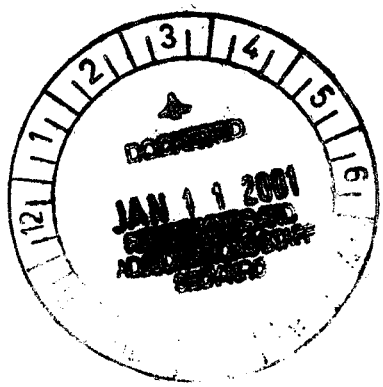
# ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE




January 3, 2001

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

**PETITION FOR RULEMAKING**

Pursuant to the provisions of 10 C.F.R. § 2.802, the undersigned Society of Nuclear Medicine and American College of Nuclear Physicians hereby petition the Commission to rescind its approval of the staff's proposed revisions to 10 C.F.R. Part 35 and, instead, to institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine which reflects the discipline's unparalleled and undisputed safety record.

## I. INTRODUCTION AND SUMMARY OF PETITION

> "Compared 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 [subject to NRC regulation] do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public."
>
> National Academy of Sciences-Institute of Medicine, RADIATION IN MEDICINE - A NEED FOR REFORM at p. 171 (1996).

The Society of Nuclear Medicine (the Society) and the American College of Nuclear Physicians (the College) hereby petition the Commissioners of the Nuclear Regulatory Commission (NRC) to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine which reflects the discipline's unparalleled and undisputed safety record. Irrationally, the NRC regulations applicable to diagnostic nuclear medicine eclipse by a wide margin the regulatory controls imposed on other dramatically more dangerous medical products and procedures. The goal of this petition is to end that unsupportable and extraordinarily expensive program. Our proposed regulatory scheme, which would assure the continued extremely safe use of diagnostic nuclear medicine products and procedures while saving the Nation millions of dollars a year, is discussed in detail in Section II, below.

The Society and the College, representing 14,000 nuclear medicine physicians, nuclear pharmacists, nuclear medicine technologists, nuclear and medical physicists, radiochemists,

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radiation biologists and other scientific specialists associated with nuclear medicine, believe that there is no scientific, medical, or public policy basis for most of the Commission's requirements governing diagnostic nuclear medicine. Despite recurring promises to the contrary, the Commission has never adopted a regulatory scheme that matches its requirements to the acknowledged minimal risks posed by diagnostic nuclear medicine. The Commission has spent almost two years revising the regulations governing nuclear medicine in 10 C.F.R. Part 35. The revised Part 35 was to be an enlightened, "risk-informed" regulatory scheme that recognized the minimal risk of diagnostic nuclear medicine. In fact, the revisions to Part 35 adopted by the Commission on October 23, 2000 offer little meaningful change from the existing regulations. Just as the Commission ignored the recommendation of the National Academy of Sciences-Institute of Medicine because it disagreed with them, the Commission staff appears to have completely ignored every significant recommendation made by professional experts board certified in nuclear medicine and nuclear pharmacy. Combined with NRC's increased use of "license conditions" to impose requirements that do not appear in its regulations, the new supposedly "risk-informed" regulations will in fact mark a step backward, not forward. Despite its pledge to adopt a "risk-informed" scheme, the Commission has adopted yet another regulatory scheme that bears no relationship to the risk sought to be protected against, and which will, by its substantial unnecessary costs, adversely impact health care. At a time of ever-increasing demands on limited health care dollars, this approach is unconscionable and must be changed. This is not an insignificant problem. The average American receives 3.8 nuclear medicine diagnostic procedures over his lifetime. The new regulatory product devised by NRC may well adversely affect the entire nation.

## II. ACTION REQUESTED

In order to more accurately match the regulatory scheme to the minimal risks presented, the Society and the College petition the Commission to regulate the use of byproduct material in diagnostic nuclear medicine solely by:

1. Protecting workers, the general public, and the environment through the radiation protection standards of 10 C.F.R. Part 20;

2. Ensuring the protection of patients, workers, the public, and the environment by enforcing comprehensive education, training and experience requirements for the use and possession of byproduct materials;

3. Relying on health care professionals with the required education, training, and experience in nuclear medicine, nuclear pharmacy, and basic nuclear and radiation science to protect the health and safety of their patients under the supervision of their respective State Medicine and Pharmacy Boards;

4. Revoking all of Part 35, except for requirements concerning comprehensive education, training, and experience of Authorized Users, coupled with a new

provision that would require evidence of mastery of basic nuclear and radiation sciences by passage of an examination given in this field by a board certified by the American Board of Medical Specialties or a single alternate examination equivalent in scope and depth to that covered in the certified boards and approved by the ACMUI;

5. Ceasing the subdivision of diagnostic nuclear medicine into smaller and smaller fragments. After completing comprehensive education, training, and experience in basic nuclear and radiation sciences, and passing an appropriate comprehensive examination in these areas, as defined in (4), above, an Authorized User may subspecialize in any portion of diagnostic nuclear medicine he/she wishes without further Commission restriction;

6. Removing all license conditions except for simple identification. This includes the name, address, e-mail address, telephone, and fax numbers of the institution, the responsible administrator, and the RSO. The license should simply state, "This license permits the possession, use, transport, and disposal of any byproduct material, in any physical or chemical form, in any quantity, for diagnostic nuclear medicine use including clinical use, research, quality control, teaching, and related diagnostic nuclear medicine professional activities." In the case of presently limited licenses, such as in nuclear cardiology, "diagnostic nuclear cardiology" should replace "diagnostic nuclear medicine." The license should also state that, "This license does not cover diagnostic uses of radiopharmaceuticals containing more than 30 microcuries of I-131."

7. Inspecting diagnostic medical licensees only in those rare situations of likely overexposures of workers, the general public, or the environment. The routine inspections now being conducted are an invitation to document meaningless paperwork "deviations" and which impose substantial unnecessary costs on licensees. As far as patients are concerned, cases of possible malpractice will be handled under existing State law by the Boards of Medicine and/or Pharmacy and the courts, without NRC involvement unless specifically requested by the Board or the Court.

8. Decreasing the size of the staff assigned to the medical use program to adequately reflect the limited role the Commission plays in assuring diagnostic nuclear medicine safety. This staff adjustment has been long overdue. As the number of NRC medical licensees decreases because of the increase in Agreement States, the number of employees assigned to the medical program paradoxically increases. Because Congress requires that the NRC recover its costs from licensees, fewer and fewer licensees are supporting an increasingly bloated NRC program. A properly sized staff alone would dramatically reduce the escalating cost of holding an NRC license.

Adoption of this proposal would assure radiation protection of patients, workers, the public, and the environment by focusing on the competence of practitioners in the basic nuclear and radiation sciences, eliminate requirements that negatively impact patient care, and end unnecessary dual regulation and meaningless paperwork and regulatory compliance costs estimated at $500 million to $1 billion annually.

We are not asking for a "deregulation" of diagnostic nuclear medicine in the usual meaning of the word, which implies a decrease in safety standards.[1] We are asking that the safety standards in 10 C.F.R. Part 20 ***continue to apply unchanged***. Instead, we are asking the NRC to remove the prescriptive regulations and license conditions that purport to tell highly qualified individuals how to achieve those safety standards. Qualified professional Authorized Users have significantly more training and real-life experience than regulators in providing the highest level of protection and safety to their patients and others. Complying with the NRC's onerous, yet ultimately unnecessary, regulations has become such an onerous task that the NAS-IOM condemned NRC's medical program in its entirety. The Society and the College believe that the recent Part 35 rewrite is ample evidence of the staff's inability to make meaningful changes to a program upon which they depend for their jobs. Accordingly, the Society and the College request that the Commissioners assign the review and evaluation of this Petition to staff members who have no vested interest in the continuation of the existing program.

## III. STATEMENT OF GROUNDS

The Society and the College believe that the unparalleled history of the safe use of diagnostic nuclear medicine products and procedures is, in itself, more than adequate support for the action requested by this Petition. That history is summarized below. For additional background, the Commission is respectfully referred to the report of its own contractor, the National Academy of Sciences-Institute of Medicine, RADIATION IN MEDICINE - A NEED FOR REGULATORY REFORM (1996), which meticulously documented the utter lack of connection between the Commission's regulatory scheme and any benefit to patients or the public.

### *A. Nuclear medicine*

Diagnostic nuclear medicine is a medical specialty that uses extremely safe radioactive drugs (tracers) to gain information about health and disease, often using modern imaging techniques. As an integral part of patient care, diagnostic nuclear medicine is used in the diagnosis, management, and prevention of serious disease. Nuclear medicine imaging procedures often identify abnormalities very early in the progression of a disease, before these medical problems are apparent with other diagnostic tests. This early detection allows for prompt treatment when the prognosis may well be much better than if the disease were allowed

[1] Although this petition deals solely with diagnostic nuclear medicine, the Society and the College believe that essentially the same arguments can be made to reduce the burden on the practice of therapeutic nuclear medicine.

to progress. Each year in the United States, over 13 million nuclear medicine procedures are performed on patients. Common diagnostic nuclear medicine procedures include radiopharmaceutical cardiac stress tests to analyze heart function, bone scans to diagnose orthopedic injuries or cancer which has spread from other organs, tumor imaging, staging of cancer, lung scans for blood clots, and liver and gall bladder procedures to diagnose abnormal function or blockages.

Diagnostic nuclear medicine procedures are among the safest patient diagnostic tests available, considering adverse drug reactions, vascular complications, anatomical disruption by foreign bodies, anoxic tissue complications, and radiation. The amount of radiation in a diagnostic nuclear medicine procedure averages 440 mrem effective dose equivalent (ede), according to NRCP Commentary No. 7, published Oct. 1, 1991 and paid for by the NRC using medical licensee User Fee money. (This number is somewhat lower today, due to significant replacement of Ga-67 citrate and In-111-white blood cell imaging by Tc-99m-HMPAO-white blood cell imaging, and a rise in the use of Tc-99m labeled cardiac tracers significantly replacing Tl-201 chloride use.) This compares with a United States average of 300 mrem natural background per year, 530 mrem in Denver, 600-700 mrem/year in Colorado ski areas, and 100 mrem/year for every 100,000 miles flown in an airplane. None of these radiation absorbed doses are dangerous and none are regulated by anyone, nor should they be.

Nuclear medicine is practiced only by state-licensed physicians who are assisted by technologists and are supported by specially trained physicists and pharmacists. Nuclear medicine combines chemistry, physics, mathematics, computer technology, and medicine in using radioactivity to diagnose and treat disease. Physicians certified by the American Board of Nuclear Medicine first must receive a medical degree and have one or more years of training in a medical specialty other than nuclear medicine. A further two years of training in nuclear medicine is then required during which special instruction is given in physics, radiopharmacy and radiation biology, as well as patient evaluation, radionuclide therapy and diagnostic studies. After successful completion of at least three years of post-doctoral training, a physician may take certifying examinations.

Nationally approved training programs for nuclear medicine technologists have been in existence for many years. These include training in radiation safety, the correct handling of radioactive materials, and techniques of performing nuclear medicine examinations.

In addition, radiopharmacy companies, universities and teaching hospitals provide specialized training to state-licensed pharmacists who specialize in compounding reliable and safe radiopharmaceuticals for patient examinations. Nuclear pharmacy is a board certifiable subspecialty of pharmacy.

### *B. The History of Nuclear Medicine Regulation*

The entire predicate of the NRC's regulation of diagnostic nuclear medicine appears to be that radiation from byproduct materials poses significant risks to patients, workers and the public. That predicate is demonstrably untrue. In fact, diagnostic nuclear medicine is extremely safe, and its use by properly trained health care professionals poses no undue risks. Accordingly, as the NAS-IOM concluded, the regulatory structure imposed on diagnostic nuclear medicine by the NRC is a costly and unnecessary burden that yields no benefit to patients, workers, or the public.

In the 64-year history of nuclear medicine in the United States, about ***one-third of a billion*** radiopharmaceutical doses have been administered. Since imaging devices were invented in the early 1950's, far more diagnosis has been performed than therapy. In recent decades, 99.5% of nuclear medicine is diagnostic. There has been one case, in the 1950's, of a radiation death due to a diagnostic radiopharmaceutical. This happened when the patient accidentally was given 1000 times the activity ordered by the physician. The tracer, Au-198 colloid, has not been used in diagnostic nuclear medicine in this country for about 40 years. This event also occurred before there was board certification in nuclear medicine, nuclear pharmacy, and nuclear medicine technology. The mistake, due to human error, would not have been avoided through any of NRC's present regulations and license conditions in any case. NRC's "Quality Management" Rule was shown recently *by the NRC* not to improve quality at all, as the number of human errors did not change with this rule in place (Secy-97-037).

A spectacular safety record like this is unknown in the rest of medicine, and reflects the intrinsic safety of the tracers in the hands of well-educated, trained, and experienced professionals. NRC regulation is not the reason nuclear medicine is safe. From 1936-1975, accelerator-produced radiopharmaceuticals were prepared for patient use solely under the authority of State Boards of Pharmacy and Medicine. FDA did not begin regulating radiopharmaceuticals until 1975, after intense insistence by the Atomic Energy Commission/Nuclear Regulatory Commission, which at the time (and wisely) did not want to regulate byproduct (reactor-produced) radiopharmaceuticals and human research any longer. Some States had put some radiation regulations in place by the 1950's and 1960's, but these were relatively benign. ***Nonetheless, nothing bad happened.*** To this day, there is no federal regulator of professionals who use accelerator-produced radiopharmaceuticals for patient care; state regulation is adequate. This, in a sense, is the "control" experiment of what would happen without NRC. Indeed, P-32 and I-131, two of the more dangerous therapeutic radionuclides used in nuclear medicine, were made by accelerator for many years before they were made by reactor. There is no evidence that there were any problems when these drugs were accelerator-produced and used without a federal (or even a State, in the early days) regulator.

Under Section 81 of the Atomic Energy Act (the AEA), the NRC regulates the medical use of reactor-generated radioactive materials to protect the public health. 42 U.S.C. § 2111.

The NRC's responsibilities include the regulation of radiopharmaceuticals and sealed sources. The NRC does not regulate machine-produced x-rays nor naturally occurring or accelerator-produced radioisotopes (such as those used in positron emission tomography).

Congress amended the AEA in 1954 to promote civilian uses of the atom, protect the public health and safety, and promote the common defense. Congress promoted civilian uses of the atom by funding isotope production and basic research using radioactive material, while public health and safety were accomplished by carefully licensing the use of radioactive material.

About 20 years later, Congress dissolved the Atomic Energy Commission, and two federal agencies took over and divided the duties previously carried out by the AEC. 42 U.S.C. §§ 5814 & 5841. The Energy Research and Development Agency (precursor to the U.S. Department of Energy) became the promoter of civilian uses of the atom, while the safety oversight authority (licensing and regulatory functions) of the AEC was assigned to the NRC. At approximately this time, FDA, under intense AEC pressure, announced that it was resuming its statutorily authorized practice of licensing and approving radiopharmaceuticals for sale in interstate commerce. Until this time, the FDA deferred to AEC/NRC licensing and regulation of radiopharmaceuticals. 40 FED. REG. 31298 (July 25, 1975).

The States have broad regulatory authority over the general public health and safety of their residents, including authority over all sources of ionizing radiation (except for any authority preempted by the Federal government). The AEA permits States to obtain authority to regulate by-product material by becoming an Agreement State. The NRC formally will relinquish its regulatory authority to an Agreement State based on the NRC's determination that the State's program is adequate and compatible with NRC's. 42 U.S.C. § 2021(b). One problem of late is that "adequacy" and "compatibility" are constantly moving targets, with increasing NRC demands that an Agreement State's medical program (including nuclear pharmacy and medical research) look more and more like NRC's. Twenty years ago, no adequacy and compatibility was expected other than with 10 CFR Part 20, the basic radiation safety standard of the United States. The fact that the number of staff members in the medical and academic program have gone ***up*** as the number of licensees has gone ***down***, reflects poorly on the Commission. In addition, the decision by Congress to require that NRC earn virtually all its operating funds through User Fees has put a huge burden on medical licensees. When they finance no additional benefit to patients or the public, User Fees are especially distasteful.

The use of radioactive material has been a highly regulated activity. All uses and possession of radioactive material are prohibited, except those uses and possessions that are authorized by an individual license. As medical uses of radioactive materials expanded with the development of new technologies, the licensure process quickly became complex, often involving lengthy documents with little consistency from one license to another license. In the late 1970's, the NRC moved to take all common license conditions and place them into regulations. This regulatory action was the NRC's attempt to simplify the licensing process and to allow greater consistency in uses and possession of radioactive materials.

In response to a 1976 report of multiple patient overexposures involving radiation oncology, an entirely different and separate medical specialty, at a Columbus, Ohio hospital, the NRC began to incidentally increase its regulation of nuclear medicine as well.[2/] On February 2, 1979, the NRC adopted a Medical Policy Statement on medical uses of radioisotopes. *See* 44 FED. REG. 8,242 (Feb. 9, 1979). In summary, the Medical Policy Statement provides that:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public;

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate; and

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

Medical Policy Statement, p. 1. In discussing the Medical Policy Statement, the NRC stated that regulations involving patient safety clearly were within the NRC's power, but that, "[t]he central question is a question of *policy* not *authority*." *Id.* at p. 2. The NRC also stated that:

> [f]rom the standpoint of *policy,* these limits [on physician discretion] depend on how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more the NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

*Id.* Further, the NRC explained that:

> [t]he second part of NRC's policy statement indicates that the NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with those standards, are inadequate. . . .
>
> NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal and State agencies or well administered professional standards. Whenever

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2/ Radiation oncology is not a branch of nuclear medicine. Instead, it uses radiation generated by a sealed source or implanted seeds to treat disease.

possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners exposure.

*Id.*

Thus, it is clear that the language in the Medical Policy Statement states that the NRC would become involved in regulating patient safety *only when* justified by the risk *and* where voluntary standards are inadequate. Nevertheless, for over 20 years, the NRC steadily has increased its regulation of nuclear medicine despite minimal changes in the materials used, their applications in medicine, and the absence of any evidence of significant problems. The NRC's increased regulation of nuclear medicine has been the source of ongoing tension between the NRC and members of the regulated medical community and the cause of needless expenditure of limited resources. Refusal of the Health Care Financing Administration (HCFA) to reimburse for NRC compliance costs, and a tightening up of healthcare reimbursement generally, have made NRC's requirements untenable, especially with the new and much more expensive regulations and licensing conditions coming out shortly.

In response to the failure of a therapeutic nuclear medicine device, the NRC in 1994 contracted with the Institute of Medicine (the "IOM") of the National Academy of Sciences ("NAS") to conduct the required external review, including a review of the NRC's regulations, policies, practices, and procedures. The NRC set three goals for the NAS/IOM study: 1) examination of the overall risk associated with the use of ionizing radiation in medicine; 2) examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical use of byproduct material. Further, the NRC sought specific recommendations on two major issues. First, the NRC requested recommendations from NAS/IOM on a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate commerce for application to human beings should be allocated among Federal Government agencies and between the Federal and State governments. Second, the NRC requested recommendations from NAS/IOM on appropriate criteria to measure the effectiveness of regulatory programs needed to protect public health and safety.

In March 1996, the IOM provided the NRC with a final report entitled RADIATION IN MEDICINE - A NEED FOR REGULATORY REFORM (the NAS/IOM Report). The NAS/IOM Report concluded that the NRC's regulations have proven to be unjustifiably intense and burdensome, may compromise the availability of the benefits of nuclear medicine and do not decrease the already negligible risks of medical use of ionizing radiation in any meaningful way. *Id.* at 173.

Specifically, the NAS/IOM Report stated 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. Further, the NAS/IOM Report 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 had "outlived its original logic." *Id.* at 175. Finally, the NAS/IOM Report argued for the need to remove regulatory authority for use of by-product material in medicine from the NRC and to replace it with a broader and more appropriate system for the regulation of all ionizing radiation in medicine. *Id.* at 174

During the time when the NAS/IOM Report was being completed, another significant event took place that impacted on the NRC's regulation of nuclear medicine. In August 1995, the NRC commenced a Strategic Assessment and Rebaselining Project intended to reassess the basic nature of the NRC's function and the means by which this function is accomplished. As part of this project, the NRC defined broad categories of Direction Setting Issues (the "DSIs") that effect NRC management philosophy and principles. A total of sixteen (16) DSIs were issued by the NRC. Strategic Assessment Issue Papers discussed details of each DSI and allowed interested parties and the public to comment on the issues proposed by the NRC in each DSI.

The NRC released a Strategic Assessment Issue Paper in September 1996 regarding DSI 7 - Materials/Medical Oversight (the "DSI 7 Paper"). The DSI 7 Paper was issued after the NAS/IOM report and was intended to evaluate the level of control and regulation needed to oversee the NRC's Nuclear Materials Program, and in particular, the NRC's regulation of Nuclear Medicine.

Subsequently, in Staff Requirements Memorandum (SRM) - SECY-96-057, Materials/Medical Oversight (DSI 7), dated March 20, 1997, the Commission directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement. Further, the SRM stated that:

> With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities

> (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.
>
> With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. *The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.*

SECY-96-057, p. 1 (Emphasis added).

In addition, the SECY-96-057 states that NRC staff must submit a program that should "describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99." *Id.* In developing the program, the SRM urges the NRC to focus on certain issues, including:

(1) Focusing Part 35 on those procedures that pose the highest risk.

(2) For diagnostic procedures, *staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.*

*Id.* at p. 2 (emphasis added).

As a result of the Commission's request, in a June 5, 1997 Rulemaking Issue, (SECY-97-115) NRC staff requested approval of certain procedures that the staff planned to follow in order to best respond to SECY-96-057 and provide the NRC with an alternative program for the revision of Part 35 and associated documents. However, after a subsequent June 13, 1997 meeting between the staff and the Commission, the Commission requested that the staff supplement SECY-97-115 with additional information. Accordingly, the staff issued a June 20, 1997 Rulemaking Issue, (SECY-97-131) that revised the staff's proposal and recommended that revisions to Part 35 be broken down by modality and develop a set of requirements that are based on risk and specific to each modality. In SECY-97-135, the staff suggested that the following seven (7) modalities be addressed:

1. low-dose unsealed materials (diagnostic nuclear medicine);

2. high-dose unsealed materials (nuclear medicine therapy);

3. low-dose sealed source applications;

4. teletherapy;

5. high-dose-rate remote afterloaders;

6. gamma stereotactic surgery; and

7. emerging technologies.

In a subsequent June 30, 1997 SRM, the Commission informed the NRC staff of the Commission's approval, with comments, of the program that the NRC staff proposed in SECY-97-131.

While the NRC has elected to disregard the NAS/IOM Report, and has refused to review the huge body of material substantiating its conclusions, the NRC has stated that it recognized the need for regulatory reform. However, regulatory reform will be beneficial to the medical community and patients only if the NRC elects to regulate nuclear medicine in direct proportion to the risks associated with nuclear medicine.

### *C. Safety of nuclear medicine*

The safety record of the use of byproduct material in diagnostic nuclear medicine is exceptional:

- The nature of the activities performed in diagnostic nuclear medicine and nuclear pharmacy permit easy compliance with worker radiation absorbed dose limits. Most workers in this field are exposed to radiation absorbed doses below 10 percent of the legal maximum. *The NRC has no evidence that suggests otherwise.*

- Members of the general public receive either no or very low radiation doses incident to the practice of diagnostic nuclear medicine. These doses (if any) are well within legal limits and have never been a cause for concern. *The NRC has no evidence that suggests otherwise.*

- Radioactive drugs are prepared in closed systems to assure sterility, thus minimizing airborne environmental contamination. Accordingly, environmental contamination has been minimal and well below legal limits. EPA examined this issue exhaustively and could not find a single example of noncompliance by any medical or academic facility, any manufacturer of radiopharmaceuticals, or any nuclear pharmacy. This included therapeutic as well as diagnostic nuclear medicine, research as well as clinical use. *The NRC has no evidence that suggests otherwise.*

- The number of misadministrations to patients is essentially at the rate of irreducible human error and regulatory attempts to reduce it, such as the Quality Management rule, produce no results. (The only way the number could be reduced is by changing the definition of a "misadministration." The NRC defines as a "misadministration" many events that no one else would.) *The NRC has no evidence that suggests otherwise.*

Because of the small amount of radioactivity required and subsequently low radiation dose, nuclear medicine diagnostic procedures pose little risk to the patient. The amount of time a radiopharmaceutical (radionuclide) remains in the body is determined by both the physical and biological half-life of the radiopharmaceutical. The physical half-life is the time it takes for a radioactive substance to reach one-half of its original strength. The half-lives of medical use radioisotopes vary from mere seconds to thousands of years and a radioisotope with short half-life (seconds or minutes) will cease to be radioactive within a day. Tc-99m, the radioisotope most commonly used in nuclear medicine, has a physical half-life of 6 hours. Biological half-life is the time it takes for a radiopharmaceutical to be eliminated from the body. Accordingly, even though a radioisotope may have a long physical half-life, the time it takes for the radiopharmaceutical to leave the body may be a matter of just minutes or hours.

The greatest risk to a patient in diagnostic nuclear medicine is for the medical professional to perform something other than the best procedure or to fail to tailor the right procedure to a particular patient's needs. Additionally, the patient may be at risk if the medical professional fails to make a diagnosis or makes the wrong diagnosis. However, the radiation dose is unimportant. For example, the average radiation dose equivalent to a patient from diagnostic nuclear medicine is 440 mrem. A dose of 440 mrem is between the yearly average background radiation in the United States (300 mrem) and the background radiation in the city of Denver, Colorado (530 mrem). Based on film badge data, the average annual exposure to workers in nuclear medicine is about 68 mrem ede (NCRP Report No. 101, 1989). It is important to note that humans continually are exposed to radiation from natural and man-made sources. For most people, natural background radiation from space, rocks, soil, and carbon and potassium atoms in his or her own body account for 85 percent of their annual exposure to radiation. Additional exposure is received from consumer products such as household smoke detectors, color television sets, and luminous dial clocks. The remainder is from x-rays and radioactive materials used for medical diagnosis and therapy. The average exposure from human activities involving radiation is 63 mrem/person/year in the United States (NCRP Report No. 93, 1987).

With most nuclear medicine procedures, the patient receives about the same amount of radiation as that acquired during the course of a year of normal living. Table 1 contains a summary of dosage levels associated with several common diagnostic nuclear medicine procedures.

# TABLE 1

## Dosage Levels Associated With Several Common Diagnostic Nuclear Medicine Procedures[3/]

| Type of study and Radioactive Agent | Effective Dose[4/] (mrem) |
|---|---|
| Cardiac | |
| Tc-99m -Sestamibi | 750 mrem |
| Bone | |
| $^{99m}$Tc-methyldiphosphonate | 440 mrem |
| Brain | |
| Tc-99m-HMPAO | 910 mrem |
| Infection | |
| Tc-99m-HMPAO-white blood cells | 630 mrem |
| Hepatobiliary | |
| $^{99m}$Tc-DISIDA | 330 mrem |
| Kidney | |
| $^{99m}$Tc-DTPA | 230 mrem |
| $^{99m}$Tc-MAG3 | 250 mrem |
| Liver | |
| $^{99m}$Tc-sulfur colloid | 260 mrem |
| Lung | |
| $^{99m}$Tc-macroaggregate | 220 mrem |
| $^{99m}$Tc-DTPA aerosol | 120 mrem |
| $^{133}$Xe gas (5 min rebreathing) | 44 mrem |
| Thyroid | |

3/ Dosimetry data from NCRP Commentary no. 7 (1991), ICRP Report No. 53 (1987), ICRP Report No. 62(1991), and FDA-approved Package Inserts.

4/ Effective dose (*E*) calculated using effective dose equivalent data from ICRP, (1987), *i.e.* effective dose (*E*) and effective dose equivalent are assumed to be equivalent for the purpose of this table. This column added by the NCRP Ad Hoc Committee.

| Type of study and Radioactive Agent | Effective Dose[4/] (mrem) |
|---|---|
| $^{123}$I-sodium iodide (25% uptake and scan) | 110 mrem |
| $^{131}$I-sodium iodide (25% uptake; no scan) | 220 mrem |
| $^{99m}$Tc-sodium pertechnetate (scan) | 40 mrem |

### *D. Safety of nuclear medicine compared to other modalities*

No medical activity, process or procedure is completely free of risk. Accordingly, in addition to the strict general regulation of the practice of medicine and pharmacy, many specific medical procedures are subject to increased regulation by specific federal and state regulatory bodies. However, in most cases, the level of regulation has some rational relation to the risks associated with the specific medical activity, process or procedure. Table 2 presents a summary of the risk of death associated with several other medical modalities.

## TABLE 2

**Comparative Death Rates of Selected Medical Modalities**

| Medical Modality | Death Rate |
|---|---|
| Non-Radioactive Drugs | 10-40/10,000 |
| Parenteral Contrast Media | 0.25/10,000 |
| Pulmonary Angiography | 25/10,000 |
| Penicillin | 2/10,000 |
| Heparin | 9.5/10,000 |
| Antineoplastics(Chemotherapy Drugs) | 58/10,000 |
| Blood Transfusions | 0.03/10,000 |
| Radiopharmaceuticals | 0.0004/10,000[5] |

The low risk of nuclear medicine procedures is put into sharp focus by the risks posed by the use of prescription drugs. According to the Food and Drug Administration, adverse drug reactions may occur in 20 percent of ambulatory patients and 2 to 5 percent of hospital admissions are attributed to drug-related illness. 60 FED. REG. 44182, 44187 (Aug. 24, 1995). Further, FDA cites a study which indicates that the case/fatality rate from drug-induced disease in hospitalized patients is 2 percent to 12 percent. *Id.*

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[5] Based on one proven death from radiation dose error with Au-198 and allergic or drug reaction deaths in 11 other cases in the course of administering 333 million nuclear medicine doses.

Similarly, although the NAS/IOM Report states that exact data regarding the risks of anesthesia are difficult to quantify, the NAS/IOM Report states that "[a]ccording to an ECRI technology assessment, more than 2,000 healthy Americans die each year during general anesthesia; an estimated 50 percent of these deaths are preventable. Derrington and Smith estimate the mortality rate from the use of anesthesia at 1:5,000 to 1:10,000 patients/procedures." *Id.* at 123 (citations omitted).

Finally, the NAS/IOM Report provides specific information regarding the risk of death associated with blood transfusions:

> More than 12 million units of red blood cells, 5 million units of platelets, and 2 million units of plasma are administered to patients in the United States each year. Adverse reactions are estimated to be as high as 20 percent. Hemolytic blood transfusion reactions occur as often as 1 in 7,000 red blood cell transfusions and carry a mortality rate of 10 percent.

*Id.* Accordingly, the risk of death associated with red blood cell transfusions is as high as 1 in 70,000 transfusions.

### *E. Safety of nuclear medicine compared to level of NRC regulation*

It is a common, but sad, joke among those in nuclear medicine that the level of regulation imposed by the NRC is more appropriate to the construction and operation of a nuclear power plant than to a medical procedure. A system failure in a nuclear power plant can lead to catastrophic consequences. The NRC can probably rightly claim that the level of regulation it imposes on power reactors is the reason there have been so few significant nuclear accidents in the United States.

In the field of diagnostic nuclear medicine, however, there is virtually no risk from which protection is needed. As virtually every careful observer has noted, the level of regulation imposed by the NRC is wholly out of proportion to the risks of the procedure. Despite the consistency of this conclusion, the NRC continues to impose unnecessary and expensive requirements. The NRC's 1979 Medical Policy Statement clearly intended to rely on the professionalism of health care professionals to protect patients. As the NRC increasingly ignored it own policy and imposed new and additional requirements, increasingly imposing on the practice of medicine, it has now revised the Medical Policy Statement to support imposition of needless regulations and licensing requirements instead of revising its regulations to accurately reflect the intent of the 1979 Medical Policy Statement. The NRC has also suddenly discovered that the Atomic Energy Commission and the public misinterpreted Section 104 of the Atomic Energy Act incorrectly for nearly fifty years, and that the caveat to make "minimal regulation" in medicine applied to reactors and special nuclear material ***only,*** and not to regulations involving byproduct materials. That is, the staff now believes that Congress decided that the direct exposure of patients to nuclear reactor radiation, and the use of U-235 and Pu-238

in medicines, should be "minimally" regulated, while the use of virtually harmless diagnostic agents using byproduct material may be regulated without regard to this Congressional injunction. *See* 63 FED. REG. 43583-84 (Aug. 13, 1998). This new NRC interpretation is preposterous, and shows the lengths the staff will go to justify its regulatory approach. The Commissioners should renounce this absurd pronouncement.

### *F. Costs to society of unnecessary regulation*

On October 21, 1998, the Society and the College presented a preliminary cost estimate of the impact of the proposed revisions to Part 35 to the NRC at a public meeting. The analysis, entitled "Preliminary Estimate of the Cost of the Proposed Part 35 for a Typical Hospital Nuclear Medicine Service; Spread Sheet Analysis," was prepared by Mark Rotman, a former Visiting Medical Fellow at NRC. The analysis did not include the costs of most of Part 20, Part 19, NUREG 1559 Volume 9 (the new licensing NUREG for nuclear medicine), typical license conditions, radioactive waste disposal, User Fees, or any costs at all to any Agreement State nuclear medicine licensees. The total costs of the NRC regulatory scheme alone came to just over $100,000,000/year. Assuming that Agreement States will be forced by NRC to have similar programs, which is indeed happening now, the cost, including Agreement State licensees, is $500,000,000. When one adds all of the other costs, it is easy to reach $1 billion /year , even with the uncertainties. The Society and the College asked the NRC to discard its own severely flawed cost analysis, which was sent to OMB, and to work with the Society and the College to produce a realistic cost estimate. The Commission has not only refused to do so, it has refused to even recognize the existence of the analysis produced by the Society and the College, refusing to discuss it, comment on it, or address the issues in it in any manner.

If this Petition is approved, most of these costs would disappear. In addition, it is likely that nuclear pharmacy costs would also decrease and, therefore, radiopharmaceutical costs would decrease somewhat as well. At present, about 80 percent of radiopharmaceutical doses are obtained unit dose from centralized nuclear pharmacies.

### *G. Benefits to the public from the actions sought by the Petition*

The public would benefit in two ways if the Commission grants the action requested by this Petition. First, substantial requirements for physician education, training, and experience, and appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. This would assure a broader scope of nuclear medicine services and procedures, with optimization of procedures for individual patients and a generally higher medical quality of procedure. Radiation safety itself would remain the same, because the standards would be unchanged. Radiation safety is not now, and never has been, an issue with diagnostic nuclear medicine practiced by competent professionals.

Second, costs to the health care system would decrease without any decrease in safety. As this petition has demonstrated, the level of regulation imposed by the Commission on nuclear

medicine bears no relationship whatsoever to the extremely low level of risk posed by diagnostic nuclear medicine procedures. The abolition of needless levels of regulation would free up scarce resources in the health care system, resources that could be used to positively impact patient care.

## IV. CONCLUSIONS

In order to assure the same level high level of continued protection to patients and the public at a reasonable regulatory cost, the Commission should revoke Part 35, both as it exists today and as the Commission has voted to revise it, and all license conditions for diagnostic nuclear medicine, with the exception of substantial education, training, and experience requirements for Authorized User physicians and pharmacists, as evidenced by board certification or equivalent testing, and identification information about the licensee, as described in more detail in Section II of this Petition.

The Society and the College would welcome an opportunity to meet with the Commission to discuss this Petition and to recommend appropriate education, training, and experience requirements for practicing nuclear medicine.

Respectfully submitted,

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