

January 31, 2000

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers */RA by Frank Miraglia Acting For/*
Executive Director for Operations

SUBJECT: SUMMARY MINUTES OF THE OCTOBER 20, 1999, MEETING
OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF
ISOTOPES

An Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting was held on October 20, 1999. Attachment 1 is a summary of the discussion, and endorsements by the ACMUI. Attachment 2 is a more detailed description of the minutes of the meeting.

Attachments:

1. Summary of Discussion and Endorsements
2. ACMUI Minutes, October 20, 1999

cc: SECY
OGC
OPA
OCA
CFO
CIO

CONTACT: Betty Ann Torres, NMSS/IMNS/RGB
301-415-0191

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NAME	BTorres	CHaney	DCool	EKraus	WKane	CPaperiello	WTravers
DATE	01/10/00	01/12/00	1/14/00	01/19/00	01/21/00	01/31/00	01/31/00

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SUMMARY OF ACMUI DISCUSSION AND ENDORSEMENTS FROM OCTOBER 20, 1999 MEETING

Discussion of Self Evaluation of the ACMUI

Draft responses to the self-evaluation criteria for ACMUI were developed and will be provided to ACMUI members for review and comment before being finalized and forwarded to the Commission.

Discussion of ACMUI's Presentation for the Part 35 Commission Briefing

Radiation Safety Committee (RSC): The ACMUI endorsed the requirement for an RSC for two or more different types of uses under Subparts E, F, and H or two or more types of units under Subpart H.

Training and Experience: The ACMUI endorsed the alternative pathway for training and experience and the 80 hour requirement for physicians who only use I-131.

Medical Event: The ACMUI had previously endorsed the dose thresholds for medical events at their March, 1999 meeting.

Reporting Threshold for Reporting Exposure to an Embryo/Fetus/Nursing Child: The ACMUI discussed the impact on medical care, including standards of practice for pregnancy testing, the financial impact of pregnancy testing, unduly alarming pregnant women by notifying them of low exposures to an embryo or fetus, patient-physician confidence, increased regulatory burden, and the relationship of the threshold for reporting to safety considerations.

Notification Following a Medical Event or Exposure of an Embryo/Fetus or Nursing Child: While the ACMUI does not support any regulation requiring notification of physicians and patients, since this is redundant with existing standards of care, the Committee unanimously voted in favor of the alternative rule text, which was provided to the Commission in response to the SRM for the March, 1999 briefing on Part 35.

Implementation Issues: Ms. Haney updated the Committee on the status of the guidance document being developed along with the Part 35 rulemaking, pointing out that a benefit of the NUREG would be to provide model procedures for licensees that are less sophisticated than some of the larger licensees, while also providing flexibility for licensees to use different types of procedures. Dr. Wagner noted that ACMUI subcommittees would be useful in the development of revised inspection procedures.

SUMMARY MINUTES
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 20, 1999

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting in Rockville, Maryland on October 20, 1999. A briefing book was provided to the ACMUI members and is available through the Public Document Room.

ACMUI members present at the meeting were:

Manuel Cerqueira, M.D., Acting Chair, representing nuclear cardiology and nuclear medicine
Nikita Hobson, representing patients' rights
Ruth McBurney, M.S., CHP, representing the states' interests
Louis K. Wagner, Ph.D., representing medical physics

Invited guests present at the meeting were:

Dennis P. Swanson, M.S., B.C.N.P, representing nuclear pharmacy

Nuclear Regulatory Commission staff present at the meeting were:

Cathy Haney, Acting Branch Chief, Rulemaking and Guidance Branch (RGB), Division of Industrial and Medical Nuclear Safety (IMNS), NMSS and Chair of the Part 35 Working Group
Donald Cool, Ph.D., Director, IMNS, NMSS

Part 35 Working Group Members present at the meeting were:

Diane Flack, RGB, IMNS
Penny Lanzisera, Region I
Barry Siegel, M.D., medical consultant to the Part 35 Working Group

OPENING REMARKS

Ms. Cathy Haney, Designated Federal Official for the Committee, opened the meeting at 2:00 p.m. with general comments on the meeting agenda and the function of the ACMUI. Ms. Haney noted that the meeting was announced in the Federal Register on October 5, 1999. She stated that any ACMUI member who becomes aware of a potential conflict of interest during the course of the meeting should state it for the record and recuse themselves from that particular aspect of the discussion. She also stated that she had reviewed the Committee members' financial and employment interests, and had not identified any conflict of interest with the items to be discussed during the meeting.

Donald A. Cool, Ph.D., made opening remarks to the Committee. Dr. Cool said that the agenda of the meeting was focused on preparing for the ACMUI's briefing of the Commission on the revision of Part 35 the next day. He noted that the briefing is a public opportunity for the

Commission to hear from the staff and the ACMUI about the revision of Part 35, and any particular issues that the advisory committee might want to bring to their attention. Dr. Cool also noted that earlier that day the Commission was briefed by the Organization of Agreement States (OAS). The OAS briefing included a presentation by Dave Walter, Chair of the Conference of Radiation Control Program Directors, Inc., SR-6 Committee that is developing the Suggested State Regulations for medical licensees. Dr. Cool reported that Mr. Walter's presentation highlighted several issues where the recommendations of the SR-6 Committee are not the same as those of the Part 35 Working Group.

SELF EVALUATION OF THE ACMUI

Ms. Haney provided background on the process and need for self-evaluation of the NRC's advisory committees. In 1998 the Commission requested that all the advisory committees develop self-evaluation criteria. The other advisory committees have already provided their self-evaluations to the Commission, but the ACMUI has had to delay their self-evaluation because of the Committee's extensive involvement with the revision of Part 35.

The committee discussed responses to the following self-evaluation criteria:

1. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the Commission?
2. Do the Committee members clearly define issues for staff and provide timely, useful objective information to the staff when requested?
3. Does the Committee provide critical review and oversight of issues?
4. Does the Committee provide expertise/advice which is not available from within the agency?
5. Does the Committee meet frequently enough to address issues in a timely manner? Are any changes needed to the meeting frequency?
6. Do Committee members bring issues from all elements of the medical community to the attention of NRC staff?
7. Does the Committee facilitate/foster communication between the public/medical community and NRC?
8. Does the Committee consider current resource constraints of the NRC when recommending new or enhanced regulatory programs?
9. Does the Committee make effective use of subcommittees to assist the staff on specific tasks or projects?
10. Does the scope and size of the Committee meet the current needs of NRC?

Draft responses to the above questions were developed and are to be provided to all the ACMUI members for review and comment prior to being finalized and forwarded to the Commission.

During the discussion of the criteria, Dr. Wagner noted that the selection process for ACMUI members results in a long lead time between when a position is vacated and filled. He feels that if the positions were filled more promptly, the ACMUI would be more effective and efficient. Ms. Haney noted that the process is underway to fill the currently vacant positions. She also

noted that there is always the option of inviting someone to participate in the committee's meetings if expertise is needed in a specific area. She said that she would note this concern in the self-evaluation that would be forwarded to the Commission.

DISCUSSION OF STAFF'S VIEWGRAPHS FOR THE OCTOBER 21 COMMISSION BRIEFING

Ms. Haney went over the staff's viewgraphs (see Attachment 1) for the Commission briefing to assist the ACMUI members in preparing their own presentation. She said that her presentation would focus on key issues where the Commission either had concerns or specific questions, or where the stakeholders had concerns that needed to be brought to the attention of the Commission. She noted where the staff's recommendations had changed since the last Commission briefing in March 1999, e.g., the training and experience requirements no longer include an examination. She also noted where the draft final requirements were different from the Suggested State Regulations being developed by the SR-6 Committee.

DISCUSSION OF ACMUI'S PRESENTATION AT THE OCTOBER 21 COMMISSION BRIEFING

Dr. Cergueira opened the discussion of the ACMUI's presentation for the Part 35 Commission briefing the next day. The ACMUI had previously developed their viewgraphs, so the discussion focused on the actual presentation that would accompany the viewgraphs (see Attachment 2).

Radiation Safety Committee (RSC). ACMUI endorsed the requirement for an RSC for two or more different types of uses under Subparts E, F, and H or two or more types of units under Subpart H. Dr. Cerqueira noted that the requirement would allow the single use physician to act as his own radiation safety officer (RSO). Dr. Wagner reported that it is administratively much easier for physicists and radiation safety individuals to justify the establishment of a committee when there is a regulatory requirement. Therefore, the requirement for an RSC is important when you have higher-risk situations.

Training and Experience. The ACMUI endorsed the alternative pathway for training and experience and the 80 hour requirement for physicians who only use I-131. Dr. Siegel noted that even if the Commission approves the training and experience requirements in the draft final rule, in the near future they will have to establish training and experience requirements for intravascular brachytherapy and other emerging technologies.

Medical Event. It was noted that the ACMUI had endorsed the dose thresholds for medical events at their March 1999 meeting. Ms. Haney pointed out that two of the biggest issues associated with medical events were patient intervention and wrong treatment site, both of which the ACMUI had previously determined were adequately addressed in the draft revised rule.

Reporting Threshold for Reporting Exposure to an Embryo/Fetus/Nursing Child. Dr. Wagner pointed out the importance of recognizing that an exposure to an embryo/fetus as a result of medical exposure of the mother has to be evaluated with the full recognition that a woman who

is sick happens to be pregnant. The sick woman and the embryo/fetus can not be treated independently. He further said that this situation can not be compared to exposure of an embryo of a working mother or to exposure of a member of the general public. In addition, he pointed out that it is important that the threshold is appropriate for all stages of pregnancy. Ms. Haney said that it would be helpful if the ACMUI provided the Commission with information on how this reporting requirement would impact medical care. ACMUI members then discussed the impact on medical care, including standards of practice for pregnancy testing, the financial impact of pregnancy testing, unduly alarming pregnant women by notifying them of low exposures to an embryo or fetus, patient-physician confidence, increased regulatory burden, and the relationship of the threshold for reporting to safety considerations. Ms. Haney noted that after this requirement was final in Part 35, NRC would consider whether a similar requirement should be in Part 20 or Parts 30, 40, and 70.

Notification Following a Medical Event or Exposure of an Embryo/Fetus or Nursing Child. Ms. Haney said that the issue for discussion is what assurance does NRC need in order to assure that a patient is informed following a medical event or exposure of an embryo/fetus or nursing child. Page 28 of the staff's viewgraphs for the Commission briefing provide alternative rule text for § 35.3045 that requires the licensee to notify both the referring physician and the individual, but does not require the licensee to provide a written report to the individual. Instead, the licensee would be required to certify that they had notified the referring physician and individual. This alternative text was not included in the draft final rule, but was provided to the Commission in response to the SRM for the March 1999 briefing on Part 35.

Ms. Hobson questioned the purpose of notifying a patient if there is no possibility that harm was done to them. In particular, if you are a cancer patient and are already fighting for your life, there is no reason to put an additional burden on the patient if no harm was done as a result of the misadministration. Unless there is scientific documentation that the misadministration or medical event is going to cause harm, she said that the act of notifying the patient is harmful because it increases the stress level, raises all kinds of other worries, and erodes the patient-physician relationship. The patient becomes less confident that the medical community can take care of their illness. However, she said that she does not have a problem with notifying NRC.

While the ACMUI does not support any regulation requiring notification of physicians and patients, since this is redundant with existing standards of care, the Committee did prefer the alternative rule text provided by staff over the existing requirements. Dr. Wagner moved that the Committee agree with the alternative rule text with regard to notification, with a change in the phraseology in (d)(vii) to indicate that the licensee certifies that they have complied with paragraph (e), i.e., both the referring physician and the individual have been notified. Ms. Hobson seconded the motion. Prior to voting, Ms. Hobson made a final comment that patient notification is not a good idea. However, she would reluctantly support the alternative rule text, rather than the current rule, if a notification requirement is included in the revised rule. The Committee unanimously approved the motion.

Implementation Issues. Ms. Haney updated the Committee on the status of the guidance document being developed along with the Part 35 rulemaking. She pointed out that the guidance document would not be used to implement "de facto" regulations. The benefit of the NUREG would be to provide model procedures for licensees that are less sophisticated than

some of the larger licensees, while also providing flexibility for licensees to use different types of procedures. She also clarified the difference between “should” and “shall.” “Should” means that it is a good practice, but there is no regulatory requirement to do it. “Shall” means that there is a regulatory requirement to do something.

Dr. Wagner voiced concern that a mind-set change would be needed to be able to adequately enforce the new regulations because of their lack of prescriptiveness. He indicated that the Committee really had to reinforce to the Commission that it was going to be a challenge for NRC staff to just look at the licensee’s performance, and just base their findings on performance and not on the details in the licensee’s own procedures about how to do things. He also noted that ACMUI subcommittees would be useful in the development of revised inspection procedures. Ms. Haney then updated the Committee on the proposed pilot program for performance-based inspections in the medical area. Under the draft proposed inspection program, inspectors would not routinely look at licensees’ procedures. Inspectors would only ask to see procedures if a major outcome, such as a misadministration or medical event, had occurred. She also indicated that the draft proposed inspection program will need Commission approval prior to implementation.

Dr. Cerqueira adjourned the meeting at 5:00 p.m.