(21)

February 12, 1997
Secretary,
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Docketing and Service Branch

Subject: Proposed Rule: Specific Licenses of Broad Scope for Byproduct Material. Federal Register, Vol. 61, No. 221, November 14, 1996.

These comments are submitted by the Radiation Safety Officers of the DuPont Experimental Station, DuPont Stine-Haskell Research Center and DuPont Merck Glenolden Laboratory. These research and development facilities serve the DuPont Company and the DuPont Merck Pharmaceutical Company. They each possess an NRC license for the use of radioactive materials in research projects involving basic research, the identification and development of pharmaceuticals for human health care or the development and study of crop protection products.

General Comments

The Commission is concerned when it becomes aware of radiation protection programs that do not meet the commitments made in the licensee's application; we share that concern. However, codifying as requirements, how licensees operate will not address performance concerns. Further, creating a "one size fits all" radiation safety program is not feasible.

As noted within the Background section of the proposed rulemaking, "Part 33 reduces the administrative burden for both licensees and the Commission, without reducing safety standards or lessening licensing requirements for training, experience, facilities, and equipment." For over 30 years this regulation has been successfully used to provide a performance standard that ties in well with Part 30. From time to time Regulatory Guides have been provided to the licensed community to help them develop license applications and the resulting radiation protection programs. These Guides encourage the use of available technology and in improved administrative, engineering and support systems. These Regulatory Guides have been useful tools but they remain useful only if they are viewed and used within their intended purpose - to provide examples of acceptable ways to structure a radiation protection program.

If Draft Regulatory Guide DG-0005, or any guidance document, is converted into a prescriptive regulation its value is greatly diminished. This is due to the inherent nature of specific licenses of broad scope - to ensure safety protection programs are developed and in place despite a large and changing variety of operations involving byproduct material. Under many circumstances, operations will be encountered where a more flexible approach will be required. A lack of flexibility will create dilemmas involving the As Low As Reasonably Achievable (ALARA) principle, the prescriptions proposed and the reasonable objectives of the licensee.

Some organizations will be able to deal with the resulting dilemma by relocating to locations outside the NRC's jurisdiction. However, for most licensees this option is not feasible and they will have to change their definition of what is reasonable - either in their ability to reduce radiation exposure or in their ability to meet their objectives, or both. This outcome is contrary to the intent of the Commission, yet this would be the result under the proposal.

The proposal would be more effective within an updated Regulatory Guide. This would allow the Commission, the licensee and the public to benefit from the recent, as well as future, advances in radiation protection program design and operations. The regulation, Part 33, should be updated to encourage and allow licensees to make prompt improvements in their radiation protection program, without the delays and burden of intensive documentation and NRC notification and approvals. The regulation should also allow nonsubstantive changes to be made in a licenses program, without NRC notification and approvals. Changing to another the licensed vendor for leak testing services is an example of a nonsubstantive change.

In summary, the regulations for specific licenses of broad scope should be remain performance based. Each licensee should be evaluated on a case by case basis when prescriptive requirements are needed. Regulatory Guides have their value in providing examples while allowing alternative solutions to be developed and evaluated.

We appreciate the opportunity to provide comments on the proposal. Feel free to contact us for additional discussion or clarification.

Sincerely,

[document retrieved from Electronic Bulletin Board]

Augusto Cordova, RSO
DuPont Experimental Station
Stine-Haskell Research Center

Norman Henry III, RSO, CIH

John Nicholson, RSO
DuPont Merck Pharmaceutical Co.

Specific Responses to Questions

1) Should Licensee Management Responsibilities Be Specified In Part 33?

The regulation should clarify that licensee management is ultimately responsible for the radiation protection program; while regulatory guidance should provide examples on how these responsibilities can be described within the license application. This will clarify that the licensee has the need and the responsibility to determine the most effective mechanism for management oversight of the radiation protection program.

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

The overall objectives of the RSO and RSC should be provided in Part 33; while regulatory guidance should provide examples of qualifications, duties and responsibilities. Necessary qualifications vary greatly depending on the licensee's program and the duties and responsibilities assigned. to the RSO and the RSC. It is not feasible to provide one set of criteria that would be appropriate for all broad scope licensed facilities.

There are many ways for an RSO and RSC to become qualified to meet their responsibilities and duties. Specifying their responsibilities and duties, and their minimum qualifications, would be a disservice to the licensee and the effected personnel. It would raise unnecessary barriers to qualified people while generating a false sense of confidence in personnel lacking the necessary qualifications to maintain an effective radiation protection program.

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

The operations, duties and responsibilities of Authorized Users vary greatly, even within a licensed programs. It is therefore not feasible to develop useful criteria for minimum training and experience. A Regulatory Guide would be the place for providing sample sets of operations, duties and responsibilities, matched with minimum training and experience criteria.

As with any other operation, it is management's responsibility to ensure personnel have the training and experience necessary to work safely and in compliance with regulatory requirements. These issues are best handled on a case by case basis.

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

NRC Region I's workshop on Security and Control of Licensed Material provided an excellent opportunity for the licensees and the regulators to discuss the advantages and limitations of various systems and criteria for inventory control and accountability. There was general consensus around the need for control systems that are reasonable, i.e., based on the quantity and hazard potential of the byproduct material. Further, many licensees described control systems they developed that met their operational needs and took advantage of the particular strengths of their facility.

It is imperative any regulation on security and control measures have provisions for considering the quantity, form and hazard potential of licensed material. For smaller quantities of material, e.g., one Annual Limit on Intake (ALI), licensees should be able to apply the same control criteria applied to non-radioactive reagents commonly present in research laboratories. A Regulatory Guide should include examples for meeting the security and control requirements, leaving implementation details to the licensee. NRC inspections would be used to ensure the programs in place are effective.

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

Committed Effective Dose calculations are already used to relate internal exposure to external exposure so the current NRC practice for evaluating risk from internal vs. external exposure is appropriate. It is also consistent with the recommendations of the National Council on Radiation Protection and Measurements and the International Commission Radiological Protection. Additional or separate dose limits are therefore not necessary.

At the same time, internal exposure prevention programs may require more controls than external exposure prevention programs. For this reason licensees often have more demanding systems where there is potential for internal exposure. A Regulatory Guide can provide examples of programs for internal exposure prevention but licensees need to be able to evaluate the operating conditions and the practices in place when developing and implementing their internal and external exposure prevention programs.

6) Are There Other Specific Aspects Of The Draft Regulatory Guide DG-0005 That Should Be Codified In Part 33?

Draft Regulatory Guide DG-0005 has value when it is used as intended - to give guidance by providing examples. It is too prescriptive to serve all broad scope license programs. The licensee's internal operating procedures and license application are the appropriate places for the level of detail described in Draft Regulatory Guide DG-0005.

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?

Broad scope licensees have some flexibility in modifying their program without a formal license amendment application. This flexibility may be explicit, such as that provided through specific wording in the license or license application. In other cases program changes are possible since they are consistent with existing license conditions. Having this flexibility is vital for the licensee's radiation protection program to constantly improve. Having additional flexibility to make minor changes would facilitate and encourage licensees to incorporate program improvements before their license is up for renewal. Reserving the license amendment application process for more significant program changes would also reduce the administrative burden to the Commission and the licensees. Minor programs changes would be documented for the next NRC inspection.

8) Should The Different Types Of Broad Scope Licenses Currently in Part 33 Be Deleted And Replaced With A Single Type?

If broad scope licenses are limited to a single type, provisions will be necessary for small programs where the current Type A conditions and the limited scope conditions are not appropriate. Otherwise up to 25% of current broad scope licensees will be forced to operate under license regulations that do not meet their needs. There should be a distinct and well-documented advantage to the licensees and/or public for this change.

10) Should Requirements For " Multi-Site Facilities" Be Codified In Part 33 Or Should This Be Defined Only In 10 CFR Part 30?

A Regulatory Guide would be the best tool for addressing "multi-site" licenses. This would allow the Commission to provide the necessary guidance while providing the licensee the flexibility necessary to develop and implement an effective multi-site radiation protection program.

11) What Balance Should Be Maintained Between A Performance-Based And A Prescriptive Approach To Regulate Broad Scope Licensees?

Regulations for broad scope licensees should be performance based. This is due to the inherent nature of the operations in a broad scope licensed facility. Prescriptive requirements would poorly serve the public, by reducing the effectiveness of the licensee's radiation protection program and increasing the administrative burden to the Commission and the licensee.

Prescriptive regulatory requirements are appropriate where measurable quantities are involved; examples include dose limits, possession limits and material release criteria. Prescriptive requirements should also involve specific features of a licensee's program, such as the need for a Decommissioning Funding Plan.

It is important that the Commission remain in its oversight role, and not try to manage the radiation protection programs of the broad scope licensees. The Commission should provide guidance to the licensees through Regulatory Guides, while leaving program management to the licensees, who have the responsibility and capability to do so.

Strong action should be taken by the Commission when it becomes aware of a licensee lacking the capability or commitment to properly manage its radiation protection program. At the same time, it should not attempt to manage all of the broad scope licenses through additional prescriptive regulations.