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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 4, 1996

MEMORANDUM TO: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES COMMENTS ON DIRECTION SETTING ISSUE PAPERS

Attached are the Advisory Committee on the Medical Uses of Isotopes (ACMUI) comments on the Strategic Assessment (SA) and Direction Setting Issues (DSI) papers, from their meeting held on November 14-15, 1996. Major topics of discussion were SA and DSI papers number 7, "Materials/Medical Oversight" and number 12, "Risk-Informed, Performance-Based Regulation." Detailed minutes of the entire meeting will be forwarded later.

Attachment: ACMUI Comments

cc: SECY
OGC
OPA
OCA

CONTACT: Torre Taylor, NMSS
(301) 415-7900

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 26, 1996

MEMORANDUM TO: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Judith Anne Stitt, M.D., Chairman
Advisory Committee on the Medical
Uses of Isotopes

SUBJECT: COMMENTS ON STRATEGIC ASSESSMENT
AND DIRECTION SETTING ISSUES PAPERS

I am providing the ACMUI's comments on the Strategic Assessment (SA) and discussion of the Direction Setting Issues (DSI) papers for submission to the Commission prior to the end of the comment period on December 2, 1996. Detailed minutes of the entire meeting will be forwarded at a later date. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) met on November 14-15, 1996. Strategic Assessment and discussion of the DSI papers were a major topic of discussion during the meeting. The ACMUI deliberated on a number of thoughts and ideas on the SA process, many of which will be detailed in the minutes. I am summarizing the main issues and the consensus items as a result of the committee's discussions.

The ACMUI had extreme difficulty in understanding DSI #12, Risk-Informed, Performance-Based Regulation. The paper is difficult to comprehend and members were concerned that members of the public would have difficulty understanding the issues, thereby minimizing the number of comments the Commission might receive on the risk paper.

The ACMUI agrees that risk should be used as a factor in establishing regulations. Members expressed concern as to who will determine risk in using a risk assessment approach to the development of regulations. Additionally, in discussing risk, it is unclear if it is risk in terms of occupational worker risk or public safety risk, and how this relates to considering a patient as a member of the public, as discussed in the 1979 Medical Policy Statement. Assessment of medical risk versus benefit is the practice of medicine, rather than a regulatory decision.

The ACMUI discussed the options outlined in DSI #7, "Material/Medical Oversight," and were concerned that it appeared that ACMUI's recommendations resulting from its February 21-22, 1996 meeting were not considered by the Commission. The members indicated that they do not have the confidence, and they do not believe the regulated community has the confidence, that the NRC, even with SA, can make the necessary changes to effectively regulate the use of byproduct material in medicine. The Quality Management rule was cited as an example, in that a performance-based rule has become very prescriptive.

After deliberation, the committee voted, by consensus, that the recommendations made during the February 1996 meeting are still the ACMUI's first choices for the direction in which the NRC should proceed. However, the

ACMUI did agree to amend the initial recommendation, that the Department of Health and Human Services should be the Federal agency for regulatory oversight, to state that a new or existing Federal agency for oversight needs to be an agency with a medical or health focus rather than a regulatory focus. These recommendations are included in Attachment 1.

However, given that these recommendations were not included within the preliminary views of the Commissioners, the ACMUI focused on the options given in DSI #7, especially low-risk versus high-risk activities. Time did not permit the ACMUI to develop a clear consensus as to what would constitute low- or high-risk activities.

As part of its discussion of DSI #7, the ACMUI focused on the 1979 Medical Policy Statement (MPS) (44 FR 8242) (Attachment 2). There was considerable deliberation that when the Commission adopted the policy that medical patients are considered a member of the public, NRC began to interfere with medical practice. There is a conflict when the policy says that NRC will not practice medicine, but patients are considered a member of the public. Statement 2 of the MPS states that, "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. Many members indicated that, based on this statement, there are many regulations for which the justification based on risk does not exist, such as misadministrations of diagnostic uses and the requirement for ALARA. While the events that prompted the MPS had to be addressed, there was some discussion as to whether NRC has gone beyond the bounds of the MPS by broadening its scope to include regulation that was not based sufficiently on risk.

The ACMUI discussed the need to revise the MPS, such as including the term "high" risk in Statement 2 of the MPS. There was much controversy over this, and how to define "high" and whether this is the direction to go. One has to consider the benefit to the patient in addition to any risk to the patient. There was discussion that the public needs to be better informed as to the risks of radiation.

Subsequently, the ACMUI made the following motion: "The ACMUI recommends that NRC revise its Medical Policy Statement to include in statement number two the word "high" before "risk." Statement #2 would then read: The NRC will regulate the radiation safety of patients where justified by the high risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

This was approved by a vote of 6 in favor to 3 opposed. One individual voting against the motion believed it was more important to indicate exclusion of low risks as regulation of high risk activities is a given. One individual believes that revising the statement to include "high" is an over simplification of the problem. It is not differentiating the risk associated with things that take place as a part of the procedure separately from the medical procedure itself. One individual did not like using the term "high" in the statement.

The ACMUI made the following amendment to the motion: "The ACMUI believes that the 1979 Medical Policy Statement should be reconsidered; and the scientific basis of the statement needs to be reviewed with consideration of current research and studies; and the ACMUI is committed to working with the staff and Commissioners to provide guidelines for determination of procedures and activities that range from low risk to high risk to patients. Therefore, the ACMUI recommends that the 1979 Medical Policy Statement be revised. This was approved by a vote of 6 in favor to 3 opposed. Again, those opposed believed that classifying activities by high risk is an oversimplification of the problem. One individual voted against the amendment due to procedural reasons. He believed the original motion should have been withdrawn; that the amendment was a way to make the motion on the floor "fit" the current discussion.

Attachments:
1. ACMUI Recommendations 2/21-22/96
2. 1979 MPS

RECOMMENDATIONS OF ACMUI

The ACMUI reached a consensus as a result of committee deliberations concerning the following actions that should be part of regulatory reform:

- Rebuild the medical use regulatory program, without using the current regulatory program as a starting point. The objectives of the regulations must be reassessed;
- Federally mandate that the states administer the medical regulatory use program, with appropriate incentives to encourage states to comply;
- State programs should be monitored by a Federal agency. The Federal agency should be an agency with an overall medical use perspective.
- Encompass all uses of ionizing radiation in medicine, not just byproduct material and not just radioactive material); and
- Conduct the medical use regulatory program in a uniform setting, whether it is conducted by a Federal agency or by the states.

ATTACHMENT 1

ATTACHMENT 2

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 10—HUMAN USES OF BYPRODUCT MATERIALS

Regulation of the Medical Uses of Radioisotopes; Statement of General Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the FEDERAL REGISTER (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 FEDERAL REGISTER notice. The comments are discussed in Section II. Copies of the comments may be examined in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:[1]

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.

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.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public *and* the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific

[1] NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term *byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term *source material* means (1) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. *Special nuclear material* means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any of the foregoing, but does not include source material.

to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of *policy* not *authority*, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of *authority*, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of *policy*, these limits depend upon 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 NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that 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] This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that 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. As noted before, NRC has the authority to regulate the radiation safety of patients.

[2]The term general public in this statement specifically excludes patients.

The NAS-BEIR[3] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgment. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

[3]National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences—National Research Council*, Washington, D.C. (1972).

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical devices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to

those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. Discussion of Public Comments

A. Comments on the policy statement

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diagnosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. Comments on specific issues

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the Federal Register for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

~~Spo CJ~~
Clare

December 4, 1996

MEMORANDUM TO: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

FROM: James M. Taylor
Executive Director for Operations
Original signed by James M. Taylor

SUBJECT: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES COMMENTS ON DIRECTION SETTING ISSUE PAPERS

Attached are the Advisory Committee on the Medical Uses of Isotopes (ACMUI) comments on the Strategic Assessment (SA) and Direction Setting Issues (DSI) papers, from their meeting held on November 14-15, 1996. Major topics of discussion were SA and DSI papers number 7, "Materials/Medical Oversight" and number 12, "Risk-Informed, Performance-Based Regulation." Detailed minutes of the entire meeting will be forwarded later.

Attachment: ACMUI Comments
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