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February 7, 1997

DOCKET NUMBER
PROPOSED RULE PR 33
(61FR58346)

Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Docketing and Service Branch

Re: 10 CFR 33 Advanced Notice of Proposed Rulemaking "Specific Domestic Licenses of Broad Scope for Byproduct Material"

Gentlemen:

The Illinois Department of Nuclear Safety (Department) hereby submits its comments on the referenced advance notice of proposed rulemaking. The proposed rule represents changes to 10 CFR 33 that would codify current licensing guidance and practices associated with licenses of broad scope. Our specific comments concerning the general considerations are as follows:

Q1. Should the Responsibilities of Licensee Management for the Radiation Safety Program be Specified in Part 33?

The drafted 10 CFR 33.12 and 33.17 rules adequately state what the responsibilities of management should be. Guidance should state that responsible individuals in the management structure must be identified by the licensee in its application. The NRC has stated that some of the failures at broad scope facilities are a result of weak management oversight. The Department believes that such weaknesses may also be a result of duties and responsibilities not being clearly assigned or understood, or there may be uncertainty as to who is responsible for a particular facet of the radiation safety program. Guidance should state that management is responsible for ensuring adequate financial and personnel resources are available in order to implement an effective radiation safety program that complies with applicable regulations and note their responsibility for performing a review of the content and implementation of the radiation safety program on an annual basis (10 CFR 20.1101(c)). This review may be done by the Radiation Safety Committee (RSC) provided a quorum including management's representative is included in the review process.

Q2. Should the NRC Incorporate Requirements for the Duties and Responsibilities of the RSO and RSC?

Duties and responsibilities of both the RSO and the RSC should be codified as they appear in the drafted language. This would clearly identify the obligations of each of these major radiation safety functions without dictating the means by which those obligations must be met. With regard to establishing minimum training and experience criteria of the RSO, the Commission may be best served by reviewing comments received from the publishing of Task OP 722-4 "Draft Regulatory Guide and Value/Impact Statement for Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program." Codification of training and experience should only require a minimum of one year of experience in applied health physics managing similar radiation safety problems regardless of the extent of formal training. The five year requirement is unduly burdensome, limits regulatory flexibility and is inappropriate for some licenses of broad scope.

Q3. Should Specific Minimum Training and Experience Criteria for Authorized Users be Incorporated Into Part 33?

The issue of codifying the minimum training and experience necessary to be named an "Authorized User" should be approached carefully. Although the largest portion of such individuals under broad scope authorizations are generally physicians or researchers with a fairly extensive background, there are a number of others whose backgrounds and authorizations vary widely. Personnel such as radioactive waste collectors, process supervisors, maintenance foremen, and housekeeping supervisors may be permitted limited functions involving handling of radioactive materials or sealed sources in devices outside of research and medical uses under current authorizations. As such, they may be an "Authorized User", but not as currently specified in 10 CFR 33.15 or 10 CFR 35. The Commission should simply require the licensee to put forth a plan of what they consider an "Authorized User." This will allow necessary regulatory flexibility.

Q4. Should the NRC Incorporate Specific Requirements for Inventory and Accountability of Byproduct Material in Use, or Modify its Existing Guidance?

It is not necessary to codify inventory and accountability records of material in use. 10 CFR 20 currently requires these records to be maintained by the licensee. In 10 CFR 33 the Commission should only require licensees to describe the means by which they will comply with this requirement for radioactive materials in active use, as waste or in sealed sources/devices containing sealed sources. The language drafted in 10 CFR 33.12 allows this necessary flexibility. In the Department's experience, licensees typically have used an annual or semi-annual bookkeeping method involving summaries submitted by the Authorized User to the RSO for tabulation. Physical confirmation is usually on a random basis at the discretion of the Radiation Safety Officer. Inventory of sealed sources and devices containing sources is typically performed at time of leak test or semi-annually, whichever is more frequent. Such flexibility should continue to be available to licensees and regulatory agencies.

Q5. Should the NRC Consider Risks Associated With Internal Exposure Pathways (e.g., Ingestion, Inhalation, Absorption) Separate From Those Associated With External Radiation?

It is not appropriate to resolve the issue of dose estimation and risk assessment within the context of 10 CFR 33 only because recent issues involved broad scope licensees. This topic should be dealt with in any future revisions of 10 CFR 20. Risk from internal exposure involves a great number of variables which are difficult to reconcile, let alone codify (e.g., such as in cases of deliberate misconduct), and have been discussed at length in separate fora. Consideration should be given to the necessity of any specified or increased protective measures. This may include new or revised guidance concerning security of radioactive material, the appropriate frequency of contamination monitoring in research environments and revised frequencies for routine bioassays for P-32, P-33, S-35, radioiodine or tritium. Current NRC policies rely on the experience and knowledge of the RSO to establish monitoring frequencies in research environments. If appropriate guidance is to be developed or modified, the NRC should study the intake/transport of radioactive material from the work environment (under actual work conditions) which may lead to an intake.

Q6. Are There Other Specific Aspects of the Draft Regulatory Guide DG-0005 That Should be Codified in Part 33.

As drafted in the proposed rule, applicants should be allowed freedom when establishing administrative procedures, but they must have and submit written policies or procedures for specific functions such as inventory control and accountability, audits, safety evaluations of facilities, frequency of re-evaluations, training of users, exposure control, etc. The Department's previously submitted comments to the Regulatory Publications Branch on DG-0005 dated January 5, 1995, and regulations drafted by the Department, also outline this regulatory framework.

Q7. 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 should not be allowed to make changes in their radiation safety program which varies from that submitted for review. This area of regulation (i.e., ministerial changes) is too subjective to be of value in enforcement. What may be considered not potentially important to safety by a licensee, could be of concern to the Department. Instead, sufficient latitude should be incorporated in submitted policies and procedures such that the flexibility necessary to run a broad scope license already exists within the applicant's radiation safety program. The applicant should be advised of this position in guidance.

Q8. 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?

All types of broad scope licenses should be replaced with a single license type which is most similar to the current Type A License of Broad Scope. The autonomy granted under Type B licenses has been largely for the naming of additional users by the RSO. Allowances can be made under specific licenses to achieve this end, provided commitments regarding training and experience of authorized users are submitted by the applicant. The table values of radionuclides for Type B and C licenses are of little value when establishing these licenses of broad scope as licensees typically request to vary from the activities authorized by the table values for certain radionuclides. Our experience mimics that of the US NRC with regard to distribution of broad scope licenses over the various types. Establishment of a single type of broad scope license and a common set of requirements would provide clear requirements to licensees as well as aid in the streamlining of licensing and inspection of these licenses.

Q9. Should a Category for "Master Materials Licenses" be Incorporated Into Part 33 With the Respective Necessary Requirements? and Q10. Should Requirements for "Multi-Site Facilities" be Codified in Part 33 or Should This be Defined Only in 10 CFR 30?

The Department has no comment regarding the establishment of Master Material Licenses as long as they are restricted only to locations/facilities of Departments and Agencies which are under exclusive federal jurisdiction. Similarly, we have no comment regarding Multi-Site Facilities under NRC jurisdiction. The Commission may note that in Illinois these facilities are licensed on a case-by-case basis under broad scope authorizations as well as specific licenses to meet the needs of the licensee as well as that of the Department. In these cases however, an RSO is established for each site and named on the license.

Q11. What Balance Should be Maintained Between a Performance-Based and a Prescriptive Approach to Regulating Broad Scope Licensees?

It appears a good balance has been adopted in the drafted regulatory language. In order to limit the expenditure of limited resources associated with an inspection intensive program, regulations have been developed which require the submission of a framework of applicant prepared procedures and policies. In the past, measurement of end goals was difficult at best, in that several policies and procedures were not specifically required and programs varied widely in their scope and implementation. To this extent a prescriptive approach has been adopted. However, in recognition of a need for performance based regulation, allowances have been given to the licensee to develop procedures which would best suit them. The major benefit of a license of broad scope is its flexibility, which is difficult to authorize under a prescriptive approach. A program based on an active management and RSC, competent RSOs and authorized users, self audits, personnel monitoring, incident control and response and active monitoring for radiation levels and contamination should be encouraged and verified through routine, frequent compliance inspections. As stated in the drafted regulatory language, a license should be granted in part based on past performance. Further, it should be noted that this privilege of "self regulation" is subject to revocation or modification pursuant to inspection and enforcement.

Comments Concerning Drafted Regulatory Language and Other Topics

We have noted several good ideas which have been developed in the drafted possible regulatory language. One example is the allowance for scheduling in the requirement that the RSC meet four times a year at a frequency not to exceed 4 months. Another is the drafted Section 33.25 for use of radioactive material under the supervision of an authorized user. However, the requirement that RSC membership consists of "one user from each department or group" could lead to a committee of 24 or more at academic facilities such that the committee would cease to be an efficient functioning body. Instead, guidance should suggest a cross section of all users in order to ensure adequate representation and require only a minimal membership on the committee to allow this flexibility. Also 10 CFR 33.21(c)(3) should be revised as a requirement of the RSC rather than restricted to the Radiation Safety Officer as they are charged with overseeing the radiation safety program. The content of the RSC meeting minutes should be stipulated in the regulation as well as they are the primary means by which the actions of the RSC are documented.

An additional suggestion is to arrive at a technically based monitoring program for areas where radioactive materials are used for facilities where research and development occurs (e.g., academia). As noted earlier, previous technical assistance instructed us that determination of monitoring program adequacy was best left to the discretion of the facility RSO. Subsequent information notices, NUREG reports and news accounts concerning broad scope facilities cause us to question this opinion. Developing a monitoring program is extremely subjective and its effective implementation varies widely based on the facility and the RSO. A determination of adequacy of the monitoring program is typically based on performance and effectively left to the discretion of the inspector without the benefit of any regulatory guidance. Guidance for these monitoring programs have been established for medical facilities and manufacturing facilities but not for research environments which have recently been subject to scrutiny. Establishing a technically based survey program should entail an evaluation of the risk associated with access to small quantities of radionuclides.

The Department is interested in receiving copies of comments or summaries of comments which the Commission receives as a result of publication of the advanced notice of rulemaking as we are in the process of similar rulemaking. It is through these cooperative efforts that both the Agreement States and the NRC can benefit the most and take advantage of the limited resources available. If you have any questions regarding these comments, do not hesitate to call me, Kathy Allen or Daren Perrero at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

SCC:dmp

cc: Jim Lynch, State Agreements Officer