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UNIVERSITY OF WYOMING

Environmental Health & Safety
P.O. Box 3413
Room 312, Merica Hall
Laramie, Wyoming 82071-3413
(307) 766-3277

January 21, 1997

Secretary
Nuclear Regulatory Commission
Washington, DC 20555-0001

Attn: Docketing and Services Branch

Dear NRC:

Enclosed are comments made by individuals from the University of Wyoming Environmental Health and Safety Office. Specifically, these are answers to the questions posed in the Federal Register on November 14, 1996, regarding the codification of regulations governing specific licenses of broad scope for byproduct materials. If you require clarification on any of the comments, feel free to call at (307) 766-3277.

Sincerely,

Jim Herrold
Assistant Manager, EHS

Comments from Jim Herrold, Assistant Manager, EHS / Radiation Safety Officer:

Because my answers to questions 1 through 8 are primarily based on my response to question 11, I will answer that one first.

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

It is preferable to leave the codified regulations flexible in order to accommodate the myriad of situations for which a broad-scope license may be needed. No matter how carefully they may be written, there will always be situations where a particular segment of the regulations does not make sense for a particular licensee. When an application for a broad-scope license is submitted it is based on realistic expectations of the scope of the individual radiation safety program. Once accepted by the NRC, the license becomes the set of regulations that the licensee must follow and upon which it will be inspected. Instead of casting the program parameters as regulations, it is better to offer them as professional guidelines (such as Regulatory Guides or NUREGS) which can contain more detail in order to be used as models for an acceptable program. This allows the prospective licensee to negotiate realistic methodologies with the regional NRC office. This is the beauty of the NRC regulatory system as it stands now. It is the process of submitting an application and negotiating with the NRC Licensing Branch that forces the prospective licensee management, RSC, RSO to work together. This promotes better awareness of the radiation safety program and cooperation with the NRC.

The problem of licensees being unaware of NRC requirements will not be solved by adding more bulk to the regulations. The real problem is that licensees are unaware of what is required under existing regulations and in their own licenses. This problem has been compounded during the renewal of licenses by the practice of incorporating all previous licenses, letters, amendments, manuals, etc. into the new license, making the license a mountainous volume of incongruent paperwork. Licensees should be required to re-file a complete, orderly copy of the renewed license on a regular basis. This would enhance license comprehension and usefulness, for both the licensee and the NRC. New and renewed licenses should have a signature page certifying the full awareness and cooperation of the RSO, Radiation Safety Committee and management.

I agree with the NRC staff that a risk-informed, performance-based regulatory approach should contain the elements of measurability and objectivity. These factors do not necessarily have to be written into the regulations, but can easily be described in the individual license. The element of flexibility in meeting performance criteria can only exist if the codified regulations allow that flexibility. It is then up to the NRC inspection branch, working with the licensee, to determine if performance criteria are actually being met in the manner intended. If programs with limited budgets are directed to follow rules that do not take actual risks into account, their only choices are to either sacrifice other more serious safety concerns or be out of compliance with the regulations.

Jim Herrold's comments, continued:

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

The specific responsibilities of licensee management should not be included in the Federal Regulations. The role of management in a small private research laboratory is very different from that of a multi-collegiate state-funded university or medical center. To try to come up with blanket statements regarding management at both of these types of businesses ignores their differences and disallows any flexibility in creating effective radiation safety programs. If anything at all should appear in the regulations themselves regarding managerial responsibilities, it should be a general statement that management is ultimately fiscally and administratively accountable for compliance with regulatory and license conditions.

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

No. For the same reasons mentioned in question 1 above, this is a bad idea. A program of twenty or forty authorized users does not require the same caliber of RSO as one with ten times that many and a medical center. Nor would the RSOs of each of these institutions necessarily have the same duties. In a small program, radiation safety is a one-man operation. In a larger program the duties must be spread over several managers.

Requiring minimum levels of education without weighing experience and non-degree training (such as from the Navy or ORISE) discriminates against otherwise highly competent applicants. On limited budgets, licensees need options in which they can find the right person for the job at an affordable salary.

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

No. This would be addressed better in guidance documents. The ability to weigh the qualifications of the Authorized User (considering the isotopes, procedures, equipment and facilities for which the person is applying) is supposedly addressed under the powers of the Radiation Safety Committee. These parameters can vary greatly at one single institution. To phrase a regulation addressing qualifications for all possible users at all possible broad-scope licenses would be nearly impossible.

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

This would best be handled under modified guidance documents in which more detailed suggestions could be made and more flexibility on handling the situation would be given to individual licensees. Procedures would be incorporated into individual licenses, which are equally enforceable by the NRC.

Jim Herrold's comments, continued:

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

The revisions to 10 CFR 20 were based in part on recommendations by the ICRP and NCRP, after twenty years of consideration and debate. It was expensive for the government and licensees to make these changes in written policies, training, dosimetry records and guidance documents. To go against these recommendations after only two isolated events would be a costly knee-jerk reaction.

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

No. Make the proposed revisions to Regulatory Guide 10.5 and leave it at that.

7. Should Broad Scope Licensees Be Allowed To Make Changes in Their Radiation Safety Programs Similar to Those Authorized for Production and Utilization Facilities in 10 CFR 50.59?

Yes, they should, but not entirely in the way suggested in the Federal Register. We have had the authorization under our license to make "ministerial" changes to our radiation safety program for almost four years and it has worked well for us. The conditions are almost the same as those in the proposed section 33.59 with some important exceptions. First, the letter incorporated into our license better describes what types of changes would be considered ministerial and what changes require a license amendment. This is a helpful detail, which might better be addressed in a guidance document instead of codified regulations. Second, the reporting requirements under paragraph 33.59(b)(2) are not a condition of our license. If complete records are kept and the changes are approved by the Radiation Safety Committee a full report to the NRC within 30 days of the change is an unnecessary waste of time and paper. The only purpose for the NRC requesting such a report would be so they can review the changes and deny them if they determine the changes were not within the scope of the regulations. What, then, is the purpose of the Radiation Safety Committee in this matter, and where is the advantage over how the regulations stand now? It would be better to either leave out section 33.59(b)(2) or allow individuals to request these changes in their individual license applications.

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?

In the light of the number of actual existing Types B and C licenses, this would not have much of an impact. However, the NRC should keep in mind the necessity for flexibility to allow Broad Scope licenses for programs ranging from relatively small to very large.

Jim Herrold's comments, continued:

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

In some cases this might make regulating these license locations more difficult. We have USDA labs housed on our University campus, which is a common practice. These labs used to be regulated under the USDA master license. More recently, however, an agreement was made with the USDA, the University and the NRC to place these laboratories under the University's NRC license. This has enhanced cooperation between the agencies involved and has made control over radionuclide usage in these facilities much simpler.

Comments from Richard Wilson, Assistant Supervisor, Hazardous Materials:

1. ***Should the responsibility of license management for the radiation safety program be specified in Part 33? (NRC is soliciting comment on the mechanism for, and the extent to which, requirements defining management responsibilities for oversight of radiation safety programs should be included in Part 33)***

This will lead to a standardization of the industry such that all institution and facilities with broad scope licenses have common practices and review standards. This will aid the smaller institution or facility, with limited resources, to concentrate on those areas that pose a significant risk if not managed properly. Larger facilities will spend less time on insignificant issues thereby saving time and money.

An effective mechanism to accomplish the required management aspects of an audit program is to establish a matrix. This management matrix would have the required section of 10 CFR 33 along the left side and the periodicity along the top. Then reviews can then be assigned by the RSC to individuals as necessary to complete the audit. Audits should be accomplished by independent reviewers, i.e. people from within the organization who do not have a vested interest in the outcome of the audit. These audits should be comprehensive and only done on an annual basis. Monthly, for each audit, there must be a supporting surveillance of the attribute or some portion of the attribute being audited.

The surveillance can and should be conducted by someone who directly supervises another person involved with the activity. This can then involve the RSO in the day to day operation of the facility that is under their management authority. The surveillance can also be used as a learning tool to improve the employee training by correcting improper procedures and explaining the "why's" of specific techniques.

As a portion of this, at facilities with over 500 employees, there should be designated an Assistant Radiation Safety Officer. The scope of the RSO position is such that it is impossible for one person to be able to conduct all of the required inspection, surveillance, and management tasks required in a larger facility, this should be incorporated into the license and 10 CFR 33. By better defining the management roles and responsibilities for the oversight of radiation safety smaller institutions would benefit greatly. Often at these institutions individuals are required to "wear several hats" and at times lines of authority can become rather "fuzzy."

Richard Wilson's comments, continued:

2. ***Should the NRC incorporate requirements for the duties and responsibilities of the RSO and the RSC? (The NRC is soliciting public comments on the need for specific requirements delineating the roles and responsibilities of the RSC and RSO and the establishment of minimum training and experience criteria for the RSO)***

This could unnecessarily constrict the scope of the RSO and the RSC's function. The idea that "one size fits all" cannot be applied to industry, education and research organizations. This would make it much more difficult for smaller institutions to maintain the necessary flexibility with more limited budgets and personnel. It also places a great deal of discretionary power in the hands of the NRC, to decide what are "necessary" qualifications and to whom they will apply.

3. ***Should the NRC specific minimum training and experience criteria for authorized users be incorporated into part 33? (The NRC is soliciting comment on whether training and experience criteria should be incorporated into the regulations or be addressed in guidance documents.)***

Training and experience should be established as guidance only. An increasing trend in this country is that of education via non-traditional means. In addition there are very few institutions in the country that offer curricula to train a RSO in the proper management techniques required for management of byproduct material. Simply having a degree in a scientific or engineering field is not sufficient qualification for a RSO. Certification by reputable professional organization would be more appropriate.

4. ***Should the NRC incorporate specific requirements for inventory and accountability of byproduct material in use, or modify its existing guidance.(The NRC is soliciting comments as to codification, in the regulation, of requirements regarding accounting for, and inventory of radioactive materials.)***

This issue must be left to the individual institutions or facilities. The adequacy of security area establishment and inventory should be reviewed by the NRC and included in the application for the broadscope license at the time of renewal.

5. ***Should NRC consider the risks associated with internal exposure pathways separate from those associated with external radiation? (The NRC is soliciting comments on whether the risks from internal exposure should be considered separately from the risks from external exposure.)***

Considering the predominance of materials with low penetrating energies, but with high ionization constants, resulting in generally an insignificant external dose but with the potential for high internal exposures. It would be reasonable to view these exposures separately. A viable method must be developed stating the target organs and dose to activity ratios. A review of a facilities invivo and invitro program must be included in and emphasized by NRC inspections and the licensing process.

6. ***Are there any other specific aspects of the draft regulatory guide DG-0005 that should be codified in Part 33? (The NRC is soliciting comments on which, if any, aspects of the draft regulatory guidance for broad scope facilities should be codified in the regulations.)***

The only addition to 10 CFR 33 should be the inclusion of internal exposure control programs as a requirement to allowing a licensee to continue operations.

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 section 50.59? (The NRC is soliciting comments on allowing broad scope licensees to have the flexibility to make changes to their radiation safety program as is afforded to irradiator and nuclear power licensees.***

Yes. Broad scope licensees should have the flexibility to make procedural adjustments and program improvements without having to change or amend the broad scope license.

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 is soliciting comments on whether to eliminate types B and C specific licenses of broad scope.)***

No. This would severely limit smaller facilities and institutions to an unnecessary set of rules which would be very costly to the institution and the government.