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TO:

Chairman Meserve

FOR SIGNATURE OF : ** GRN **

CRC NO: 02-0019

DESC:

NRC Regulation of Diagnostic Nuclear Medicine
- 10 CFR Part 35

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For Appropriate Action.

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American College of Nuclear Physicians/Society of Nuclear Medicine
GOVERNMENT RELATIONS OFFICE

January 9, 2002

The Honorable Richard A. Meserve
Chairman
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Re: NRC Regulation of Diagnostic Nuclear Medicine

Dear Chairman Meserve:

On behalf of The Society of Nuclear Medicine and the American College of Nuclear Physicians, we greatly appreciate the time you took to meet with our representatives on December 19th to discuss our concerns about further reducing unnecessary regulation and costs imposed on diagnostic nuclear medicine. There has been considerable interaction with the Commission and staff during the development of 10 C.F.R. Part 35, however, there has been a disappointing lack of constructive dialogue and a summary dismissal of the formal petition which we submitted at your suggestion. This is why we appealed to Congress and why we hope that this new opportunity will not have a similar outcome. We recognize that much of the work to develop the revisions to 10 C.F.R. Part 35 as adopted by the Commission on October 23, 2000 was completed prior to your tenure as Chairman and that we have not previously had an opportunity to discuss Part 35 in depth with you. At the same time, the leadership of the Society and the College has changed over the years as well, giving us the opportunity to review the Commission's actions with a fresh eye. We believe that our meeting was a useful beginning to what we hope will be a productive dialogue. We recognize, as you noted, that while you are the Chairman, you are but one of five Commissioners. We are taking the liberty of sending copies of this letter to your fellow Commissioners and would welcome an opportunity to meet with them as well.

As we discussed, Congress has prohibited the Commission from implementing the new Part 35 insofar as it relates to diagnostic nuclear medicine (with the exception of the new training and experience requirements) until the Commission reports to Congress on why the burden imposed could not be further reduced. (The Office of Management and Budget, which reviewed Part 35 pursuant to the Paperwork Reduction Act, also conditioned its approval on a review of the burden imposed.) On behalf of the diagnostic nuclear medicine community, we asked you to use the Congressional directive as an opportunity to engage in a joint effort with us to further streamline the regulations

that apply to such inherently safe procedures. We have never advocated the “deregulation” of diagnostic nuclear medicine. While diagnostic nuclear medicine is, in fact, safer than most medical procedures that are essentially unregulated by the Federal government, we recognize that the public’s perception may be at odds with the reality. Our concern, however, involves the level of regulation imposed. As we noted during our meeting, the National Academy of Sciences/Institute of Medicine report on the Commission’s medical use program concluded that it could not identify any additional benefit to the public from such a high level of regulation. We recognize that the Commission has made progress in removing some of the regulatory burden on diagnostic nuclear medicine in Part 35. However additional significant changes are needed. Because of the low level of radioactivity, extremely low radiation risk intrinsic to diagnostic nuclear medicine, and the absence of any demonstrable harm, many of the Commission’s proposed requirements regarding diagnostic nuclear medicine are not risk-based or risk-informed and, therefore, are simply unnecessary. In the Attachment to this letter, we specify, as you requested, changes that should be made to Part 35 to further reduce the unnecessary regulatory burden imposed on diagnostic nuclear medicine without compromising the protection afforded to patients, workers, and the public. In addition, Part 35 cannot be looked at in isolation. The Commission’s regulatory framework consists of several interrelated documents, including Title 10 of the Code of Federal Regulations (especially Part 20), statements of policy, regulatory guides, and licensing and inspection procedures. Requirements that have been eliminated in Part 35 have reappeared in other documents. As you requested we provide some examples of this in the Attachment.

It is essential to eliminate the use of license conditions and regulatory guidance that replace requirements that have been removed from the regulations. Regulation by license conditions has been ongoing for over 50 years, but this practice should be discontinued. In 1966, Atomic Energy Commission Chairman Glenn Seaborg appointed a Radioisotopes Licensing Review Panel to review the regulations of the AEC. One of their conclusions was that emphasis on the licensee’s own responsibilities for developing safe radiation practices will produce better results than detailed regulation and licensing conditions (see http://search.dis.anl.gov/plweb-cgi/mhrexpage.pl?0717604+1+65+_free).

Some examples where license conditions add requirements not present in the revised Part 35 or remove the rights given in the regulations are:

1. While Section 35.200 states that a “licensee may use *any* unsealed byproduct material prepared for medical use for imaging and localization studies...”, licensing takes away this privilege because the licensee is limited to the use of specified radioisotopes. Inspectors are instructed to check for “unauthorized uses of licensed material” by NRC Inspection Manual Temporary Instruction 3800/029, Revision 1 dated August 28, 2000.
2. The Commission contradicts its revised Policy Statement on the Medical Use of Byproduct Material, which provides that the “NRC will not intrude into

medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public,” since the Commission does not permit, by license (despite the regulations stating otherwise), physicians to use *any* appropriately authorized and available diagnostic radiopharmaceutical. Unless this is changed, a physician is forbidden by his or her license to use a radiopharmaceutical for an indication deemed appropriate by a licensed Authorized User.

3. “Guidance” procedures in NRC NUREGs (*e.g.*, NUREG-1556, Volume 9, dated July 2001) add requirements that do not appear in Part 35 regulations. Regulatory guides should provide guidance that conforms to current CFR requirements. NUREG-1556, Volume 9 provides guidance to an applicant in preparing a medical use license and also provides guidance on NRC criteria for evaluating a medical use license application. This guidance document corresponds to the revised 10 C.F.R. Part 35 and is not meant to be a substitute for the regulations. The regulations require the licensee to develop, document, and implement procedures that will ensure compliance with the regulations. Model procedures in NUREGs should not have to be adopted; licensees may develop their own procedures to comply with the applicable regulations. While this appears to be a useful tool, it is of limited real value since the licensee’s own procedures are not submitted as part of the license application. As the NRC staff in response to a comment in NUREG-1556, Volume 9, explains, “The adequacy of the licensee’s procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.” It is unreasonable to expect many licensees to deviate from the Commission’s “guidance” if the first time its alternative is examined is during an inspection. If a procedure is found wanting this could result in license revocation or fines. Thus, the Commission’s guidance is likely to become *de facto* regulation, thereby undermining the goal of providing licensees with additional flexibility.

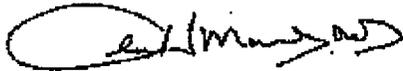
Another issue that is central to the concern of the diagnostic nuclear medicine community is the intermingling of requirements for diagnostic and therapeutic nuclear medicine. Part 35 contains regulations for both uses of byproduct material (not just nuclear medicine but also brachytherapy, remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units). Were the requirements for diagnostic nuclear medicine to be separately stated from those governing therapeutic nuclear medicine, it would become much clearer that certain regulatory provisions have been eased and that certain requirements, appropriate for therapeutic use, are inappropriate for diagnostic nuclear medicine.

As we proposed during our meeting, a cooperative effort by the Commission and the diagnostic nuclear medicine community could readily make the additional changes to reduce the regulatory burden imposed by Part 35. These reductions in regulatory burden

would not adversely affect public health and safety. Should the Commission agree to such an approach, we would join with the Commission in asking Congress for additional time in which to respond to its directive.

Thank you again for taking the time to meet with us. We believe that the issues we have raised can be resolved to the benefit of patients, the public, and the medical community, and we look forward to working with the Commission to do so.

Very truly yours,



Alan H. Maurer, M.D.
President
Society of Nuclear Medicine



Gary L. Dillehay, M.D.
President
American College of Nuclear Physicians



Jeffrey A. Siegel, Ph.D.
Chair,
ACNP/SNM Government Relations Committee

cc: Commissioner Greta Joy Dicus
Commissioner Nils J. Diaz
Commissioner Edward McGaffagan, Jr.
Commissioner Jeffrey S. Merrifield

Attachment to Letter to The Honorable Richard A. Meserve

Proposed Revisions to 10 C.F.R. Part 35 (as adopted by the Commission on October 23, 2000)

35.6 Provisions for the protection of human research subjects.

Subsections (a) and (c) should not apply to diagnostic nuclear medicine. The NRC should not make regulations on human research a license condition as research involving approved diagnostic nuclear medicine agents containing byproduct material should be permitted so long as the investigator complies with the existing Federal Policy for the Protection of Human Subjects.

35.10 Implementation.

Paragraphs (b), (c), and (d) mention license conditions.

Eliminate license conditions for any diagnostic nuclear medicine use.

35.13 License amendments.

Paragraphs (a) and (d) involve license conditions.

No license amendment should be required (*e.g.*, it is not required if licensee adds to or changes areas of use for diagnostic nuclear medicine per paragraph (e), only that NRC must be notified of this change pursuant to 35.14(b)(4)). According to 35.200, "licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies" as long as the material is obtained and prepared according to the requirements in this section. No mention is made of license authorization as in paragraphs (a) and (d) as long as the material is obtained or prepared properly a licensee should be able to use it. The requirement in these two paragraphs should be eliminated as it unnecessarily limits licensee access to byproduct material for use in diagnostic nuclear medicine due to the need for license amendments.

35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

For diagnostic nuclear medicine use of unit dosages, paragraph (b)(2)(i) or (ii), or non unit dosages, paragraph (c)(3), supplied by Part 32 licensees or equivalent Agreement State licensees, a dose calibrator is not necessary and no further documentation above that supplied by the Part 32 licensee (as required in 10 C.F.R. § 32.72) or equivalent Agreement State licensee should be required. Licensees can use the values (decay corrected) as supplied and should not have to be required to again record the activity of these dosages.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

This should be eliminated for diagnostic nuclear medicine since the NRC should not be prescribing what is medically acceptable.

35.204 Permissible molybdenum-99 concentration.

Licenses performing diagnostic nuclear medicine have no way of assuring compliance with the molybdenum-99 concentration limit since they are not required to have dose calibrators if they only use unit dosages and/or non unit dosages obtained from Part 32 licensees or equivalent Agreement State licensees according to 10 C.F.R. § 35.63. Similarly, they are therefore unable to keep the records of molybdenum-99 concentration required by section 35.2204.

The following requirements do not appear to apply to diagnostic nuclear medicine and, thus, lead to confusion rather than simplification. It would be clearer to indicate that these are likely to apply only to therapeutic uses of byproduct materials.

35.27 Supervision.

The level of supervision is not appropriate for diagnostic nuclear medicine.

35.2045 Records of medical events.

35.2047 Record of a dose to an embryo/fetus or a nursing child.

35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

35.2063 Records of dosages of unsealed byproduct material for medical use.

35.3045 Report and notification of a medical event.

35.3046 Report and notification of a dose to an embryo/fetus or a nursing child.

Some of the requirements that have been eliminated reappear in NUREG-1556, Volume 9.

35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

The majority of diagnostic nuclear medicine licensees use unit dosages and/or non-unit dosages obtained from a manufacturer or preparer licensed under section 32.72 or equivalent Agreement State requirements. According to section 35.63, diagnostic nuclear medicine licensees using these dosages do not require a dose calibrator. This section could be made clearer to indicate that diagnostic nuclear medicine licensees do not require a dose calibrator. The dose calibrator procedures are, however, reinstated as proposed Appendix J (entitled "Model Procedures for Dose Calibrator Calibration") recommendations in NUREG-1556, Volume 9. Thus, licensees that commit to NUREG-1556, Volume 9 may be required to perform procedures not required in the regulations.

35.70 Surveys of ambient radiation exposure rate.

(a), (b), and (c). Area radiation and contamination surveys are no longer required for diagnostic nuclear medicine.

With the removal of these specific requirements for diagnostic nuclear medicine, the more general requirements of Part 20 (specifically, 10 C.F.R. § 20.1101 and 10 C.F.R. § 20.1501(a)(1) and (2)) apply. Basically, 10 C.F.R. § 20.1501(a)(1) specifies conducting surveys that may be necessary to demonstrate Part 20 compliance. Section 20.1501(a)(2) also requires that these surveys are reasonable under the circumstances to evaluate: 1) the magnitude and extent of radiation levels, 2) concentrations or quantities of radioactive material, and 3) the potential radiological hazards. Thus, according to Part 20, no surveys would be reasonable for diagnostic nuclear medicine (except perhaps after a spill or contamination event) since it is not likely that exposures may exceed 10% of occupational limits or that members of the public would receive doses in excess of those specified in 10 C.F.R. § 20.1301. These area radiation and contamination surveys are, however, reinstated as proposed Appendix R (entitled "Model Procedures for Area Surveys") recommendations in NUREG-1556, Volume 9. Thus, licensees that commit to NUREG-1556, Volume 9 may be required to perform surveys not required in the regulations.