COMMENTARY

SUPPORT NEEDED FOR NRC PROPOSAL

After four years of internal deliberation, the U.S. Nuclear Regulatory Commission (NRC) finally announced a proposal that would reduce the impact of unnecessary regulations on the practice of medicine (see page 1113). The NRC staff managed to disentangle a briar patch of requirements for Human Uses of Byproduct Material (10 CFR Part 35) and put together a readable and meaningful set of regulations. The overhauling of 10 CFR Part 35 is welcome news to nuclear medicine, and we must make every effort to assure that the NRC codifies most of this proposed rule into a final rule. It's a definite improvement over current requirements, which are snarled within NRC regulations, guides, license conditions, and branch policies. The proposed revision would place all the regulations for clinical use of radioactive materials within one concise reference.

Even though the revision consolidates 30 years of licensing practice into one working document, however, it could go a bit further to redirect agency policy and settle some recent major issues. The commissioners are sensitive, for example, about misadministration, so the NRC staff did not change even the wording of the current misadministration rule. It appears that the commissioners are not likely to remove this reporting requirement in the near future. Another problem still with us is the revised training and experience criteria for physician users in various specialties. In this case, the NRC staff will probably go to the commissioners for guidance before publishing any proposed changes.

In spite of these unsettled areas, the 10 CFR Part 35 revision is a giant step forward for a more efficient licensing procedure without sacrificing any demonstrable safety factors. In addition to pruning away unnecessary rules for licensing, the 10 CFR Part 35 revision would cut down on the long hours and reams of paperwork required for filing requests for changes in current licenses. However, we need to encourage the commissioners to approve this revision and address these unresolved questions as well.

The agreement states have become involved in the debate over the revision. They endorsed the prescriptive text that establishes day-to-day requirements, but they objected to the section that allows licensees to make minor changes in their radiation safety programs. Although the technical basis for their concern is unclear, and although they would not be required to adopt the "minor change" feature as a matter of compatibility, their political clout should not be underestimated.

Approval of the 10 CFR Part 35 revision by the commissioners would be a giant step forward for the nuclear medicine community. But once that step is taken, I would also urge the agreement states to follow suit. Today there are 27 agreement states, which control their own licensing procedures. It is not enough to gain a regulatory improvement for only one-third of the medical licenses in the United States which are located in the 23 nonagreement states where the NRC licenses nuclear facilities. We need to lessen the impact of unnecessary regulations throughout the country.

For now, though, the immediate task before us is to write to the NRC and express our support, in general, for the proposed 10 CFR Part 35 revision. When you comment on the proposed regulation, keep in mind that we will all have to live with the final document for at least the next decade or two. This may be your last chance to comment on the misadministration rule, the requirement to follow package insert instructions, removable contamination levels, delegable chores, and so on.

The Society of Nuclear Medicine will be taking a close look at the regulatory analysis (value impact statement) that the NRC staff prepared to support the revision. But it is not enough for those in the nuclear medicine community to let their associations speak for them. The comments from organized groups need to be supplemented by comments from individuals. Without our input to challenge possible opposing comments from groups which fight any lessening of nuclear regulatory control, the NRC could receive an inaccurate reflection of public opinion on this issue. Comments may be addressed to: Secretary of the Commission, Docketing and Service Branch, NRC, Washington, DC 20555, and the deadline is November 18, 1985. If you miss it, you could miss a chance to help shape your own regulatory environment.

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