UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-000'

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: CERTIFICATION OF THE MINUTES OF THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

I hereby certify that, to the best of my knowledge and belief, the attached minutes for the meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) held on November 14-15, 1996, are an accurate record of the proceedings for that meeting.

Judith Anne Stitt, M.D., Chairman

January 13, 1997
Date

Attachment: Minutes - ACMUI mtg.
11/14-15/96

SUMMARY MINUTES

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

NOVEMBER 14-15, 1996

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting on November 14-15, 1996. A briefing book with background information for the issues under discussion was provided to the ACMUI members in advance of the meeting, and is available through the Public Document Room.

ACMUI members present at the meeting:

Judith Ann Stitt, M.D., Chairman
Daniel F. Flynn, M.D.
Andrew Kang, M.D.
Dennis P. Swanson, M.S., B.C.N.P.
Theresa Walkup, C.M.D.
Judith Brown
John Graham
Will B. Nelp, M.D.
Louis K. Wagner, Ph.D.
Jeffrey F. Williamson, Ph.D.

Also present: Larry W. Camper, M.S., M.B.A., Branch Chief, Medical, Academic, and Commercial Use Safety Branch, Nuclear Regulatory Commission (NRC), (Designated Federal Official for the Committee); Donald A. Cool, Ph.D., Director, Division of Industrial and Medical Nuclear Safety, NRC; Carl Paperiello, Ph.D., Director, Office of Nuclear Materials Safety and Safeguards; and Sally L. Merchant, Acting Section Leader, Medical and Academic Section, NRC. Naomi Alazraki, M.D. and Jill Lipoti, Ph.D., also attended the meeting as invited guests, representing nuclear medicine and the States' perspective, respectively.

The Office of the General Counsel provided a briefing on ethics as NRC special employees. The session was closed to the public to prevent the invasion of personal privacy of the members.

Mr. Camper officially opened the meeting at 8:04 a.m. with general comments on the meeting and the function of the ACMUI. Mr. Camper stated that he had reviewed the Committee members' financial and employment interests, and had not identified any conflict of interest with items to be considered during the meeting. Mr. Camper stated that any ACMUI member who becomes aware of a potential conflict of interest during the course of the meeting should so inform him or Dr. Stitt.

Carl J. Paperillo, Ph.D., and Donald A. Cool, Ph.D., made opening remarks to the Committee.

STRATEGIC ASSESSMENT AND DIRECTION SETTING ISSUE PAPERS

Larry Camper led the discussion on the Strategic Assessment (SA) and Direction Setting Issue (DSI) Papers, specifically DSI #7, 'Materials/Medical Oversight,' and DSI #12, 'Risk-Informed, Performance-Based Regulation.' He indicated that senior staff members prepared the DSI papers, and interfaced with senior management to develop the papers.

To begin, Mr. Camper provided an overview of the National Academy of Sciences, Institute of Medicine, report on the medical use program and reviewed the

ACMUI's recommendations on the report, as detailed in the minutes of the ACMUI meeting, held on February 21-22, 1996. Mr. Camper emphasized that the States and the Department of Health and Human Services (DHHS) commented negatively on the report. The States indicated that it was an unfunded Federal mandate. The DHHS did not believe that a compelling case had been made in the report, and that it doubted that the Congress would put in place the resources for such a program within the DHHS.

Mr. Camper discussed DSI #7, 'Materials/Medical Oversight' and #12, 'Risk-Informed, Performance-Based Regulation,' identifying the options presented in the papers as well as the preliminary views of the Commission.

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 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. There was concern as NRC has not followed the recommendations of low risk activities given by the medical community in the past. 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 (MPS). Assessment of medical risk versus benefit is the practice of medicine, rather than a regulatory decision.

In discussing DSI #7, 'Material/Medical Oversight,' the ACMUI expressed concern that it appeared that ACMUI's recommendations resulting from its meeting, held on February 21-22, 1996, 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 unanimous decision, 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, which stated that the Department of Health and Human Services should be the Federal agency for regulatory oversight. The recommendation is now amended 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.

Many members do not believe that Option 1 is a viable option under NRC regulatory authority as NRC has limited expertise in the medical arena, and it would be difficult if regulation of other types of radiation, such as x-ray, accelerator produced and naturally occurring material, were included. The agency with regulatory authority should be one with a health focus rather than a regulatory focus.

Dr. Wagner believes that the ACMUI should look at the history of the development of the regulations and the regulatory process. There was considerable deliberation by the Committee regarding the policy that medical patients are considered a member of the public, and when the Commission adopted this policy, NRC began to interfere with the practice of medicine, a major source of controversy between NRC and the medical community. There is a conflict when the policy says that NRC will not practice medicine, but patients are considered a member of the public.

As part of its discussion of DSI #7, the ACMUI focused on the 1979 Medical Policy Statement (MPS) (44 FR 8242) (Attachment 2). The discussion focused on the issue of risk. 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. One member indicated one such rule is that which governs diagnostic misadministrations [in those Agreement States which have not adopted the Quality Management rule and have regulations for diagnostic misadministrations]. Two other examples are the requirements for ALARA and for wipe testing unit doses of diagnostic radiopharmaceuticals. 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, and what these risks are in comparison to other areas of health care.

Dr. Wagner stated that the technology today is entirely different and NRC and the medical community have to evaluate the regulations from the current situation and practices. The committee discussed the origin of the exposure criteria of 100 millirem, and that it is for the whole population. There were comments that there is no evidence that this limit has any adverse health effects on the population. Dr. Wagner indicated that this is not based on any known risk, but rather, it is an extrapolation from higher doses that did produce effects. Additionally, the Biological Effects in Radiation report did not really express any risks except for excessive doses, in the range of

15 rem. The National Council on Radiation Protection used 100 millirem as a recommended exposure limit based on estimates of what might occur and using a very conservative, safe level for the public. The only studies which have shown any correlation between the medical application of radiation and some effect are those at high doses. The Committee discussed the need to review the current scientific literature to serve as a basis for establishing risk and move away from the concept of the 100 millirem exposure limit.

Another comment is that the regulations are necessary for those practitioners who are not responsible. The committee must be clear about what is low risk, not necessarily no risk. Additionally, the probability and consequences have to be considered, as well as the competence and control of the individuals who handle radioactive material.

Dr. Kang expressed concern of classifying activities as known risk. He indicated that there might be a high risk with an activity of which the medical community is not yet aware.

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.

MOBILE HIGH-DOSE-RATE AFTERLOADERS

Robert Ayres, Ph.D., discussed mobile high-dose-rate afterloaders (HDR). NRC received its first application in March 1996 for authorization for mobile HDR, which necessitated the need to develop corresponding guidance necessary to license this modality. The staff is using Business Process Re-engineering to work on the application. A team was established to work on the review of the application and to develop the guidance. The team consisted of a team leader from NMSS, representative from NRC's office of the General Counsel, Region I, the State of California, and the State of Maryland. California and Maryland were invited to participate since California has issued a mobile HDR license and Maryland has issued the source device review. A representative from California and from NRC's Region I office were unable to attend the working group meeting. The guidance developed by the working group is undergoing management review. The guidance supplements existing guidance contained in draft Regulatory Guide 10.8, Rev. 2, "Guide for the Preparation of Applications for Medical Use Programs" and HDR licensing guidance contained in Policy and Guidance Directive 86-4, "Information Required for Licensing Remote Afterloading Devices."

The guidance specifically addresses the licensing of the medical use of mobile HDR as either a fully self-contained mobile HDR therapy treatment system (within a van) or a transportable device relocated from one facility to another. The guidance addressed relevant regulatory and health and safety issues. The critical regulatory issue is that the regulations do not authorize mobile therapy services. An exemption from 10 CFR 35.29(a), which authorizes mobile nuclear medicine, and specifically excludes mobile therapy, is needed.

The guidance addresses the following health and safety issues: 1) locations of use, 2) radioactive material, 3) facility diagram, 4) operational and safety checks, and 5) transportation. A central base location for the mobile treatment facility or a transportable device is needed for routine maintenance, byproduct material deliveries, source exchange activities, and central records location. For temporary client sites, a letter from the client is needed, which authorizes the use of byproduct material at the client's address of use. A signed agreement with a nearby medical facility is needed to ensure emergency care is available for a patient which is undergoing treatment by the licensee. The agreement should include procedures for handling emergencies arising from the inability to remove the HDR source from a patient. If the applicant can provide assurance that no treatment will be performed that could result in a source which cannot be removed from the patient by the licensee, the agreement will not require such provisions. For transportable mobile HDR treatment services, the additional information is needed. For each site of use the applicant should provide the information requested under "Facility Section" of the guidance. If the applicant will provide the radiation treatment to the patient, proof that establishes that the applicant has full control of the treatment room during its period of use is required. If the applicant is requesting authorization limited to

providing a transportable HDR device to clients, then the applicant should provide a copy of each client's NRC or Agreement State license demonstrating that the client is authorized to provide HDR treatments with the specific device provided by the applicant. The initial installation and function checks at each client site must be made by the HDR device vendor.

Only those sealed sources and/or devices specifically approved for mobile HDR brachytherapy applications are authorized for such use. A radiation safety evaluation, specifically authorizing that type of use, by either the NRC or an Agreement State, is necessary for licensure of the device for mobile brachytherapy treatments.

Applicants for self-contained mobile HDR treatment systems should provide drawings with sufficient detail that conformance with the facility's sealed source and device radiation safety evaluation can be verified. This presumes that the entire facility was evaluated as the device. A drawing should be provided for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations that could be occupied by members of the public. The location of the device/vehicle must be on client-owned or controlled property covered by the letter of agreement. Additionally, no vehicular traffic should be permitted in the immediate area of the treatment facility that could potentially inflict damage to the facility or adversely affect patient treatment.

There is a concern that the device has been subject to vibration and other effects in the process of being transported. Therefore, certain operational and safety checks must be repeated prior to patient treatments. The applicant should include a procedure establishing those radiation safety checks that will be conducted on the HDR device following any relocation of the unit and prior to patient treatment. The licensee should submit procedures for performing radiation surveys to establish the integrity of the radiation shielding after each relocation. The procedure should include a preliminary or baseline survey to establish normal exposure rates that include the source housing, with the source in the shielded position, and all areas adjacent to the treatment room with the source in the "treatment" position.

Transportation of mobile HDRs must be in accordance with the Department of Transportation (DOT) regulation, 49 CFR Parts 170-189. The necessary DOT Type 7A package certification is established via prior approval of the sealed source and device review. The licensee should submit a procedure that includes its emergency response regarding an accident scenario. Any accident should be immediately reported by telephone to the NRC Operations Center, followed with a written report within thirty days. Following any accident, no treatments should occur until all safety systems pertaining to radiation safety have been tested and confirmed to be operational by either the medical physicist or the radiation safety officer.

Dr. Flynn indicated that the radiation safety officer may not have the technical knowledge to confirm operational safety checks. The medical physicist and the radiation safety officer should be present. Dr. Ayres indicated that the radiation safety officer may not always accompany the van.

Dr. Stitt did not understand how the agreement with a nearby facility would solve the issue of emergency practice of medicine issues. A medical emergency is difficult within one's own institution. It will be difficult to coordinate with another facility. Several members stated that these are practice of medicine issues.

Two additional issues that needs to be addressed are reciprocity and overnight storage.

STATUS REPORTS AND DISCUSSION

Advance Notice of Proposed Rulemaking for Part 33

Patricia Holahan, Ph.D., provided an update on the status of the Advance Notice of Proposed (ANPR) Rulemaking for Part 33. A draft was discussed with ACMUI in May 1996. Revisions were made as a result of the ACMUI's comments and recommendations. The Commission approved the ANPR with three changes. The Commission directed the staff to expand the definition of broad scope. Two additional questions were added: 1) Should NRC consider the risks associated with internal exposure pathways separate from those associated with external radiation? and 2) What balance should be maintained between a performance-based and a prescriptive approach to regulating broad scope licensees?

The ANPR was published in the Federal Register (61 FR 58346) on November 14, 1996, and staff will provide the committee with a copy. The public comment period is 90 days.

Memorandum of Understanding with the U.S. Food and Drug Administration

Larry Camper provided a report on the status of the Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA). The MOU was originally signed on August 26, 1993, for a period of three years. There is an annual meeting between the FDA and the NRC to evaluate the MOU and its effectiveness. On August 8, 1996, both parties agreed that the MOU should be renewed. The staff is preparing a commission paper expressing its desire to renew the MOU. The intent to renew the MOU will be noticed in the Federal Register. The staff will provide a copy of the MOU to the ACMUI, at their request.

Modules for Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs"

Sally Merchant provided an update on the status of the modules for Regulatory

Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs." The modules should be published as a Draft NUREG in January 1997. The modules will provide guidance for those areas of use for which there is no guidance. As a reminder, the modules cover the following modalities: a) mobile nuclear medicine, b) radiopharmaceutical therapy, c) brachytherapy, d) high dose rate afterloaders, e) manual brachytherapy, f) teletherapy, and g) gamma stereotactic radiosurgery.

Implementation of the Quality Management Rule

Sally Merchant provided an update on the implementation of the Quality Management Rule. The staff was directed by the Commission to report on the implementation of the Quality Management rule after three years. Ms. Merchant provided an overview of the background of the rule and its requirements. A temporary instruction for inspection of the rule was put in place, which was a description of how to do the inspection and included a checklist for each modality of use. The information was collected and entered into a database. The staff is currently analyzing the data and comparing it to other data bases, such as the Office of Enforcement's data base, the Nuclear Materials Events data base, the licensing tracking systems, and the inspection follow-up systems.

The following is a list of percentage of licensees not meeting the objectives of the Quality Management Rule:

1) Objective 1 - 7%
2) Objective 2 - 3%
3) Objective 3 - 13%
4) Objective 4 - 7%
5) Objective 5 - 11%

Additionally, 11% did not perform a review of the quality management program within each 12 month period.

The inspection was for compliance with the definitions in Part 35, rather than the licensees' written quality management program since many written programs had deficiencies. When the results were compared to the written program, for each modality of use, the implemented program met the Quality Management Rule objectives more often than the written program.

During the four years the rule has been in effect, there have been 138 errors in administration that met the misadministration criteria. Of these, there were at least 51 events that were actual misadministrations. By severity level (SL), three were SL 1, four were SL 2, 36 were SL 3, and eight were SL 4 violations. All 51 misadministrations involved failure to meet either Objectives 3 or 4.

Dr. Nelp asked for the total number of administrations. There is not a denominator for each modality, though there is a total of the number of

administrations and written directives in the facilities that were inspected. There was concern expressed that the rate is very low, and one can not eliminate human error. At the time of the inception of the Quality Management Rule, the frequency of occurrence was only 0.0001.

Mr. Swanson asked about the true effectiveness of the rule. He was surprised that there continue to be misadministrations. He asked if we had the incidence of misadministrations before the rule compared to those after the rule. Mr. Swanson also asked if there is data to demonstrate that there are more errors with those programs not doing a good job versus those that are doing a good job, and whether any information has been gained regarding trends or patterns to prevent misadministrations. Ms. Merchant responded that the numbers are about the same, but the types are different due to the different criteria now in Part 35.

Dr. Alazraki asked if there is any relationship to the training levels of the individuals involved in the misadministrations. Ms. Merchant stated that occasionally there is in the sense of the requirements of 10 CFR Part 35.25, "Supervision."

Regulatory Authorization for Intravascular Brachytherapy

James Smith discussed the regulatory authorization for intravascular brachytherapy. NRC's current regulations do not allow for the treatment of intravascular brachytherapy. Section 35.400 only allows for the use of sealed sources. There are several manufacturers who are planning to use beta emitting stents, either coated or implanted. The problem is that the radioisotope can be released as the design is such that the beta radiation can get out.

In April 1996, NRC prepared guidance for research involving intravascular brachytherapy. The guidance was published in the FDA guide, entitled, "Intravascular Brachytherapy - Guidance for Data to be Submitted to the Food and Drug Administration in Support of Investigational Device Exemption (IDE) Applications."

A broad scope licensee can approve the use of intravascular brachytherapy through the approval process of the Investigational Review Board. A limited specific licensee will have to request an exemption from the regulations and receive approval.

There are several options that the staff is evaluating. One is to change the wording under 10 CFR 35.400 to include intravascular brachytherapy and the use of unsealed and unencapsulated sources. Another option is to include a new section under 10 CFR Part 35 to specifically address the use of sealed and unsealed sources for treatment to prevent restenosis. Or each request can be reviewed and approved on a case-by-case basis, with line item authorizations. Another possibility is to restrict the investigations under the IDE to broad scope medical use licenses.

Issues that need to be addressed are:

1) Should NRC alter its training and experience requirements to allow cardiologists to be named as authorized users for this modality?

2) Should NRC amend its regulations to specifically address the modality of intravascular brachytherapy?

3) Should the microcurie range permanent implants require less training than HDR treatments, even if each is designed to deliver a total dose of 10 to 20 Gy to the vessel wall?

4) For permanently implanted beta-emitting coated stents, should NRC use the same criteria for misadministrations as migrated seeds for the coating or activity that flakes off or leaches out and irradiates other tissues? Or should NRC view these sources as unsealed sources under 10 CFR 35.300?

5) Are there unique radiation safety considerations associated with this modality? For example, where is the most likely location within the medical institutions for such implantation?

Dr. Williamson indicated that there are a broad range of modalities ranging from conventional high dose rate to low activity sources which are held manually in place, in addition to permanent implants. The issue of dose response and how accurately the treatment has to be delivered is not known. There is uncertainty in this area as it is an emerging technology.

Dr. Flynn discussed the training and experience issue. This is a therapeutic use of radiation and there are many considerations. One has to consider the normal tissue dose tolerances. There may be complications that a cardiologist may not be aware of, such as a patient who has received treatment with chemotherapy or a patient with insulin dependent diabetes, whose vessels will not tolerate the same radiation dose as another patient without insulin dependant diabetes. This is a treatment modality that lends itself to a team approach of medical specialties. Dr. Flynn recommended that this treatment not be authorized for cardiologists who have not had any training in therapeutic levels of radiation. The use of the radiation itself should be under the supervision of an authorized user.

Ms. Brown indicated that the ACMUI needs to hear the views of a cardiologist. Ms. Merchant indicated that the American College of Cardiology is holding their national meeting and; therefore, a representative was not able to attend the ACMUI meeting.

There was continued discussion regarding the training and experience requirements. Dr. Stitt stressed that there are differences in the isotopes and the modalities used for intravascular brachytherapy. Much of this is in developmental stages. There are conferences on this issue being conducted by

professional organizations, so NRC will be seeing more requests for this use.

Dr. Alazraki stated that it is important that NRC not compromise any training and experience for authorized users who are going to be handling these materials and be responsible for the care of the radiation, not just for protection of the patient, but also for protection of personnel. She indicated that there have been some near disasters in the research labs because of inexperience and lack of knowledge on the part of the people involved. She believes that if cardiologists want to utilize this technology, they will get the training and experience needed.

Mr. Graham indicated, that from his perspective, and trying to control costs for the largest single source of mortality in the United States resulting in cardiology being the largest piece of business of health care, one could operate a cardiology hospital with no oncology delivered at that site. In addressing the questions presented to ACMUI, he split the issue into permanent low dose applications and high dose rate applications. He believed that NRC could amend training and experience requirements such that cardiologists, under the right set of conditions, could implant the low dose isostents. For the higher dose applications, he would recommend a team approach. He thought that NRC should amend its regulations to specifically address the modality of intravascular brachytherapy. For permanent implants, NRC should not use the same criteria for misadministrations as is used for migrated seeds for the coating or activity that flakes off or leaches out, irradiating other tissues. Additionally, he does not believe that there are unique radiation safety considerations associated with this modality for the permanent implants. Radiation is used in the cardiac cath labs, which are secured and protected radiographic rooms. So there is some knowledge of radiation in the cardiology field.

Dr. Kang indicated that there is still uncertainty in how to deal with the radiation safety issues. However, if cardiologists will perform the procedure without a radiation oncologist present, they should be able to understand the basic principles of radiation safety applicable to the procedure.

Dr. Williamson indicated that it is important to define basic credentials for the various modalities involved with intravascular brachytherapy.

Dr. Lipoti expressed a concern about extending authorization to cardiologists as they do not appear to appreciate the radiation effects. She cited a study conducted by the Center for Devices and Radiological Health regarding skin burns on patients that were involved in a cardiac catherization.

Dr. Wagner stated that he was familiar with these events. He indicated that it is important to ensure that users have to be well educated in the procedures. However, one does not want to exclude a certain category of users. It is difficult to define the level of training needed at this time as the modality is so new. Initially, a conservative approach to the handling and manipulation of these devices should be used until the medical community

can refine their knowledge as to the types of training and experience and qualifications an individual wil need in order to properly and safely perform these procedures, both for the personnel involved and the patient.

A member of the public, Manual Cerqueira, M.D, a practicing cardiologist, made comments on the training and experience issue involved with this modality. He indicated that there has been discussion with cardiologists. The intent is not to have cardiologists using these modalities without assistance from radiation oncologists, but to work with people that are knowledgeable about the types of radiation that can be used and the doses that will be administered to the patients. Training requirements need to be established such that people are not restricted from working with low levels of radiation which are not a risk to the patient or personnel. When dealing with higher levels of radiation, there needs to be cooperation with the radiation therapist and people working in this field. It is important to work with the cardiology community to look at existing training requirements and develop new requirements for this modality.

Ms. Brown expressed a concern that not all physicians will admit that they do not know everything, and that there will be some who will perform these procedures without being thoroughly knowledgeable in them. Dr. Cerqueira stated that the American College of Cardiology is interested in assistance to develop guidelines that will allow only certain people who have received the appropriate training to perform these procedures. Additionally, hospitals have credentialing processes for cardiologists, processes which have to be met in order to perform these procedures.

Security and Control Issues of Byproduct Material in Medical and University Settings

Cynthia Jones discussed the recent workshop, held in Region I, to specifically address the issues of security and control. The licensed community is indicating that although many private research and developmental research activities can comply with strict implementation of the regulation in 10 CFR 20.1801 and 1802, many types of facilities like broad scope medical and academic programs are having difficulty. Ms. Jones discussed the history of Part 20 and how the language, "...under constant surveillance and immediate control..." evolved. The revision to Part 20, begun in 1986, has very similar words, requiring licensees to secure radioactive material stored in controlled or unrestricted areas from authorized access. NRC has received comments that these security requirements place unnecessary restrictions on research. However, the Commission at that time felt that locking radiotracer laboratories when they are not being used was a small inconvenience compared to the consequences of unauthorized access to, or theft of, radioactive materials. From 1957 to the present, there appears to be an intent from the Commission to secure all quantities of radioactive material, no matter how small. Recent inspections have shown that security and control of radioactive materials were weak in that licensees have some controls, but not all of the time. Part of the difficulty is with conflicting guidance with regard to the

need to control material as it is applied to the requirements for labeling.

There was discussion during the workshops as to whether NRC should include certain questions in an inspection or factor in different items, such as whether a licensee has an audit program, whether a licensee finds its own security and control violations and provides a corrective training program, or whether authorized users are knowledgeable about security and control of material. Also, large programs with thousands of labs are held to the same standards as a much smaller program, with only a few labs. An issue that is being evaluated is whether there should be a threshold as to the number of labs in violation before there is a concern. Additionally, one has to consider where unsecured radioactive material is found. There are several factors that could affect compliance decisions, such as whether the material was found in an unrestricted, restricted, or posted area, or found out in the middle of the university somewhere.

Another question is whether there is some threshold of radioactive material, below which, does not need to be controlled in a manner that means always secured or in attendance by an individual. It has been proposed by licensees that it be a multiple of Appendix C. NRC has also looked at a multiple of Appendix B. One consensus from the workshop is that if the material is a stock solution and/or it is a very large quantity of material, it should be secured and locked. Everyone agreed that for very low levels such as those in Appendix C, and a regulation exists stating that the material does not have to be labeled, then that material should not have to be secured and controlled in the same way.

The staff is evaluating the current regulations and will be proposing a policy to the Commission for either changes to the regulations or changes to the enforcement policy for security and control of radioactive material. A problem is that the regulation applies to all licensees, both reactors and materials.

Questions for the ACMUI:

1. Are there materials that require no security or control or are adequately controlled by the normal laboratory environment? If so, what quantity?

2. What is the basis and the threshold for materials that require a) no security/controls, b) low, medium, and high-level security and controls?

3. What level of detail is needed in guidance from NRC to licensees regarding security and control at laboratory facilities? How specific or prescriptive should any NRC guidance be?

4. What items or issues MUST be included or addressed in NRC guidance to licensees about security and control of material?

5. What factors should be considered by the NRC in determining the appropriate level of enforcement for security and control violations, and what thresholds, if any, should exist?

Dr. Wagner indicated that certain quantities of materials could be placed into the "exempt" category that NRC has in place. Dr. Flynn expressed concern that a potential bureaucratic process would be put in place. People in labs will receive a certain amount of basic training and follow certain procedures. However, if they start a new project, with much different levels of radiation, there could be problems. Labs are constantly changing; it will be confusing to constantly change the category one's lab falls into and what kind of training is needed or what kind of security is needed. The main focus in the labs is research, not radiation.

Mr. Graham stated that scientific parameters must be established that would allow for security where there is a clear danger to the public and avoid the inconsistency of implementation during an inspection.

Dr. Williamson reminded the committee that ACMUI agreed that quantities of radioactivity that were below the threshold for being labeled should not require the extreme security measures. There was further discussion on the lack of consensus among the workshops as to whether the limit should be Appendix C quantities, or some multiple of that quantity, such as ten or one hundred times.

Dr. Wagner asked if the security issue is to prevent an unknowledgeable person that might have access to the material from contaminating themselves and spreading radiation or if it is securing against sabotage or malicious acts, which are unlikely events. Such events cannot be regulated to zero. He believes that this will put very strict requirements on many facilities for which sabotage and maliciousness is an unlikely event and who have good controls over their work force. Another consideration is that maliciousness may be coming from someone within the lab itself, who will be knowledgeable, and will have authorized access to material, even when it is secured. Ms. Jones indicated that it is for protection for individuals who may enter a lab and not be knowledgeable about radiation.

Mr. Swanson indicated that it is an issue not only with signs indicating the presence of radioactive material, it is also an issue of labeling. Material should be labeled. Additionally, there are risks with toxic chemicals within the labs, many of which are not locked or secured in any way. Many of these are much more toxic than the levels of radioactive material that one will encounter in the labs. He is not sure that anything beyond posting and labeling, and ensuring that exposure rate limits are within appropriate limits, is necessary.

Dr. Wagner indicated that it is important to remember that these discussions were triggered by the recent malicious events, which are already controlled by regulation. The discussion about things such as storage and signs is a

different issue. He recommended that the Commission change its policy from the strict enforcement of the regulations, which is the way it is currently done. A zero tolerance policy for relatively minor things is a major problem within a large institution. The concern is whether a facility is really making appropriate efforts necessary to keep materials secured.

Regarding an acceptable threshold for the number of labs in violation, Mr. Swanson stated that it should be more performance-based, rather than prescriptive, as to the amount of security and control a licensee has over the use of radioactive material.

Ms. Jones indicated that there is not a consensus as to how much should be done through regulations and how much should be done through inspection/enforcement. An immediate fix to the problem is to change the enforcement policy.

Dr. Wagner believes that NRC should give radiation safety committees at large institutions more authority and responsibility to ensure that the spirit of the law is met, and remove the prescriptive aspects.

Mark Rotman, a member of the public, made a statement. He referred back to Dr. Paperiello's opening remarks and his discussion of diagnostic nuclear medicine as a low risk activity. He indicated that there are some 10 million radiopharmaceutical doses given annually, with the release of patients with various levels of radioactivity, some of which could be biologically excreted by these patients, with a potential impact on the dose to the public. He believes that there is a discrepancy in the amount of regulation as it relates to the public health and safety between the release of patients, and the potential exposure to other individuals, and the security involved with the low level of radioactive material used in biomedical research facilities.

The National Institutes of Health submitted a written statement on the issue of security and control (Attachment 2), from which excerpts were read.

Inspection Guidance for Final Patient Release Rule

Joe DeCicco discussed the inspection guidance for the final Patient Release Rule, which became final in October 1996. The staff is working on guidance for inspection against the new rule, to be used at the same time as when the final rule takes effect. Mr. DeCicco reviewed the four parts of the rule for the release of patients and necessary instructions for certain criteria.

Mr. Swanson and Dr. Wagner both noted that the word "consequence" was not removed from the rule language, an issue on which the ACMUI had a strong consensus resulting from discussion at the last meeting. There was a strong belief that "rationale" would be a better choice as it is not possible to give information on the consequences of low doses of material. Rationale covers a broad spectrum of activities and why one does certain things. Ms. Brown did not believe it was an issue from a patients rights perspective. The

consequence could be that there are none, or that it is not known. Mr. Camper explained the deliberative process between the program offices, and that some recommendations are taken and others are not. Additionally, the Commissions' staff may direct changes to the rule. Mr. Graham suggested that rather than re-deliberating on an issue that is final and about to be published, that the committee focus on the issue of inspection of the rule, as asked by the staff. The committee can comment on the instructional material that goes to inspectors. The committee did not wish to pursue programmatic procedures for evaluating the possibility of replacing the word "consequence" with "rationale."

Under a performance-based inspection, an inspector should ask the licensee how it demonstrates compliance with authorizing release of patients administered radiopharmaceuticals, and ask such questions as:

- Is there a process to determine the total effective dose equivalent to other individuals not likely to exceed 5 millisieverts?

- Is there a process to determine if the maximally exposed individual is a breast-feeding infant or child?

- Is there a process to determine the dose to the breast-feeding infant or child.

Inspectors should review instructions provided to the released individual. The inspector should determine if instructions or a sample of written instructions are available. The inspector should look to see if there is instruction available for the individual breast-feeding and if there is guidance on interruption of breast-feeding and the consequences of failure to follow the guidance.

Inspectors should review samples of maintained records that indicate the basis for authorizing the release of a patient, looking for a record, basis for authorizing release documented, and if the non-medical assumptions used in the basis for release reasonable. Inspectors should review samples of maintained records that indicate instructions were provided to an individual breast-feeding an infant or child.

A question was raised as to the requirement for documenting the process. Are licensees in compliance if they respond by indicating that they use the chart in the regulatory guide and ask every woman if she is breastfeeding an infant or child? Mr. DeCicco indicated that there is only a requirement to determine whether a woman is breastfeeding an infant or child, not to document that the question has been asked. Mr. Swanson expressed concern that this is how many problems start in the enforcement process. An inspector will ask for documentation that the process is taking place. Mr. Camper indicated that the questions in the guidance will be the ones that inspectors will ask, and that an inspector should not ask for further documentation. Dr. Stitt indicated that the committee's concern is that many things get interpreted and put into

practice, even though they are not required in the regulations. Mr. Graham also stated that a hospital looking at risk management will set up a documentation process to avoid future liability, even though the documentation is not required by the regulation.

Status Report on Rulemakings and Regulatory Guidance

Time constraints prevented the presentation of this topic. The members were provided a written summary of the status of rulemakings and regulatory guidance, a copy of which is attached (Attachment 3).

Administrative Issues

Some members of the committee requested information on NRC's organizational structure, how the committee's decisions flow through that structure, if decisions/recommendations from the ACMUI are not taken, consideration for providing the rationale for not accepting recommendations, and the scientific basis for going a different direction.

The committee unanimously agreed that a briefing to the Commission in conjunction with the Spring meeting might be useful.

The meeting adjourned at 12:49 p.m.

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