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

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 April 10 and 11, 1997, are an accurate record of the proceedings for that meeting.

Judith Anne Stitt, M.D., Chairman

4-23-97
Date

Attachment: Minutes - ACMUI mtg.
4/10-11/97

Minutes of the Spring Meeting of the
Advisory Committee on the Medical Uses of Isotopes
April 10 and 11, 1997

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting on April 10 and 11, 1997. 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; and Cathy Haney, M.S., Section Leader, Medical and Academic Section, NRC. Barry Siegel, M.D.; Aubrey Godwin; and Larry Satin, M.D. also attended the meeting as invited guests, representing nuclear medicine, the States' perspective, and Nuclear Cardiology respectively.

Mr. Camper officially opened the meeting at 8:17 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.

Donald A. Cool, Ph.D., made opening remarks to the Committee regarding the upcoming revision of Part 35 and the Committee's involvement. He stated that NRC is about to take a fundamental re-examination and re-crafting of the regulations pertaining to the medical uses of isotopes. This will involve a whole new view, "a white piece of paper", at regulating the medical use of radiation. The new revision of Part 35 will be risk informed and performance based.

Commissioner McGaffigan addressed the Committee. The Commissioner stated that he was there to give insight of how the Commission came to their decision regarding DSI 7. The Commissioner also discussed various topics including: the IOM report; DSI 12; linear no-threshold hypothesis (LNT); and ACMUI's input to the revision of Part 35. The Commissioner noted that regulations can not be totally non-prescriptive but we should strive to be as performance based as possible. He also requested that the ACMUI give their input to the staff early.

Hugh Thompson discussed how the other NRC Advisory Committees operate in comparison with ACMUI. Mr. Thompson noted that the ACRS has a full time NRC staff to deal with the Committee actions and each Committee member spends about half of their time on work related to ACRS. This is in comparison to the ACMUI which is supported by staff in NMSS. On this same topic he encouraged the Committee to give their input to the staff. He offered to give more feedback to the Committee regarding their recommendations and on the status of various projects.

Discussion of the Advisory Committee Process

Larry Camper presented on the Advisory Committee Process. This presentation covered much of the history of the Committee and how it has evolved over the last ten years. Also covered was the current recommendation process of the Committee and recommended improvements of the process. There was a discussion of the recommendation process and a feeling that more feedback to ACMUI from the staff is needed to keep the Committee updated as to how their recommendations are used.

In accordance with the ACMUI bylaws and recent direction from the Commission, the Committee is expected to formalize its recommendations, including dissenting opinions, within the minutes of each meeting. The minutes along with the meeting transcripts are provided to the Commission. ACMUI recommendations and concerns are considered by the staff and Commission in the development of regulations, guidance, and policy.

Dr. Flynn observed that the Commission seems to still be very reactor oriented. He suggested that there be one Commissioner who has a medical background. He also suggested that the NRC staff be expanded to include individuals with medical experience or the medical fellow program be expanded to make individuals with medical experience available to the current staff. Mr. Camper responded by describing contributions made by Dr. Polycove as a visiting medical fellow.

Dr. Siegel, an invited guest, noted that the bylaws state a member's term is two years, as opposed to three years which has been the practice. Mr. Camper responded that this was a good administrative point and that appropriate action will be taken to address the discrepancy.

Discussion of Staff Requirement Memorandum Regarding Direction Setting Initiative 7

Larry W. Camper discussed the Commission's Staff Requirements Memorandum (SRM) entitled "Materials/Medical Oversight (DSI 7)" dated March 20, 1997. He described the NRC staff's planned actions to complete the revision of Part 35 by the Commission's target date of June 30, 1999.

Mr. Aubrey Godwin, an invited guest representing the States' perspective, remarked that the SRM did not specifically address the "enforcement issue." Mr. Camper responded that, although the SRM does not specifically address enforcement, DSI 7 does indicate that the effort toward risk-informed performance orientation should also be brought to bear in terms of implementation as it

relates to inspection and enforcement.

Mr. Godwin and Mr. Camper discussed the need to reduce the inspection frequency for low risk activities. They were in agreement that a reduction in regulatory presence would, in many cases, result in a reduction in inspection frequency.

Several members of the Committee expressed an interest in identifying the NRC Office that would lead the revision of Part 35. Mr. Camper explained that the lead for the Part 35 revision had recently been transferred to the NMSS program office; and the Office of Nuclear Research will be providing resources and contract support. Dr. Stitt questioned the difference she might see on a rule developed by the program office compared to a rule developed by the Office of Research. Mr. Camper responded that, because the program office implements the rule for both licensing and inspection, and because he interacts directly with the ACMUI, it may be more sensitive to changes that are needed.

Mr. Camper proceeded to describe the plan for the staff revision of Part 35. This plan included submitting a program for the rulemaking to the Commission by June 6, 1997 and have the final revision of Part 35 by June 30, 1999. Dr. Nelp asked if NRC planned to revise each of the subsections of Part 35. Mr. Camper responded that we have "a clean piece of paper." We have the opportunity to develop a completely new Part 35. However, if there are parts that do not need to be changed, the ACMUI should point them out. Mr. Camper proceeded to describe a possible model that had been provided to the program office. If this model were adopted, Part 35 would be organized by modality. Each subsection would contain all of the requirements for that particular use. This would enable the staff to easily make changes pertinent to a particular modality of use when needed.

Dr. Nelp stated that he believed the ACMUI could best be used in discussing "focused" issues rather than organizational writing.

Dr. Stitt encouraged the Committee to give the NRC staff feedback on the issue of risk. Dr. Williamson asked for definitions for risk-informed, and performance-based. Mr. Camper suggested the Committee begin with DSI 12, which defines the Commission interpretation.

Dr. Williamson asked, for the purpose of revising Part 35, what the term "performance-based criterion" means? According to Dr. Williamson, one of the major concerns of the regulated community he represents is enforcement resulting from "paper-work sorts of violations that have no clinical significance."

Mr. Camper responded that NRC will license, inspect, and enforce the written regulation. When the regulation changes, there will be a corresponding change in licensing and enforcement.

At this point, Dr. Stitt allowed Mark Rotman to read a statement prepared by the American College of Nuclear Physicians/Society of Nuclear Medicine which discussed risk and their support

of the IOM report.

Mr. Godwin, returning to the general topic of revising Part 35, pointed out that there was no apparent provision to take immediate action on current regulations that might be determined to be unneeded.

Ms. Walkup questioned whether the revised rule would be implemented in steps, or all at once. Mr. Camper responded that they can be implemented either way. However, he would expect that there would be an effective date, and implementation dates for NRC and Agreement States licensees.

Dr. Barry Siegel, an invited guest representing the nuclear medicine perspective, made the statement: "diagnostic nuclear medicine is low-risk." He stated the belief that the revision of Part 35 should start with changes to NRC's Medical Policy Statement "so that the physician-patient interface is no longer the purview of the NRC."

Mr. Graham recalled the subject discussion, and moved forward to the Commission's directions to the staff for the revision. He reiterated the need to focus Part 35 on those procedures that pose the highest risk, and that the ACMUI further discuss the Medical Policy Statement, and how it would be modified to direct all of its other activities. He suggested that the staff should consider oversight alternatives for low over-all risk activities; and regarding misadnimistrations the staff should only capture precursor events in the whole process of changing from "misadministration" to "medical event."

Dr. Swanson stated that, in discussions of "risk," you must first define risk of what? He questioned what NRC was trying to regulate - public, occupational, or patient exposure? He also questioned the components of a risk matrix. He believed regulators would probably factor in political and public perception consequences. He also believed that medical use is low risk if you used NRC's probabilistic methodology.

Dr. Williamson suggested that, in discussing relative risk, the ACMUI should discuss three different populations that can experience consequences: the public, the workers, and the patients, and rank modalities separately. Depending upon how the issue of the Policy Statement is resolved, patients could be dropped. Dr. Stitt agreed with that approach.

Dr. Stitt called for a lunch break at 11:50 am.

Discussion of the Medical Policy Statement of 1979

The importance of the Medical Policy Statement of 1979 to the entire process of revising the medical use regulations in 10 CFR Part 35 was brought out by Barry Siegel in the preceding discussion of DSI 7. Dr. Siegel believed the ACMUI had to start with the policy because it was

the driving force that set the boundaries on the Commission's regulatory oversight of medical use programs. Extensive discussion followed.

Dr Siegel proposed dropping Statements 2 and 3 from the Medical Policy Statement (once the 2nd statement is dropped, the 3rd becomes irrelevant). This would remove the physician-patient interface from NRC's purview and have NRC focus its efforts on the workers and the general public. He recommended the ACMUI develop its recommendations based on both the track "without" and the track "with" patient safety as a part of NRC's medical regulations. Dr. Siegel pointed out that in the past the Commission's perspective was if one or several patients could be hurt because of the application of byproduct material then that risk to the patient justified the regulation.

Several members pointed out that the Medical Policy Statement did not need to be changed if it was interpreted differently. Mr. Swanson stated that if a probabilistic risk assessment approach is used (the probability of risk times the potential outcome), for risky procedures with low probability the result is low risk. Dr. Nelp believed that the policy did not need to be changed, all that was needed was for the ACMUI to determine that regulation of the patient radiation safety was not necessary or justified. Dr. Stitt proposed focusing on the phrase "where voluntary standards or compliance with these standards are inadequate." She pointed out that from 1979 to 1997 many adequate standards have been developed thus, the current policy statement could be used to support that there is no need for regulations.

Dr. Stitt also supported the idea that the Medical Policy Statement should be composed only of Statement 1 (NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public).

Others explained their reasons for supporting Dr. Siegel's proposal. Dr. Wagner believed regulations addressing radiation safety of patients are not justified by the risk, since the probability of an event occurring is extremely low, even if the once-in-a-while incident has a high risk. He also thought as long as individuals have the proper training to handle radiopharmaceuticals, the risk is low. Dr. Williamson made the argument that although not substantially different from that of other medical subspecialties practicing procedures of similar intensity and complexity, the Medical Policy Statement allows NRC to impose an artificially low acceptance probability for misadventures upon the small discipline of radiation medicine. Dr. Flynn thought Statements 2 and 3 are covered by State licenses, which can be revoked by the State, and the patient was protected by various malpractice laws.

Ms. Brown did not agree with Dr. Siegel's proposal. She likes nuclear medicine's attention to detail and accountability, items that she believes may be lacking in the rest of medicine.

A significant amount of time was spent discussing whether user training and experience requirements could still be imposed if Statements 2 and 3 were dropped. Dr. Siegel thought the training and experience requirements needed to protect the workers and general public would also

insure well trained physicians and indirect protection for the patient. Mr. Godwin believed if Statement 2 was omitted from the Medical Policy Statement all clinical experience requirements would be dropped and only minimal radiation safety training would be needed.

Mr. Swanson's indicated rather than trying to argue for a new Medical Policy Statement, it may be better to ensure that the regulations reflect the Medical Policy Statement.

Dr. Nelp make the motion that Statements 2 and 3 be omitted from the Medical Policy Statement. The motion was seconded and open for discussion. Both Mr. Swanson and Dr. Kang had reservations about the motion. Mr. Swanson's concern was that the NRC answers to the public, and it would be difficult for the NRC to take out any statement that makes it appear that they are giving up regulatory authority over a risk issue. Dr. Kang agreed with Dr. Siegel's position that NRC should not interfere in medical practice, but was concerned that Statement 2 should be changed and not dropped. He thought NRC has a particular duty with respect to reasonable assurances for the radiation safety of the public, including the patient.

After a lengthy discussion about whether the NRC could have training requirements without the 2nd and 3rd statements, and Mr. Graham's suggestion that Statement 2 be changed and not dropped, the motion to delete Statements 2 and 3 from the Medical Policy act was withdrawn. Dr. Siegel suggested two additional modifications to Mr. Graham's suggested change to Statement 2. The first was to have the beginning read "NRC will regulate the radiation safety of patients only where justified by the risk to patients, and only where voluntary standards or compliance with these standards are inadequate" and secondly to add another sentence to the end. The second sentence was "Assessment of the risks justifying the regulations will reference comparable risks and comparable modes of regulation for other components of medical practice." He concluded that it defines the universe, and the reference framework. Mr. Graham suggested revisions to Statement 3.

Mr. Graham made a motion to revise Statements 2 and 3 of the Medical Policy Statement. Mr. Swanson suggested a minor change to Mr. Graham's recommendation. The ACMUI recommended by a 9 to 1 vote that Statements 2 and 3 of 1979 Medical Policy Statement be revised to read as follows:

- Statement 2: The NRC will regulate the radiation safety of patients **only** where justified by the risk to the patients, and **only** where voluntary standards or compliance with these standards are inadequate. **Assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.**

- Statement 3: The NRC will **not intrude** into medical judgements affecting patients and into other areas traditionally considered be a part of the practice of medicine.

The dissenting vote was cast by Ms. Brown. She indicated that the current Medical Policy

Statement is adequate and that no changes were needed.

Discuss Criteria and Ranking of Medical Procedures Involving Byproduct Materials by Risk

Cathy Haney led the discussion on the criteria and ranking of medical procedures by risk. Ms. Haney asked ACMUI to discuss the following items: identification of key modalities and the relative risk; ranking of the modalities by their relative risks; identification of criteria to be used in the ranking; description of the level of regulatory presence needed for each modality; and identification of the key items to be regulated under each modality.

The Committee began with the first discussion item, identification of key modalities and the relative risk. Due to time constraints, the Committee did not address each item separately however, some of the discussion did touch upon related topics, such as, ranking the modalities by their relative risks.

The first issue discussed by the Committee was defining what was meant by risk, particularly in a medical context. It was generally agreed that overall risk for a given modality is defined by the product of the probability of occurrence of an error multiplied by the severity of the consequences of that error.

This was followed by a discussion on whether risks, for a given modality, to the patient, worker, and public should be treated separately or combined. To simplify the discussion, it was proposed that only risks to the patient be considered. However, after further discussion, it was generally agreed that most modalities presented some risk to all three populations. Thus, a determination of the overall risks associated with a given modality would need to consider all three populations. The point was made that risks to the patient differed in one substantial way from those to the workers and public. Namely, the patient risks were single short time span events, whereas, the risks to the workers and the public tend to be cumulative over time.

In order to better focus the Committee's discussion, it was recommended and agreed upon to begin by discussing the risks associated with diagnostic nuclear medicine. There was general agreement among the Committee that this was readily classified as a low risk modality with little risk to either the patient, worker, or the public. This classification was based on the Committee's perception that the risks associated with this modality had both a low probability of occurrence and that the non-stochastic consequences of an error were negligible. It was, however, pointed out that this was not the case for many diagnostic quantities of I-131 due to the significant probability for damage to the thyroid from a misadministration or medical event. Also, recognized was the potential for injury to the workers and public from the use of I-131.

The potential for patient harm from misadministrations of I-131 led to a discussion of how a diagnostic procedure or isotope could be classified in terms of risk. While generally agreeing that most diagnostic procedures should be classified as low risk, it was recognized that not all could be

so classified. It was generally agreed that the Committee wanted to avoid doing an isotope by isotope evaluation of risks associated with diagnostic nuclear medicine procedures. This led the a proposal by the Committee to define the risk associated with a given diagnostic nuclear medicine procedure as follows:

> "Diagnostic isotopes should be classified as low risk unless there is the potential for observable clinical injury to the whole body or an individual organ".

Discuss the Regulatory Use of Industry Standards

Susanne Woods led the discussion on the regulatory use of industry standards. She indicated that item 7 of that SRM directed staff to consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they may meet NRC's needs. The Committee was asked to discuss how to bring available industry guidance and standards into the regulatory framework, where they should be located, and how to keep the information current.

The Committee did not reach a consensus but actively explored a number of perspectives and issues associated with Item 7.

Dr. Siegel thought the partial answer was in the medical policy statement already, i.e., NRC will make a regulation where voluntary standards or compliance with voluntary standards are inadequate. He believed that it was not necessary to reference standards in the regulations, but rather look to see if the standard of care is being defined by the existence of those voluntary standards; then decide whether or not there's general compliance with those voluntary standard. If this was the case, he believed a regulation was not needed.

Mr. Graham pointed out that each standard has a potential to be handled differently. For example, the potential ANSI classification of a sealed source that might be used in brachytherapy, might be put in the regulations as a minimum standard for the type of sealed source. On the other hand, AAPM guidance documents should be put in guidance so that the documents can be modified by an institution. He also pointed out a number of problems in using industry standards. First, NRC will be lagging the industry practice as updates come out. Since an update has to be reevaluated and put in the Federal Register to give people a chance to comment on it before it is adopted. Secondly, users of standards may not be willing to adopt revised standards although NRC has endorsed the revision. The community then continues to follow a document that is no longer accepted by NRC. Dr. Siegel pointed out an additional problem in that industry standards, in substantial part, were predicated on existing NRC requirements. He stated a concern that if regulations did not exist, standards may not be developed. Dr. Flynn pointed out that some standards, while applicable to a medical use NRC regulates, really have very little to do with NRC.

Mr Swanson concluded that the Medical Policy Statement says NRC will regulate where

compliance and standards are inadequate. If inclusion in the regulatory guidance does not constitute regulations, then by definition, NRC would have to put industry standards and guidance in the regulations. Others had concerns that documents meant to be flexible would become engraved in stone if they were incorporated in regulatory guides. Dr. Flynn recommended referencing the standards in regulatory guides and updating the guides annually.

Dr Williamson concluded that simply saying standards of practice will be in the licensing guide for implementing a given regulation might not be appropriate. He indicated that it might be better to go through the various standards one by one and isolate the recommendations pertaining to the issue of direct concern.

Discussion of Quality Management and Misadministrations

Sally Merchant requested that the ACMUI identify the incidents, events, and occurrences that should be reported to the NRC. Patient harm, including a dose to the wrong patient or wrong treatment site, and the following possible failures were provided as potential reports.

Mr. Swanson discussed his preference that medical events be reported to one organization, rather than establishing reporting levels. He believed that this organization need not be the NRC. He also provided the following positions. Diagnostic events should be captured to (1) provide more data and (2) identify poor therapeutic practices that are likely to accompany poor diagnostic practices. The reporting environment should not be punitive, in order to encourage reporting for the purpose of cause determination.

Dr Swanson cited the USP medication errors reporting program of voluntary and, possibly, anonymous reporting to FDA as an example of a reporting program. Dr. Swanson further commented that the nuclear medicine community does not appear to be following this standard well, and, as such, the Medical Policy Statement would need to support initiating requirements to participate in the USP program. A peer group would identify the need to examine a site identified for several events. Participation would be identified upon inspection.

Dr. Williamson agreed that all precursor events should be reported, including near misses and irregularities. He emphasized that few radiation oncology events are likely to result from machine failure. Dr. Nelp commented that diagnostic misadministration have a very low incidence. He believed that a tremendous amount of data would not be collected. He felt that the concept is punitive, and the determination has been made that there is no risk.

Mr. Graham indicated the need to explicitly define, at a national level, the cost-benefit for a national tracking system. He preferred that the reporting and analysis be kept within the health care system. He believed that the system is large enough to collect a large amount of data and small enough to analyze it, while changing the way care is delivered.

Dr. Kang commented that the FDA Center for Device Evaluation receives all machine failure

reports. Mr. Camper commented that NRC will need to avoid duplication of FDA efforts.

Mr. Godwin commented on several areas. He indicated that the listing provided by FDA is a data-base print-out with both time-line and organizational problems, and that an analysis is not provided to address generic failure, single event failure, or whether the community should be alerted. He also discussed the need to add "wrong pharmaceutical" to the reporting listing provided by NRC, and the need to include listed items in Part 21 requirements. He introduced the FAA pilot-reporting system as demonstrating a non-punitive approach to reporting.

Mr. Williamson suggested that the term "medical event" be reserved for events with a high probability of resulting in an adverse medical effect on the patient. This type of event should be distinguished from (1) "bookkeeping" errors, (2) treatment delivery errors without medical consequences, and (3) precursor events. Dr Stitt indicated that "medical event" appears to be a health care/patient related term.

Mr. Camper emphasized that the definitions used are as important as the actual terms they define. Events such as software failures, machine failures, and leaking sources may be reported without calling them misadministration. He indicated that reporting levels need to be defined for those events that result in exposure to a patient. Dr. Nelp commented that the threshold would be high, if based on harm to the patient.

Mr. Williamson commented that a case-by-case review would have to be made to isolate events involving patients with significant risk of being harmed and establish reporting requirements. He referred to a definition of misadministration that he and Ms. Brown submitted to ASTRO and ACR, which established a threshold overdose of greater than 20 percent, when the entire course of therapy (i.e., external beam and radioisotope therapy) is included. The lower threshold for wrong site was at least 2 Gy to a site that was not planned to be in the treatment field, or 10 percent more than the dose that would have been delivered via the planned treatment, whichever was greater.

Mr. Swanson commented that the complexity of the current misadministration definition is a problem that is confusing when, in practice, it differs from state requirements for reporting events associated with accelerator-produced products.

The discussion was summarized by Mr. Graham as falling into two areas of thought: (1) a non-threatening system that collects as much data as possible for identification of system or process issues/patterns to be corrected; and (2) a system of reporting only those things that clearly represent probable damage to the patient.

At this time the meeting ended and reconvened at 8:12 am Friday April 11, 1997.

Status Report on Rulemaking and Guidance

Cathy Haney gave a status report on the following topics: patient release rule and guidance; NUREG-1569, Program Specific Guidance for Medical Use Licenses; TI QM analysis; ANPR for Part 33; Carbon-14 petition for rulemaking; and a new petition from the University of Cincinnati.

Ms. Haney indicated that the patient release rule (10 CFR 35.75) becomes effective on 5/29/97, and that the associated Regulatory Guide would be available in about two weeks.

She indicated that NUREG-1569 was due to be published in draft during the spring of 1997. This document was being issued for public comment and is not to be used in the preparation or review of applications for medical use licenses.

She provided a brief summary of the public comments received in response to the advanced notice of proposed rulemaking (ANPR) on Part 33. This presentation resulted in the ACMUI bringing the following motion to the table: "ACMUI recommends retention of the current regulatory approach for [Part] 33." The vote was 9 for and 1 opposed. Dr. Williamson stated in opposition that "[he does not] feel able to assess the rigidity and flexibility of the current process relative to what might happen at this time."

Ms. Haney indicated that revised inspection guidance on performing inspections of the quality management (QM) rule has been provided to the regional staff. She indicated that a summary of the QM inspection procedures was provided to ACMUI in the briefing book. The ACMUI discussed the nature of the QM inspection procedures and brought the following motion to the table: "[the ACMUI recommends that the NRC] modify the QM inspection procedures with the intent to reflect the spirit of the Commission direction in the SRM [regarding DSI 7]." The vote was 9 for the motion and 1 abstention. Judith Brown abstained because she was not familiar with all of the elements of the issue. Dr. Wagner wished to go on the record stating that the QM rule as a regulation was unnecessary.

Cathy Haney introduced the subject of the carbon-14 petition which was received in 1994. This prompted a discussion of the rulemaking process and the timeliness of the process. The rulemaking plan to resolve the petition will be forwarded to the EDO this month.

Ms. Haney informed the ACMUI that the staff was reviewing a petition submitted by the University of Cincinnati. This petition requested that the NRC amend 10 CFR 20.1301, "Dose limits to individual members of the public," to authorize "specified visitors" of hospitalized radiation therapy patients, as individual members of the public, to receive 500 mem. per year Ms. Haney indicated that additional information on the resolution of this petition would be made available at the next meeting of ACMUI.

Preparation for the May 8 Commission Briefing

The Committee members prepared for the Commission briefing on May 8 at 9 am. Dr Flynn suggested that the Committee spend only 15 minutes on the Medical Policy Statement and the remaining 45 minutes addressing the 8 items of the SRM regarding DSI 7.

Larry Camper requested that the Committee prepare their recommendations on the revision to Part 35 and submit them to the staff before the May 8 Commission Briefing. The Committee indicated that they would use telephone conferences to discuss issues associated with the revision of Part 35.

The meeting closed at 12:25 pm.