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Secretary, U.S. Nuclear Regulatory Commission
Washington, D.C., 20555-0001

DOCKET NUMBER
PROPOSED RULE PR 35
(63FR43516)

Attention: Rulemakings and Adjudications Staff
Reference: *Federal Register*, August 13, 1998 (Volume 63, Number 156, page 43516 ff.)

Dear Sir:

This letter is in reference to the proposed changes to 10 CFR Part 35, "Medical Use of Byproduct Material".

1. We agree with commenters at the Public Meeting in San Francisco that a "committee of peers can have more influence on internal enforcement of policies than an administrator". Elimination of the requirement of a Radiation Safety Committee may be appropriate for very small operations authorized under the proposed 35.100, part 35.500, and possibly under part 35.200. However, we believe that the committee should remain mandatory for activities under part 35.300 and 35.400 or for larger operations involving imaging.

2. We believe that the Nuclear Regulatory Commission (hereinafter called "the Commission) should take this opportunity to make a significant change in the method of licensing of clinical uses of radioactive materials, namely, in the sections related to specific medical licenses and/or licenses of broad scope including medical uses (10CFR Part 33).

Specifically, we propose that the Commission recognize, as meeting license requirements in specific medical areas 35.100, 35.200, 35.300, etc., institutions that possess accreditation by recognized accreditation organizations that specify standards for operation of clinical services, for example, American College of Radiology, American College of Nuclear Physicians, American College of Radiation Oncology, or other similar professional accreditation groups. The regulation should include a reference to a list of accreditation organizations whose standards for safety meet or exceed those of the Commission and which perform regular on site accreditation inspections to ensure that the standards are met. We propose that the Commission would review the safety elements in the accreditation program to ensure that all Commission standards are met before approving it. The list of approved programs would be maintained on the web in a similar manner that is currently proposed for training accreditation.

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We propose that the Commission grant licenses to those institutions that furnish evidence that they possess such accreditation and that the Commission inspection program be changed to randomly accompanying accreditation inspectors. That inspection by the Commission would be limited to verification that the accreditation program (including accreditation inspections) continues to meet Commission safety standards. We propose that this would be a substitute for separate Commission-conducted inspections at licensee sites. Further, as a safeguard we propose that such licenses include a condition that the licensee be required to provide copies of their re-accreditation and notify the Commission within 30 days, if their accreditation is changed, suspended, or terminated. Likewise, the Commission would notify the licensees if the approval of an accreditation program has been rescinded.

Those licensees or areas of usage under a license that are not under a accreditation program approved by the Commission would continue to be licensed under the current licensing and accreditation system.

This proposal would encourage more self-regulation utilizing the accreditation programs in the various specialties that utilize radioactive materials that are regulated by the Commission. This licensing process would promote development of comprehensive safety programs that would review the quality of the medical service as well as the particular safety issues normally inspected by the Commission. Such a comprehensive review is an important element in the *benefit vs risk* assessment required for a "*risked based*" regulation. The reviewers and inspectors under the accreditation program would possess expert safety and clinical knowledge in their area of oversight; they might include requirements to have a member of the inspection team undergo training by the Commission. The change would also minimize redundant inspections of the limited safety issues that are to be regulated by the Commission under the proposed regulation. This could reduce the cost of such redundant reviews both to the licensees and to the agency.

We believe that this step would also address many of the concerns raised in the report by the NAS/IOM Report of 1996 entitled, " Radiation in Medicine – A Need for Regulatory Reform". It would be similar to accreditation of other areas of radiation medicine. This proposal also fits into the general goals of more streamlined regulatory processes in the "Reinvention of Government" initiative. Further, it could stimulate similar reforms at the Agreement State level and, overall, would greatly benefit the public which utilizes the services provided by licensees by encouraging high quality clinical practices as well as safety.

Very truly yours,

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