Agency Simplifies Medical Licensing Procedures

NRC Proposes Revised Regulations for Medical Use of Byproduct Material

The U.S. Nuclear Regulatory Commission (NRC) recently published a proposed revision of 10 CFR Part 35, its regulations that deal specifically with the medical use of byproduct material (*Federal Register*, July 26, 1985, pp. 30616-30651). In the summer of 1981, the agency began the revision because of the time-consuming nature of the licensing process under the current regulations. A quick review of the evolution of nuclear medicine from the regulator's perspective will help clarify the problem.

Over-the-shoulder approach

When byproduct materials were first introduced into clinical practice over three decades ago, neither the physician nor the regulator was certain of the direction or extent of future use. Radiation safety problems were not clearly defined, and few physician and technologist training programs had been developed. Thus, the regulatory method chosen to assure public health and safety was case-by-case review.

The regulations in Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material, noted that a license to use byproduct material would be granted if: the material would be used for a purpose authorized by the Atomic Energy Act, the applicant's facilities and equipment were adequate, and the applicant was qualified by training and experience to use the material safely.

Part 35, Human Uses of Byproduct Material, was first published in 1965. It clearly required that the authorized user be a physician licensed to dispense drugs in the practice of medicine. To obtain a specific license for medical use, the applicant had to submit a complete description of a radiation safety program.

A condition that required licensees to conduct their programs "in accordance with the statements and representations made in the application" was applied to each license. Any change in the program required a license amendment.

The single exception to this regulatory method was the general license established in Section 35.31, "General license for medical use of certain quantities of byproduct material." The general license was effective without filing an application or issuance of a license document. It authorized the use of a few named radiopharmaceuticals, when received as prepackaged individual dosages, for a few specific uptake, volume, and absorption clinical procedures.

Case-by-case review outdated

The case-by-case review method, originally established with the publication of Part 30 in 1956, allowed for the evolution of nuclear medicine from its birth through the invention of the technetium generator. Because of its nonspecificity, only a few additional paragraphs were added to the regulation following that development.

On the negative side, the criteria that the NRC developed over time for issuance of a license had become scattered in the regulations, agency guidance publications, licensing policy and procedures, and standard license conditions.

Under this system, which is still in place, it is difficult for an applicant to submit a nondeficient application simply because of the amount of detail required and the fact that the criteria are scattered. The requisite detail also impedes the implementation of new management and safety procedures because changes in the radiation safety program require NRC approval.

The NRC undertook the revision of Part 35 to reduce licensee and agency staff time consumed by the licensing process.

Simplified licensing process

The strategy developed by the drafting committee was to consolidate and clarify the essential radiation safety criteria that apply to the various medical uses of byproduct material. The source documents that provided the foundation for the regulation were gathered, sifted to remove items that do not apply to radiation safety, and consolidated.

Keeping in mind that the goal was to simplify the licensing process, the drafting committee purposely avoided addressing certain major technical issues such as physician training and experience criteria, and misadministration. The committee decided it was more appropriate to address them as separate items at a later date.

After reviewing the licensing process, the drafting committee did propose to allow applicants to review

(continued on page 1114)

(continued from page 1113)
their own training and experience credentials and day-to-day radiation safety operating procedures, and simply certify in the application that the requirements had been met.

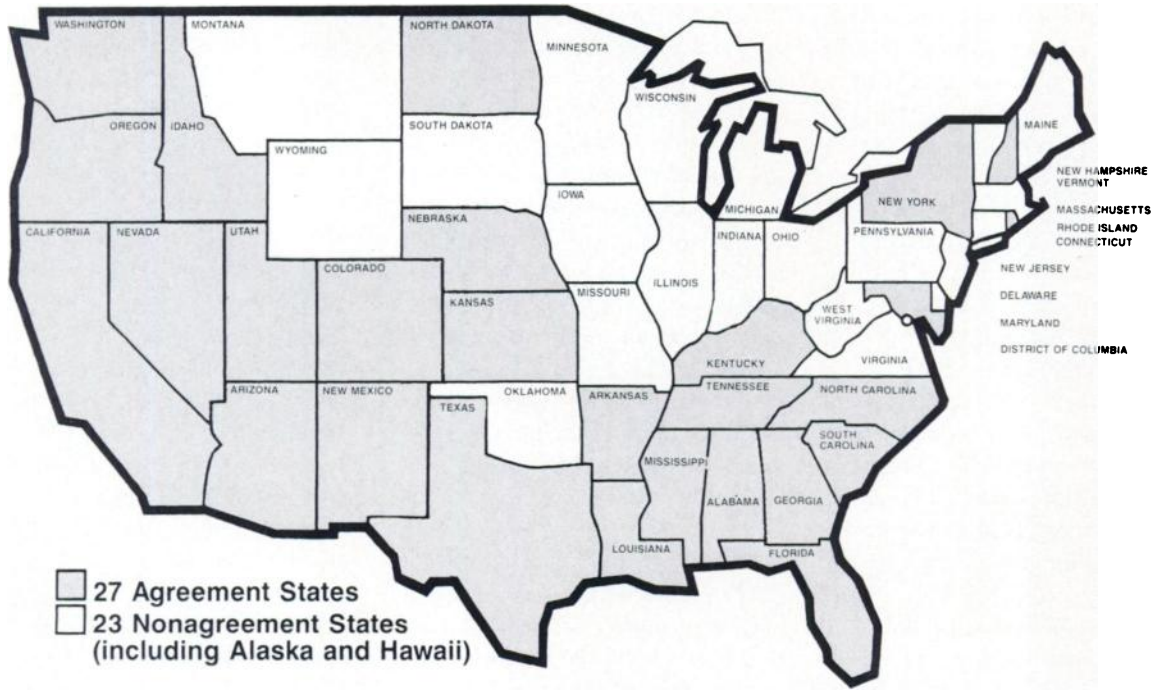
At a public meeting on that proposal, however, some NRC staff and representatives of the Agreement States expressed concern over the potential hazard of safety problems that, under the current application review system, are brought to light and resolved in the licensing process. (An Agreement State establishes its own licensing requirements and procedures under an agreement with the NRC.)

The NRC Commissioners directed the staff to revise the proposal to continue prelicensing review of physicians' credentials and applicants' operating procedures. The proposed revision, therefore, retains the current application process under which the entire radiation safety program is described, but allows licensees to make minor changes in their radiation safety programs. (Major changes that require an amendment are: new authorized users, new types of use, increased possession limits, and new locations of use; all other changes are, by tacit definition, minor.)

This revision of the regulatory process should reduce NRC medical licensing items by about 30 percent.

Although it will not relieve licensees of the paperwork burden associated with minor amendments because an internal approval process is required, it will avoid the lengthy turnaround time associated with license amendments, and the amendment fee.

NRC Agreement State Program



The 1959 Federal-State amendment to the Atomic Energy Act of 1954 was drafted to provide a definitive mechanism for adjusting federal-state relations in the area of atomic energy. This amendment's primary purpose was to authorize the Atomic Energy Commission (whose regulatory functions were reassigned to the newly established Nuclear Regulatory Commission in 1975) to relinquish to the individual states certain areas of regulatory jurisdiction.

"This approach reflected the general view that most citizens look to their local health officers for advice and protection against hazardous materials used in the community," according to the 1977 Final Task Force Report on the Agreement States Program (NUREG-0388).

Certain provisions were included to authorize the Commission to provide training and other services to state employees, and to authorize states to perform inspections in cooperation with the Commission. Kentucky became the first Agreement State in 1962, and the most recent addition was Utah in 1984.

As noted above, this draft of 10 CFR Part 35 does not include a re-examination of criteria for physician training and experience, which has been handled as a separate project. If the agency decides that changes are in order, they will be incorporated later in the rulemaking.

Misadministration issue

The misadministration issue is of particular interest to most licensees. During the pubic meeting on the proposed revision, the NRC Commissioners asked if the current misadministration reporting requirement had been modified. As noted above, the drafting committee had elected to retain the current rule.

Protection of patients from unnecessary radiation is considered to be an important facet of NRC's responsibility to protect the public health and safety. To some individuals, the suggestion that the misadministration reporting rule represents "an unprecedented intrusion into the practice of medicine" rings hollow.

"Supervision" clarified

Some licensees have been cited for noncompliance with requirements by allowing physicians who are not authorized users to interpret diagnostic studies. The rationale for the citations is that such a task is delegable only to a physician-in-training.

The proposed revision provides an operational definition of supervision that requires the authorized user to instruct supervised employees and be promptly available if needed. Thus, physicians who are not authorized users could interpret diagnostic studies if they do so under the supervision of an authorized user.

Agreement States voice concern

At this time it appears the major issue among the regulators regarding the rulemaking is the provision for minor radiation safety program changes without agency review and approval. The Agreement State program directors are almost unanimous in voicing concern about untoward events resulting from reduced agency oversight. Some believe that field inspections will take longer because inspectors will have to review program changes on site.

The drafting committee had said that inspection would be quicker because each licensee would be inspected against the same set of requirements.

Although Agreement States would not be required by the NRC to adopt this feature in their regulatory programs as a matter of compatibility, they believe it eventually "will be required by the pressure of circumstance."

Comments invited

The Administrative Procedure Act of 1946 as amended spells out steps that federal regulatory agencies must follow when preparing regulations. One of those steps is opportunity for public comment before a regulation is finalized and made effective.

The NRC has invited public comment on both the policy and technical features of the revision. A major point should be noted.

The public comment step allows affected persons and members of the public to bring to the attention of the agency facts or principles that should be kept in mind during the regulatory process–it is essentially a request for information that may not be available to the agency, or that may not have been given proper weight. It is not a vote-taking process.

If a regulatory agency has selected an improper goal (either too lenient or too stringent) or ignored alternative methods of meeting a goal, however, this step provides individuals an opportunity to help correct the mistake. Also, if the intent or method of a regulation is unclear, it can be corrected.

> "Under the current system, it is difficult for an applicant to submit a nondeficient application."

In addition to publishing the proposed revision of 10 CFR Part 35, the NRC has prepared a proposed revision of its Regulatory Guide 10.8, "Guide for the preparation of applications for medical programs," that contains instructions for applying for an NRC medical license, as well as many appendices useful to applicants and licensees who are designing or revising their radiation safety programs. The draft regulatory guide was distributed to affected licensees in August 1985 with a request that comments be submitted by November 18, 1985.

The public is encouraged to submit comments on the proposed revision. Each letter will be read, and all substantive comments will be addressed in the "Resolution of Comments" section that accompanies the final rule. Comments should refer to Federal Register Notice 50 FR 30616, Medical Use of Byproduct Material, and may be mailed to the Secretary of the Commission, Docketing and Service Branch, NRC, Washington, DC 20555.

Norman L. McElroy

Mr. McElroy is a health physicist in the NRC's Material Licensing Branch.