appropriate to define RSO and RSC duties and responsibilities in 10 CFR 33. This would be too prescriptive. Any one set of duties and responsibilities is unlikely to be appropriate for all licensees. NRC has full authority to require licensees to clarify duties and responsibilities in the license application. If NRC thinks that licensees need guidance in determining duties and responsibilities this guidance should be provided in a regulatory guide. The guidance should be flexible in full recognition of the extreme range of conditions and practices at licensee site.

4. **Page 58348, column 2, paragraph 4:**

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

CORAR recommends that overall program objectives should be specified in 10 CFR 33 and that guidance on licensee management be provided in Regulatory Guide 10.5.

5. **Page 58348, column 3, paragraph 2:**

"2. Should the NRC Incorporate Requirements for the Duties and Responsibilities of the RSO and the RSC? [in 10 CFR 33]".

CORAR recommends that overall program objective should be specified in 10 CFR 33 and that guidance on RSO and RSC qualifications, duties and responsibilities be provided in Regulatory Guide 10.5.

6. **Page 58348, column 3, paragraph 4:**

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

CORAR contends that it is not practicable to specify training and experience criteria in 10 CFR 33 that would be appropriate for all licensees. Instead, CORAR recommends that the NRC provides guidance on qualifications for key personnel in Regulatory Guide 10.5.

7. **Page 5834, column 1, paragraph 2:**

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

CORAR participated in the NRC Region I Workshop on Security and Control of Licensed Materials. The general consensus at this meeting was that NRC needs to define a level where a formal program for the control and security of licensed material would be required. Guidance or actual requirements could most usefully be conveyed in a Regulatory Guide or specified as a license condition on a case by case basis. Inventory control of sealed sources should be specified as a license condition as is current practice. The consensus at the NRC Workshop was that formal security and control measures should be considered when possession of unsealed licensed material exceeds one Annual Limit on Intake or one hundred times the quantities specified in 10 CFR 20 Appendix C. A higher limit should be specified for sealed sources. Licensees should also be able to demonstrate control of smaller quantities of licensed material, but the requirements should be no more restrictive than those applying to the control of chemicals commonly present in the research laboratory.

8. **Page 58349, column 1, paragraph 4:**

"5. Should the NRC Consider the Risks Associated With Internal Exposure Pathways...Separate From Those Associated With External Radiation?"

The current NRC practice for considering risk from internal and external exposure is compatible with recommendations of the National Council on Radiation Protection and Measurements and the International Commission Radiological Protection. This current practice is appropriate because the risk from committed effective dose from internal exposure is defined to be generally equivalent to the risk from a similar external dose. Hence there is no need for a separate nor different internal or external dose limit and CORAR agrees with the present radiation standard.

However, because there is a difference in the way individuals are exposed to internal and external radiation, it is necessary that licensees have different procedures for controlling these exposure pathways. As a consequence it would be very difficult for regulators to prescribe appropriate control procedures since these will differ considerably for different licensees. In practice, licensees

generally apply more restrictive controls on operations that can produce internal exposure. This is in recognition that internal exposure is often more difficult to monitor, internal dose estimates less accurate than external and because employees perceive internal exposure to be less acceptable than external. Consequently, the current practice is for licensees to apply stricter controls on internal exposure. Licensees should be allowed to continue to apply controls that are appropriate to the conditions and practices they encounter.

9. **Page 58349, column 1, paragraph 6:**

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

CORAR does not recommend that any guidance in Draft Regulatory Guide DG-0005 be codified in 10 CFR 33. CORAR believes that the guidance provided in Draft Regulatory Guide DG-0005 is better presented as guidance than specified as a regulatory requirement. Specific requirements can be addressed more effectively as license conditions.

CORAR also has concerns with Draft Regulatory Guide DG-0005. The main concern is that DG-0005 is too prescriptive. CORAR members have had direct experience with the recommendations in DG-0005 and found some of them to be unworkable. For example, CORAR maintains that licensee management has ultimate responsibility for establishing policies and procedures and the RSC serves best in a review and advisory capacity. Generally, in an organization where there is a need for effective action, there should be an individual who is held accountable for completing the action. For important actions, such as maintaining a radiation protection program, that individual needs to be high in the organization, i.e. needs to be a manager.

In large manufacturing programs, we have observed that a designated Radiation Protection Officer cannot also serve as RSC chairperson or manage the whole radiation protection program. It is very rare that an individual will have both the management experience and maintain the technical expertise necessary to combine both functions. In large manufacturing facilities the most successful arrangement is to provide a management organization for those who use the licensed material with the plant manager having ultimate responsibility. This enables the Radiation Protection Officer to be free to apply their specific radiological skills that are necessary for a successful program. The RPO will often supervise a Radiation Protection Support Group who have specific audit and service responsibilities, but the effectiveness of such an arrangement will depend critically on the complexity of the operations and is best determined by the licensee.

Again the main issue we have with DG-0005 is that it is too prescriptive and often prescribes practices that are not effective.

10. **Page 58344, column 2, paragraph 2:**

"7. **Should Broad Scope Licensees Be Allowed to Make Changes in Their Radiation Safety Program Similar to Those Authorized for Production and Utilization Facilities".**

Broad Scope licensees are already allowed to make changes to their program without making a formal license amendment application. There are several practices that are currently allowed. Some licensees have specific wording in their license or license application that allows a certain amount of flexibility. In other cases NRC will grant verbal authorization to a change from license conditions. These changes either maintain or improve performance and are documented for NRC inspection. Where necessary, the changes are subsequently included in an application when a substantive license amendment or license renewal is needed.

The NRC also provides for changes in Emergency Plans without formal license amendment. CORAR recommends that current practice for making changes to radiation protection programs should be defined in 10 CFR 33. CORAR urges that such changes should just be documented by the licensee and, that only when license conditions are changed, there should be a requirement for notifications to and authorization by the NRC. Many licensees find it necessary to make frequent minor changes to their radiation protection programs. The ability to make these changes without formal application for license amendment avoids involving the NRC in a large number of trivial licensing actions. Another advantage is that it will encourage licensees to take advantage of rapidly changing technical improvements that can improve licensee performance in radiation protection.

11. **Page 58349, column 2, paragraph 4:**

"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?"**

While we recognize that there are few Type B or Type C licenses of broad scope, those licensees who have them want to preserve the flexibility that a broad scope license provides without having to maintain the complex radiation protection program that a Type A license requires and avoiding the submission of

unnecessary Emergency Plans and Decommissioning Plans. Some Type B Licensees will have difficult in achieving the current requirements for a Type A license. The NRC should consider to discontinue issuing new Type C and Type B licenses, but grandfather those that are currently active.

If the NRC intends to continue Type C licenses, there is a need to reconsider the user training requirements which are excessive for the small quantities of byproduct material authorized under a Type C license.

12. **Page 58350, column 1, paragraph 4:**

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

CORAR maintains that regulations applicable to Broad Scope licensees should be performance based and that prescriptive requirements should be limited. The NRC should be aware that in States that do not have licensing programs, accelerators and accelerator produced radionuclides are controlled with the same level of care as byproduct material and without any prescriptive regulations.

Broad scope licensees and organizations where equivalent quantities of accelerator produced radioactive materials and radiation are managed have long found it necessary to maintain comprehensive radiation protection programs employing considerable expertise and resources. This is proof that broad scope licensees typically have mature radiation protection capability and do not need prescriptive regulations to meet performance standards. Indeed, CORAR claims that most of the prescriptive requirements in 10 CFR 30 and 10 CFR 33 are counterproductive and only add costly administrative burdens to licensee programs without any benefit to safety or society. Performance based regulations that are beneficial include occupational and public dose limits, derived limits such as these in 10 CFR 20, Appendix B, possession limits and diminimis levels including exempt quantities, excepted quantities, and exempt concentrations. Regulations should also provide general requirements for maintaining exposures to ALARA and requiring licensee responsibility. These standards and requirements should be uniformly compatible with the standards of other regulatory agencies and recommendations of the NCRP and ICRP.

Prescriptive regulatory requirements are needed to establish a practical working relationship with the regulatory agency including licensing, inspection and enforcement procedures. Prescriptive regulations should also include notifications of overexposures and significant losses of control of radioactive material.

Other prescriptive requirements should be mentioned in the regulations, but applied only on a case by case basis as license conditions. These include the need for an Emergency Plan, Decommissioning Funding Plan and other conditions typically applied to licenses.

Most of the prescriptive requirements currently contained in the regulations should be transferred to regulatory guides and presented as examples of radiation protection program elements that can be used to satisfy regulatory requirements. The value of such an arrangement is that it forces licensees to take responsibility for their radiation protection programs and returns the regulator to a proper oversight function rather than prescribing how licensees should manage their operations.

CORAR has submitted additional comments on 11/27/96 on the need for risk-informed performance based regulation in comments on NRC's Strategic Assessment and Rebaselining Initiative. These comments also include CORAR's recommendation for an independent radiation standard setting agency to replace the EPA in this function.

13. **Page 58350, columns 3, paragraph 5:**

Management means the chief executive officer (or equivalent) or that person's delegate or delegates."

This is a useful definition of management.

14. **Page 58350, column 3, paragraph 6:**

"Radiation Safety Committee means a committee responsible for the development and administration of a licensee's radiation safety program, including responsibility for approval of all proposals for radionuclide use and users."

The best organization for administration and development of the radiation protection program in a major manufacturing facility is line management. Management has ultimate responsibility, takes the necessary action and controls the resources needed for an effective program. Managers may also serve as members of the Radiation Safety Committee (RSC). The RSC is usually the preferred group for reviewing and approving radionuclide use and users. The proposed definition for RSC would undermine current effective programs at manufacturing facilities. This is a good example of how a prescriptive requirement from a regulatory agency can be counterproductive.

15. **Page 58350, column 3, paragraph 7:**

"Radiation Safety Officer means the individual, identified on the license, responsible for the day-to-day operation of the licensee's radiation safety program."

Consider the following definitions:

"Radiation Safety": Protection of personnel against harmful effects of ionizing radiation by taking steps to ensure that people will not receive excessive doses of radiation and by monitoring all sources of radiation to which they may be exposed.

"Radiation Protection". Legislation and regulations to protect the public and laboratory or industrial worker against radiation. Measures to reduce exposure to radiation.

CORAR observes that most broad scope licensees control radiation to preclude safety concerns and that they are more properly involved with radiation protection. We would recommend the term Radiation Protection Officer rather than Radiation Safety Officer in the context of this proposed rule.

In major manufacturing facilities where hundreds of employees are working daily with licensed material the radiation protection program is the responsibility of many supervisors who supervise day-to-day operations and support services. It is not feasible that one person can be responsible for the day-to-day operations of hundreds of employees. In major manufacturing facilities the Radiation Protection Officer (RPO) is appointed to liaise with regulatory authorities, address regulatory, licensing, inspection and enforcement issues and provide technical and regulatory consultation to the RSC and line management. In some major manufacturing facilities, the RPO may also manage a Radiation Protection Support Group who's main function is to audit the uses of licensed material and document data to demonstrate compliance with regulatory requirements and license conditions. Use is often made of the RPO and Radiation Protection Support Group to utilize their particular expertise in providing services to the licensed material users such as dosimetry and training services. Considering that these arrangements have been found most effective through decades of operational experience, CORAR contends that the proposed rule is unworkable at complex facilities and at facilities where regulatory requirements are complex.

This is another example of where a prescriptive requirement for the duties of a Radiation Protection Officer are counterproductive and will undermine current effective programs at major manufacturing facilities.

16. **Page 58351, column 1, paragraph 5:**

"Applications for a new license, an amendment, or a renewal of a specific license of broad scope.."

CORAR has submitted comments on NRC's Business Process Re-Engineering initiative. CORAR urges that the license amendment procedure should be made more flexible and provide licensees with the opportunity of maintaining up-to-date licenses and discarding obsolete material from the license. Such a program would result in broad scope licensees having concise and easy to manage and easy to use licenses instead of the patchwork sequence of license attachments that currently prevails. CORAR recommends that the license amendment process be improved and the license renewal process deleted.

In the subsequent text following the above sentence, the term "applicant" is used without definition. Is the "applicant" the licensee, the licensee manager or the RPO? A definition and some discussion would help clarify this issue. The NRC should be aware that some Agreement States have difficulty with defining who can be acceptable as an applicant.

All the requirements listed under this section appear reasonable and appropriate to place in regulations to foster an effective working relationship between the NRC and licensee. Exceptions are references to Sec. 33.21 and 33.22 which are addressed below.

17. **Page 58352, column 1, paragraphs 1 and 2:**

"Sec. 33.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program."

In a major manufacturing facility, it is not feasible that a Radiation Protection Officer can be held responsible for implementing the radiation protection program and monitoring daily operations. CORAR maintains that the current practice of assigning line management with these responsibilities is effective and should be confirmed. This is a good example of how a prescriptive regulatory requirement is unworkable.

The prescriptive requirement that a Radiation Protection Officer shall have at lest 5 years experience is impractical for some broad scope licensee and certainly unnecessary for Type B licensees. CORAR recommends that guidance on RPO qualifications should be put in a regulatory guide and presented in a flexible way such as "5 years or equivalent experience and qualifications".

This section references "Sec. 33.17 (f)", but this is not in current or proposed regulations. Clarification would be helpful.

Proposed 33.21 (c) (3) refers to "byproduct material program". It is not clear whether this is the "radiation protection program" or some other undefined entity. CORAR recommends a definition or use of just one term as appropriate.

18. Page 58352, column 1, paragraph 12, lines 1-10:

"Sec. 33.22 Radiation Safety Committee."

"Membership shall consist of...at least one representative of management who is neither an authorized user nor a Radiation Safety Officer."

It is not clear why the NRC would want the RSC to include a manager who is not an authorized user. It would seem that to include such a person might dilute the effectiveness of the RSC if this person has no expertise in using licensed material. For some licensees, all the managers are also users.

This requirement is sometimes not workable and not effective for many licensees. This is another example of how a prescriptive regulatory requirements can be counterproductive.

The membership of the RSC could be better presented in a regulatory guide with explanatory material. For example, this section requires members from each department, group or activity. Unless this was fully explained licensees might interpret that every group, however small, needs at least one representative which could result in a safety committee with several tens of members.

19. Page 58352, column 1, paragraph 13:

"The Committee shall meet four times a year..."

This is too prescriptive and implies that the committee is not permitted to meet five times in a year, for example.

20. **Page 58352, column 2, paragraph 4:**

"Ensure programs meet the requirements of 20.1101..."

We are unaware of 10 CFR 20.1101 in current or proposed regulations. Clarification would be helpful.

21. **Page 58352, column 2, paragraphs 7 and 8:**

"(ii) Review on the basis of radiation safety...."

"(iii) Review and approve radiation safety program changes on the basis of safety;"

CORAR would recommend that "safety", should be replaced by "protection" since this will then include ALARA considerations and is more in line with current practice which is very effective.

22. **Page 58352, column 2, paragraph 11:**

"(vi) Establish investigation levels for occupational doses that, when exceeded, require investigations and considerations of action by the Radiation Safety Officer;"

This requirement is too prescriptive. CORAR agrees that most licensees would want to establish administrative action levels for radiological data. However, licensees should be given the flexibility to assign appropriate staff to act. The danger of this proposed rule is that appropriate action may be delayed if an overexposure is discovered when the Radiation Protection Officer is on vacation. Licensees should have access to alternate qualified individuals to act on overexposures. Any program that must depend on the constant availability of key individuals is not likely to be sustainable.

23. **Page 58352, column 3, paragraph 6:**

"Sec. 33.25 Supervision".

NRC should be aware that in many research communities there are no supervisors.

24. **Page 58352, column 3, paragraphs 12 and 13:**

"Sec. 33.59 Radiation Safety program changes

(a) The holder of a specific license of broad scope... 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 than the regulations."

CORAR agrees with this provision and believes it is a necessary addition to the regulations to qualify current practice. Its main benefit is that it will encourage licensees to make changes that improve the radiation protection program.

25. **Page 58352, column 3, paragraph 14 and Page 58353, column 1, paragraph 1:**

(b) (1) The licensee shall maintain records of changes in the facility and of changes in procedures ...until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new facility or procedure, the reason for the change, a summary of radiation safety matters that were considered before making the change, and the signatures of the Radiation Safety Officer, Radiation Safety Committee chairman, and the management representative.

CORAR agrees that the licensee should maintain a record of the change. However, we believe it should only be retained until the next NRC inspection and then incorporated in any subsequent updates to the license. This would avoid any unnecessary paperwork. The method of documentation in the proposed rule is too prescriptive and should be left to the licensee. For example, one method would be to include the change in RSC minutes. The requirement for signatures is unnecessary for changes that improve the radiation protection program.

26. **Page 58353, column 1, paragraph 2:**

(b) (2) The licensee shall submit a report within 30 days of the effective date of the change, containing a brief description of any changes, including the reason for the change and a summary of the radiation safety matters that were considered for each.

This proposed rule is counterproductive. It actually involves licensees in more unnecessary work than a license amendment would. CORAR recommends that the requirement for documenting and reporting a change in proposed 10 CFR 33.59 (b) (1) above and in (b) (2) should only apply to changes that substantially reduce the effectiveness of the radiation protection program. This is another example of how prescriptive regulations can be counterproductive.