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December 16, 1998

BY HAND

DOCKET NUMBER
PROPOSED RULE PR 20, 32+35
(63FR43516)

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Rulemakings and Adjudications Staff

Re: Proposed Revision of 10 C.F.R. Part 35;
63 FED. REG. 43516 (Aug. 13, 1998); RIN 3150-AF74

Gentlemen:

I. Introduction and Summary

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals ("CORAR") in response to the proposal by the Nuclear Regulatory Commission ("NRC" or "the Commission") to revise its regulations governing the medical use of byproduct material. The proposal was published in the Federal Register of August 13, 1998, and, in a subsequent Federal Register notice (63 FED. REG. 64829), the comment period was extended until December 16, 1998.

CORAR members include manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical programs. CORAR members also operate nuclear pharmacies. CORAR appreciates the opportunity to submit these comments. CORAR has been actively involved both in this rulemaking and in the various activities which preceded this rulemaking. CORAR has previously supplied the Commission with comments on the approach this rulemaking should take (filed January 28, 1998), provided written and oral comments on the NRC's Strategic Assessment process, participated in the facilitated public workshops which both preceded and followed the publication of the proposed revisions to Part 35, and has met with the Commission staff to discuss many of these issues. In short, CORAR has been an active and, we believe, helpful participant in this important process.

Because of the time and effort CORAR has invested in assisting the Commission in revising Part 35, we particularly regret that the proposed rule falls far short of the goal which the Commission set for the staff: the creation of a performance-based regulatory scheme which

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recognized the low risk of the products and procedures involved. In its 1996 report on RADIATION IN MEDICINE: A NEED FOR REGULATORY REFORM, the National Academy of Sciences/Institute of Medicine concluded that "[c]ompared to the regulatory systems in place for the other 90 percent of medical use of ionizing radiation, the more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public." *Id.* at 171. The NAS/IOM Report also concluded that:

> [r]egulation of reactor-generated byproducts exceeds in intensity and burden that of all other aspects of ionizing radiation in medicine. The regulation of reactor-generated byproduct material is also more vigorous than that of any other aspect of high-risk health care. It greatly exceeds the regulation of chemotherapy, surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

Id. The NAS/IOM report labeled the NRC's current regulatory framework as "illogical" and "counterproductive" and stated that the NRC's regulation of the medical use of reactor generated byproduct material has "outlived its original logic." *Id.* at 175.

The safety of diagnostic nuclear medicine in part derives from the very low doses used. When it examined the issue, the National Council on Radiation Protection and Measurement found that "[m]ost diagnostic tests in nuclear medicine involve doses . . . well below thresholds for deterministic [*i.e.*, adverse] effects . . . ."[1]

The Commission itself has recognized the low risk involved in diagnostic nuclear medicine. In its Staff Requirements Memorandum (SECY-96-057), the Commission directed the staff to "describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation . . . " and to "consider regulatory oversight alternatives consistent with the lower overall risk of these procedures."

Instead, the Commission now proposes to revise, edit, and amend the existing regulatory structure without making any meaningful change to it. That is not the message the Commission delivered to the regulated community when this process started, and it is not the direction it gave to its staff. Whatever the reason, the proposed revisions to Part 35 offer little meaningful change despite the considerable time and energy invested by all concerned. Accordingly, we believe that the Commission must once again direct the staff to revisit this issue and to prepare a rule which has a meaningful relationship to the very low risks associated with nuclear medicine. We believe that a rule which accurately reflects the very low risks associated with nuclear medicine would

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[1] NCRP Commentary No. 7, "Misadministration of Radioactive Material in Medicine -- Scientific Background."

simply require observance of the radiation protection requirements of 10 C.F.R. Part 20 and the specification of appropriate training and experience requirements for authorized users. Any additional requirements are unnecessary and provide no public benefit. If the Commission disagrees with the undisputed body of evidence regarding the low risk posed by diagnostic nuclear medicine, then it must conduct a risk assessment to justify the requirements it seeks to impose.

CORAR also associates itself with the views and positions expressed in this proposed rulemaking by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

II. Background

The origins of the current review of the nuclear medicine program can be dated to the report of the National Academy of Sciences/Institute of Medicine. That report, commissioned by the NRC, concluded, among other things, that the NRC's regulatory oversight of nuclear medicine was unnecessarily burdensome and provided no benefit to patients or the public. The NAS/IOM report went on to propose that the NRC be divested of jurisdiction over nuclear medicine. Although CORAR originally supported that proposal, we were moved to reconsider that position when the Commission seemed to be willing to address many of the problems identified by the regulated community and the NAS/IOM report, especially the persuasiveness of prescriptive and unnecessary regulation. Accordingly, in our comments to the Commission on DSI No. 7, we supported the Commission's tentative conclusion to decrease regulatory oversight of low risk activities, such as nuclear medicine and nuclear pharmacy.

When the Commission directed the staff to undertake its review of Part 35, the Commission stated that: "The program [for revising Part 35] should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation . . . ." In that regard, the staff was directed to consider, among other things,

1. Focusing Part 35 on those procedures that pose the highest risk, and

2. For diagnostic procedures, consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.[2]

A year before the proposed rule was published, the Commission sought public input on how to best regulate nuclear medicine. Representatives of CORAR participated in the workshops held in Philadelphia and Chicago in October and November of 1997, and followed up

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[2] Memorandum to L. Joseph Callan, Executive Director for Operations (March 20, 1997).

with written comments in January, 1998. We believe that portions of our written comments bear repeating here:

> While the need to protect the public, workers and patients from unnecessary and excessive exposure to ionizing radiation associated with the medical use of byproduct material is recognized, we believe that these concerns are addressed without the need for invasive, prescriptive and categorical regulation of the medical use of radionuclides under Part 35. Under the Federal Food, Drug and Cosmetic Act (FFDCA) and its implementing regulations, there exists a comprehensive regulatory scheme that requires documentation of adverse effects relating to the use of all drug products, including radionuclides. Part [35] provides no added benefit to this comprehensive regulatory scheme as it applies to the medical use of radionuclides. In fact it is duplicative regulation that merely raises the final cost of these medical products to the patient. . . .
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> The NRC should follow its Strategic Plan (NUREG-1614, Volume 1) for Nuclear Materials Safety and "regulate material consistent with the level of risk involved by decreasing oversight of those materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities." Based on the established history of the performance of activities in the area of medical use, it is clear that this is an area where risk to the public is lowest. This warrants the elimination of specific regulations to protect the public from medical use materials. . . .
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> The perception is that this rulemaking effort has become an editorial exercise with an unrealistic deadline rather than a comprehensive re-write of regulations which, for the most part, should be deleted.

Sadly, the fears we expressed in January, 1998, have been amply borne out by the proposed rule and the draft guidance document, NUREG 1556, both issued in August, 1998.

III. The Proposed Rule

The proposed revision of Part 35 and the accompanying proposed revision of the Commission's Medical Policy Statement fall short of the risk-informed rule the Commission sought. Instead of developing a new, risk-informed approach to the regulation of nuclear medicine, the proposed rule largely tinkers with existing regulations, resulting in the continuation of a regulatory scheme that bears no meaningful relationship to the minimal risks posed by nuclear medicine. Indeed, concepts of risk seem to play little role in the proposed regulation.[3]

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[3] The Commission has indicated that it believes that there is a difference between a rule that is "risk-informed" and a rule that is based upon a risk assessment, and that it intended only to produce a risk-informed rule. It is unclear to us how a rule can be "risk-informed" if it ignores the body of evidence which demonstrates the safety of diagnostic nuclear medicine. As noted

The Commission's failure to abandon prescriptive, risk-insensitive regulations can be seen in a few examples:

1. Proposed section 35.63(d) provides that a licensee may not use a dose of a radiopharmaceutical if the dosage differs by more than 20 percent from the prescribed dosage. In view of the very low levels of radioactivity used in diagnostic radiopharmaceuticals, a dosage difference of 20 percent is a very small difference that is unlikely to impact either patient safety or the resulting image. Accordingly, CORAR believes that the nuclear medicine physician should determine whether or not to use a dose that differs by more than 20 percent.

2. Proposed section 35.69 concerns labeling of vials and syringes. The labeling of radiopharmaceuticals is regulated both by the Food and Drug Administration, which regulates the generator and cold kit labeling, and by state boards of pharmacy, which dictate the requirements for labeling dispensed doses. We see no reason for the Commission to add anything to this subject.

3. Proposed section 35.204 establishes a limit on molybdenum-99 content of technetium-99m and requires that a licensee that uses a molybdenum-99/technetium-99 generator check the molybdenum-99 content after the first eluate after receipt of the generator. As the molybdenum-99 content is regulated by FDA in generators subject to approved New Drug Applications, there is no reason to require the licensee to perform this duplicative test.

IV. Medical Policy Statement

As CORAR has previously stated in comments to the Commission, revisions to the Medical Policy Statement are futile because the Commission has not observed the provisions in effect since 1979. We recap those comments here.

1. "NRC will continue to regulate the medical uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public."

The radiation safety of workers and the general public can be, and is, protected by the provisions of Part 20. The addition of Part 35 adds nothing to public or worker protection. In addition, we note that the NRC's jurisdiction is limited to byproduct material, not all "radionuclides."

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above, CORAR believes that if the Commission disagrees with the existing data, it is obligated to conduct a risk assessment to justify, if it can, the requirements it seeks to continue or to impose.

2. "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public."

We find it hard to imagine those situations where the interest of the patient and the interest of workers or the public would clash. But if such an instance exists, we doubt that the NRC is the right body to intrude into medical judgments affecting patients since its experience in this area is extremely limited.

3. "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides in accordance with the physician's directions."

CORAR believes that any attempt by the NRC to regulate the radiation safety of patients would duplicate the efforts of the Food and Drug Administration and the state boards of medicine and pharmacy. Any such attempt would, therefore, be an unwarranted intrusion into the practice of medicine.

4. "NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety."

The current provision on this point, which is part of the statement on protecting the radiation safety of patients, provides that NRC would only regulate in the absence of voluntary standards, or where such standards are not observed. Sadly, it does not appear that the NRC has honored the existing policy; it does not look to professional standards to protect patients, when it is, in fact, precisely such standards which offer the first line of protection to patients. CORAR sincerely hopes that, in proposing the new policy, the Commission will accord to industry and professional standards the respect they deserve. In the preamble to the proposed rule, the NRC said that it endorsed the concept of "emphasizing, where possible, the use of standards developed by private, consensus organizations." 63 FED. REG. at 43586. If it translates that endorsement into action, the revised policy may prove to be a needed and valuable improvement. If, on the other hand, the NRC changes its policy statement but not its policy, then nothing meaningful will have been accomplished.

V. Conclusion

For the reasons stated above, CORAR respectfully concludes that the Commission has failed to produce a risk-informed rule to govern diagnostic nuclear medicine. CORAR believes that the documented history of the safe use of nuclear medicine products compels a conclusion that nothing beyond observance of 10 C.F.R. Part 20 and appropriate training and experience

requirements are needed to protect patients and the public. Indeed, if the Commission believes otherwise, the rulemaking record is devoid of support for that position. Accordingly, the Commission must assemble data in support of its rule if the rule is to withstand legal scrutiny.

Respectfully submitted,

Roy W. Brown
Chairman, Health Care Committee

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