UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON D C 20555-0001

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Barry A. Siegel, M.D., Chairman
Advisory Committee on the Medical
Uses of Isotopes

SUBJECT: SUMMARY REPORT - MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES, MAY 3 AND 4, 1993

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting on May 3 and 4, 1993, at the Ramada Hotel and Conference Center in Bethesda, Maryland.

Committee members present at the meeting were:

Barry A. Siegel, M.D., Chairman
Peter R. Almond, Ph.D.
William H. Briner, Capt., USPHS (Retired)
Judith I. Brown
Steven C. Collins
Daniel F. Flynn, M.D.
Melvin L. Griem, M.D.

Carol S. Marcus, M.D., Ph.D.
Joan A. McKeown
Gerald M. Pohost, M.D.
Edward W. Webster, Ph.D.

FDA:

Donald R. Hamilton
A. Eric Jones, M.D.
David Woodbury, M.D.

Also present: John E. Glenn, Ph.D, Nuclear Regulatory Commission (NRC), (Designated Federal Official for the panel), and Larry W. Camper, Section Leader, Medical and Academic Section, NRC.

John E. Glenn, Ph.D., NRC, announced that a closed session of the Committee would be held to discuss the credentials of two physicians. (This closed session was held at the end of the public meeting on May 3rd.)

Prepared presentations were made by John E. Glenn, Ph.D., NRC; Larry W. Camper, NRC; Catherine Haney, NRC; Donald Cool,Ph.D., NRC; Samuel Jones, NRC; Anthony Tse, Ph.D, NRC; Ann Wright, Ph. D., Omnitron Corporation; and Alvaro Martinez, M.D., American College Radiology.

The ACMUI discussed the issues and made the recommendations indicated below.

1. Medical Management Plan

Mr. Camper reviewed staff efforts to develop a management plan for the regulation and inspection of medical users of byproduct material. The ACMUI expressed its desire to be able to comment on the medical management plan as it evolves. Several committee members also indicated concern that the NRC should not overreact to the Indiana, Pennsylvania incident, since existing regulations would have prevented that event if they had been followed by licensee staff. It was suggested that licensing, rather than regulations, was the more appropriate focus for action.

The ACMUI provided the following responses to the specific questions posed by the NRC staff:

A. **What would be the impact of requiring that room radiation monitors for designated treatment rooms where teletherapy or remote-afterloading devices (high-and medium-dose rate [HDR and MDR]) are used have audible as well as visual alarms/indicators?**

Several members expressed concern that audible alarms would frighten patients, would be intrusive to the medical care of patients, and probably are unnecessary. They noted that an audible alarm also would be undesirable since it might result in increased patient motion, thereby impairing the accuracy of delivery of the treatment dose or dislodgement of a treatment catheter. Radiation levels within the treatment room during routine treatment are high enough to activate the visible alarm and thus would activate an audible alarm on the same detector. Some members noted that an unobtrusive beeping or chirping sound from the area radiation monitor might be worthwhile and would not frighten the patient.

Dr. Flynn noted that a detector connected with the room interlocks and set to alarm if sources were not in the shielded state when the doors were opened would be an acceptable concept. However, he also noted that this could result in licensees substituting such an automated tertiary check for the required secondary check with a radiation survey instrument. Some members, including Dr. Marcus, noted that requiring use of a tertiary check may not provide additional assurance when some licensees already fail to perform a mandatory secondary check, and that there was not clear evidence to justify requiring a tertiary system. Additionally, it was noted that a tertiary system, especially if connected to the room interlocks, was one more system that could fail and preclude use of treatment room on a given day, thereby inconveniencing patients who had traveled long distances for therapy.

Ms. Brown voiced the strong opinion that a tertiary system should be required. Additionally, she believes that an audible alarm need not be frightening. The alarm could be as simple as a series of low-intensity beeps, just loud enough to call the staff's attention to the dangerous radiation levels.

There was no consensus among the ACMUI members. The majority of the ACMUI members did not recommend requiring that radiation monitors be equipped with audible signals because of the potential for disturbing the patient or requiring a tertiary monitoring system. Ms. Brown expressed a dissenting opinion, indicating that a patient has a right to know if something has gone wrong.

B. **What would be the benefits of NRC developing performance and calibration standards for room radiation monitors used in designated treatment rooms where remote-afterloading devices (HDR and MDR) are used? Should licensees be required to conform with such standards by license condition or through implementation of additional rulemaking?**

The committee agreed that either: (1) 35.400 should be modified to impose a requirement for room radiation monitors in MDR and HDR treatment rooms similar to those for teletherapy treatment rooms; or (2) if more complex calibration standards were imposed, they should be uniformly imposed by modifying both 35.400 and 35.600. The committee believed that rulemaking was more appropriate to achieve these goals than imposition of license conditions, and that the silence of Part 35 with regard to HDR and MDR brachytherapy should be addressed.

Dr. Flynn noted that alarming room monitors should not be required for remote-afterloading low-dose-rate brachytherapy rooms if they were not similarly required for rooms where manual brachytherapy is performed.

C. **The current regulations in 10 CFR Part 35 require that room radiation monitors be repaired promptly if found inoperable. NRC is developing licensing standards for the use of HDR and MDR remote-afterloading brachytherapy devices that will require that each designated treatment room be equipped with a permanent radiation monitor. Should more specific requirements be developed for the repair or replacement of such equipment when it is found inoperable?**

It was noted that electromagnetic fields have been found to disturb alarming room monitors, and the ACMUI questioned if NRC had requested that the vendor (Victoreen) study the problem further. The ACMUI recommended that, before any specific requirements were imposed on licensees, NRC should obtain some scientific data for the committee to review. However, licensees should have a plan for dealing with circumstances where room radiation monitors and/or survey monitors are inoperable.

Dr. Siegel expressed the opinion that the requirements described in 35.600 were sufficient. In addition, in reference to the Indiana, Pennsylvania event, he questioned whether a room monitor that provided intermittent "false-positive" signals could really be classified as inoperable. If the monitor was sometimes activated by electromagnetic, fields rather than by radiation and yet performed reliably when exposed to a radiation field, then the room monitor may not be "inoperable."

D. **What would be the impact of requiring that when the room radiation monitor is inoperable (or unreliable), personnel be provided with audible dosimetry devices?**

Dr Siegel was in favor of this requirement. Dr. Flynn noted alternatively that a hand-held survey instrument could be used by a second individual to perform a survey as personnel entered the treatment room. Dr. Siegel contested this idea, noting that requiring a second individual to use the same survey instrument as the first would not satisfy the goal of a redundant check (since most departments only have one instrument available for use at any given time).

The ACMUI unanimously agreed with the proposal to require that personnel wear an audible dosimeter while working in a dedicated HDR/MDR treatment room during periods when the ARM was not operable.

E. **In view of comments received by NRC following the incident at Indiana, Pennsylvania, should criteria be developed for notification of local authorities, specifically a medical coroner, following a serious misadministration event? If so, when should local authorities be informed of the investigation of a misadministration event and what criteria should be used in determining which events would require notification?**

Dr. Flynn noted that in the Indiana, Pennsylvania case, the coroner was notified within 24 hours of Dr. Flynn's determination that radiation could have been responsible for the patient's death. He also noted that the referring physician bears the responsibility of completing the death certificate, and that NRC has already mandated that the referring physician be notified in the event that a misadministration occurs. Further, he noted that NRC's medical consultant is available to discuss the potential implications with the patient's physician during the misadministration investigation. Parenthetically, Dr. Griem noted that NRC must be cautious not to put medical consultants into situations where their actions might be construed as practicing medicine without a license in the State where the consultation is being performed.

Several members, specifically Drs. Flynn, Marcus and Griem, noted that state laws are very specific regarding a physician's responsibility to

note the cause of death on a death certificate. Specificly, if the cause of death was initially determined incorrectly, the physician can, and should, submit a modified death certificate to state authorities. They also noted that the authorized user, as well as the licensee, have no responsibility to notify the state of the cause of death. The ACMUI considers this to be a professional responsibility governed by state law; the NRC should not be involved nor should NRC require medical licensees to notify the local coroner as a matter of Federal regulations. It was also recommended that further assessment of applicable State law was appropriate before NRC determine whether it has any responsibilities or jurisdiction in these matters.

F. **Should the approval for distribution for sources and devices containing byproduct material for national distribution be approved by a Federal agency, or should it be delegated to the States as is currently done?**

Mr. Collins noted that State licensees have not had any more problems than NRC licensees. Omnitron appeared to represent an example of a failure to perform a review that is consistent with NRC's guidance. He asked if NRC knew whether or not the state had required that Omnitron submit information on the 10,000-cycle test usually required for source assemblies. NRC staff were unsure, but Dr. Paperiello supplemented this statement noting that, in two tests prior to the incident, the source guide wires broke in Omnitron units after 3,500 and 4,000 cycles, respectively.

FDA representatives were also questioned regarding the device approval process at FDA. They noted that the majority of the devices intended for medical use are marketed pursuant to a 510K application (premarketing notification). In this program, the devices are not fully tested and are instead permitted to be introduced into interstate commerce if judged to be substantially equivalent to an existing device already on the market.

The ACMUI had no recommendation because it felt it had insufficient data and expertise to assess whether the current system of shared NRC, FDA, and State regulation is deficient. However, the committee noted that, following upcoming NRC-FDA meetings, NRC may have further information to share with ACMUI that could be discussed at a future meeting.

G. **Notification of radiation exposure provided to members of the public with specific reference to the letters mailed to exposed individuals by NRC following the Indiana, Pennsylvania event.**

This item was discussed in response to a request for comments made by Chairman Selin at the February, 1993 Commission briefing, on the adequacy of NRC's approach to notification of exposed members of the

public. After that briefing, ACMUI members were sent copies of sample letters used following the Indiana, Pennsylvania incident. No member of the ACMUI was sent the letter for review prior to its distribution to exposed individuals. Committee members voiced concerns regarding the risk-assessment statements in NRC's letter. Their concerns were focused on several problems: (1) the technical, probabalistic content of the statement, which many members of the public would not readily understand, thus leading to unnecessary alarm; (2) the risks were not presented in a consistent manner (e.g., a range of dose estimates was given, but only a single cancer risk estimate was given); and (3) failure of the letter to acknowledge that, based on the BEIR V report, there is considerable uncertainty whether low doses actually result in an increased probability of stochastic effects (i.e., at doses below 10 rems, the risk of radiation induced cancer may be zero). The ACMUI also questioned whether the risk estimates had been adjusted for the low dose rates that were typical of the exposures in these cases.

2. Modification in Licensing and Inspection Guidance for HDR Afterloading Devices

Dr. John E. Glenn, provided an overview of draft documents under development by the staff in response to the findings of the Incident Investigation Team (IIT) regarding the event in Indiana, Pennsylvania. The actions currently under development are (1) modification of the Policy and Guidance Directive (FC 86-4) for licensing remote-afterloading devices and (2) specific inspection guidance for licensed programs using remote-afterloading devices.

The ACMUI provided the following responses to the staff's specific questions:

A. **Are there any additional items that should be incorporated in the DRAFT Policy and Guidance Directive (FC 86-4, Rev. 1) for remote-afterloading devices?**

The committee discussed issues surrounding this question, but did not provide any specific additions.

B. **It appears that medical certification programs do not provide device-specific training for routine operation and emergency recovery/response for remote-afterloading devices. Can the ACMUI identify a performance-based approach that would ensure that technical staff receive adequate training to conduct routine operation of such devices as well as source recovery or emergency response if necessary?**

Many members agreed that device-specific training does need to be provided for physicians, and that improved training requirements need to be developed for nursing staffs. Dr. Flynn noted that he has recommended to the Residency Review Committee that specific HDR training

and instruction in quality assurance and quality management programs (mandated by JCAHO and NRC) be incorporated into the special requirements for residency programs in Radiation Oncology.

Several members acknowledged that ABR does not include device specific questions about brachytherapy on board examinations.

For training of nurses, Dr. Flynn recommended incorporating the concepts given in NCRP Report 105, and noted that this report should be included as a reference in Regulatory Guide 10.8. Others noted that several training video tapes were available from vendors of remote-afterloading devices.

Those committee members familiar with remote-afterloading devices recommended that training incorporate hands-on practice of emergency procedures. The committee noted that NRC should take a more active role in addressing training weaknesses and should lead in the development of training curricula.

C. **On April 13, 1993, NRC published IN-93-31 regarding the training of nursing personnel involved in brachytherapy treatment. Is there anything ACMUI can identify that may have been overlooked in either 10 CFR 35.410 and IN-93-31 for training nursing personnel?**

Dr. Flynn noted that nursing training should include demonstration of the mock sources, so nurses can recognize a source if one is dislodged by the patient, and should also include discussion of expected doses that nursing personnel may receive while caring for the brachytherapy patient. (so that inappropriate fear of radiation exposure does not result in avoidance of patient care responsibilities).

Dr. Siegel noted that many small programs have problems related to maintaining current training for nursing staffs, particularly when brachytherapy procedures are only performed infrequently. He suggested that NRC assist the medical community by developing training materials (or by funding their development).

D. **Are there issues NRC needs to resolve with regard to licensing mobile remote-afterloading brachytherapy programs?**

Dr. Siegel noted that small community hospitals, or those in rural settings, could benefit from shared mobile remote-afterloading brachytherapy programs. However, he noted his preference that all personnel, including the radiation oncologist, be dedicated to the mobile unit. This would maintain expertise and reduce the potential for errors by physicians who performed such procedures infrequently. The committee agreed. Two dissenting views were expressed in favor of also

allowing hospital personnel to assume responsible duties if the unit was used at a particular facility frequently enough. As an example, they noted that two facilities might prefer to share a mobile unit, with the unit in use at both facilities for a portion of each week. At this frequency of use, they felt that the staff members could maintain their proficiency. Committee members also noted that the hospital physician could place the applicator and catheters, even though a dedicated radiation oncologist would be required to supervise patient treatment.

E. **Are there issues NRC needs to resolve with regard to licensing multiple-site HDR/MDR programs under a single license, and thus allowing "corporate" oversight of a radiation safety program?**

The following factors were identified:

1. There should be a requirement that the RSO have frequent working interaction with each facility's staff and not be dedicated to the corporate facility;

2. There may be practical limits to the number of facilities and the extent of their geographic dispersion that allow for adequate central management.

The ACMUI did not want to prohibit such programs categorically; however, the committee recommended that NRC take greater care in licensing such programs and implement lessons learned from the Indiana, Pennsylvania event. The ACMUI noted that program commitments from each facility should be examined during the licensing process of each additional facility and that pre-licensing (or early post-licensing) inspections be considered. The committee also noted that licensing such programs places extra burden on NRC to (1) ensure strong central program control and (2) structure the license in order to ensure programs at each facility are adequate.

F. **NRC is currently preparing guidance for annual inspections of brachytherapy programs. Are there reasons to consider another inspection frequency?**

The ACMUI was unable to provide guidance in answer to this question and instead recommended that NRC base its approach on the frequency of violations identified in inspections of brachytherapy programs. NRC is collecting these data as part of the implementation of the Quality Management rule, and expects to have some results within the near future.

G. **NRC has identified a need to inspect each site for multiple-site brachytherapy programs. Are there indicators that should trigger other changes in inspection schedules for brachytherapy program inspection beyond this?**

Several reasons were discussed, including substantial changes in program size, number of locations of use, changes in number of authorized users and changes in RSO. The ACMUI emphasized the need to inspect multi-site programs prior to issuing the license.

3. NRC Medical Consultants, Review of Manual Chapter 1360

The staff is updating NRC Manual Chapter 1360, which documents agency policy and guidance regarding the use of medical consultants. Several items in the manual chapter have been changed to reflect the current focus on specific aspects of misadministration events. For example, greater emphasis is placed on the medical consultant's evaluation of (1) patient notification, including emphasis on the basis for not notifying a patient of a misadministration; and (2) the licensee's plan for follow up medical care subsequent to a misadministration, and determining whether the plan has been formalized in writing. Cathy Haney, of NRC, provided a review of the draft document.

The ACMUI provided the following responses to the questions provided by the NRC staff:

A. **In the February 1993 briefing of the Commission, the ACMUI recommended that NRC make use of medical consultants in evaluating licensee follow up of patients after a misadministration. NRC regulations do not currently require that a licensee develop and implement a formal plan for medical follow up after a misadministration. Should NRC regulations be modified to require such a plan? If so, what criteria should be considered in determining the adequacy of such a plan? What period of time would be considered appropriate for the licensee to continue follow up?**

Dr. Marcus noted that the majority of misadministrations don't require medical followup and have no observable effect on the patient. She further noted that the best reason for not notifying the patient was that most misadministrations are "trivial" and the patient suffers no consequence.

Dr. Siegel reiterated his comments, made during the February 1993 Commission briefing, that when an event occurred and a patient suffered (or was likely to suffer) an adverse consequence, the patient's physician and patient should be given sufficient information to determine the best course of action. The ACMUI noted that medical consultants should talk with the referring physician to determine whether adequate followup was provided. The committee further noted that since the licensee will probably not be asked to provide longtime care for the patient, the licensee should not be the party required to develop such a plan.

Dr Siegel also noted that the medical consultants should help to ensure that adequate information is given to the patient and the referring physician, and indicated that he would support sending the medical consultant's report to the referring physician. In addition, the consultant should evaluate the basis for not informing the patient and whether the judgement was sound. The members of the ACMUI were in agreement with these objectives.

NRC staff questioned whether the licensee should be required to evaluate the consequences of a misadministration. Most ACMUI members voiced their opinion that this was an implicit requirement of the existing regulations. Dr. Siegel noted that emphasis should also be placed on using the medical consultant to ensure that the physicians' or licensee's initial assessment was correct.

In summary, the committee noted that it did not support requiring such a plan for patient follow-up to be developed and implemented by the licensee. However, they noted that the reports of consultants could be used as a data basis to determine whether there is a significant generic problem related to adequacy of patient and referring physician notification. If NRC determines that there is such a problem, regulations could then be developed.

B. **In the DRAFT Manual Chapter 1360, is the guidance provided for the medical consultant adequate to prepare the consultant to fulfill his/her role? Should additional guidance be included? If so, what items would the ACMUI suggest?**

No comments were offered, other than noting that the draft document was satisfactory.

C. **Is it appropriate for NRC to request that a medical consultant perform an independent assessment of the consequences of a misadministration?**

The ACMUI determined that this was a suitable request, provided that the determination did not require physical examination or testing of the patient (lest the medical consultant becomes engaged in the practice of medicine in a state where he/she is not licensed).

D. **Current NRC regulations do not require that a licensee document the basis for a referring physician's decision not to inform a patient of a misadministration. What burden would be imposed on licensees if such a requirement existed?**

The committee recommended that the consultant deal with the referring physician, the licensee, and the patient when this issue arises. Additionally, NRC should work through the next several incidents to assess the extent of the problem before taking any action.

4. TRAINING AND EXPERIENCE FOR PHYSICIANS INVOLVED IN THE THERAPEUTIC APPLICATIONS OF BYPRODUCT MATERIAL

Dr. Alvaro Martinez, M.D., representing the American College of Radiology, presented information regarding requirements for certification in brachytherapy.

Larry W. Camper, of NRC, provided a review of existing NRC training and experience requirements for physicians involved in the therapeutic application of byproduct material. He provided the following list of questions on this topic.

1. Are the current training and experience criteria for I-131 therapy appropriate?

2. Does experience with I-131 for therapy qualify a physician to use P-32?

3. Should a separate set of criteria be developed for training and experience of physicians involved in the use of high-energy beta emitters, such as Sr-89, Re-186, and Sm-153, for palliative purposes?

4. Should 10 CFR 35.932 and 35.934 be retained, with NRC seeking a prompt revision to 10 CFR 35.930 to require case-specific descriptions of physician experience for new applications of radiopharmaceuticals?

At the outset of this discussion, Dr. Marcus expressed the opinion that this entire approach to modifying the training and experience criteria was flawed. She sees little value in mandating hours of instruction and hours spent presumably performing tasks. She feels that such training approaches may be acceptable for technologists, but not for physicians, who are the responsible decision makers. She believes that physicians need a thorough basic nuclear and radiation science education, in order to be able to think their way through the varied problems encountered in the handling and management of radioactive materials. She further believes that the current training and experience requirements for therapeutic uses of unsealed byproduct material are insufficient to achieve these objectives.

Dr. Siegel pointed out that this discussion was one more example of the inability to separate the current disagreements over NRC approaches to physician licensing from interspecialty "turf" battles. He strongly recommended that the time had come for a "paradigm shift" based on the following concepts. First, it should be assumed that medical procedures that involve byproduct materials are just one class of high-technology tools available to physicians for mitigating disease, that all physicians are capable of making the medical judgements necessary to use

the tools, that all physicians have equivalent knowledge of disease, and have (at least potentially) access to all high-technology tools used in medicine. The NRC's job should be to determine what level of education (and validation of that education) is necessary to use the particular set of tools under its regulatory purview, irrespective of whether a physician wants to use only one tool or many tools. The complexity of the educational requirements should be clearly linked to the potential hazards of a particular tool or set of tools. These educational requirements should be collected in "syllabi" to be developed by NRC (or with NRC funding), the training should be given by whatever approaches best serve the needs of trainees (formal residency programs, commercial courses, etc.) and the training should be validated by examination administered for the NRC by a suitable contractor, such as the National Board of Medical Examiners. This will allow NRC licensing to become completely separated from the existing medical-specialty system while ensuring that individuals who are licensed will have the basic science knowledge needed to use a particular procedure (or group of procedures) and respond to related emergencies. Hospital privileges, on the other hand, should be determined by the usual hospital credentialing processes and should be entirely divorced from the minimal prerequisite of NRC licensure.

The ACMUI unanimously agreed with the need for such a sweeping change in the approach to physician licensure. Hence, the committee's responses to the specific questions posed by the staff were provided only as "temporary" answers that did not address the fundamental issues.

The ACMUI suggested that 10 CFR 35.930 retain the current 80 hours of didactic instruction for now, but be modified to include a requirement for documentation of case-specific experience to be submitted with the request for authorization or with the preceptor statement. Separate criteria for P-32 or other beta-emmitters were not considered necessary.

5. **Should physicians who are certified in therapeutic radiology or radiation oncology, who have experience in teletherapy and/or low-dose-rate brachytherapy, be approved for HDR brachytherapy without providing evidence that they have received additional training in this modality?**

Dr Martinez, representing the American College of Radiology, stated that the medical use of HDR brachytherapy is based on the same principles as manual brachytherapy when it comes to defining tumor volume, inserting applicators, and determining a dose distribution to cover the entire tumor volume. Therefore, it is unreasonable for NRC to expect that further training in these principles is necessary.

The consensus opinion of the ACMUI was that these physicians should automatically be approved, with a caveat that device-specific training is a must for all who operate afterloading devices. The committee saw this as a matter more closely linked to licensing of use in a specific facility rather than one of determining authorized-user qualifications.

5. Status Report on the Expansion of ACMUI

Larry W. Camper, of NRC, provided a brief status report on the proposed expansion of the ACMUI. In a Staff Requirements Memorandum, dated April 19, 1993, (enclosed in briefing book) the Commission directed the staff to maintain the ACMUI at, or near, its current size. To that end, the Commission approved the appointments of five of the six nominees recommended by the staff. Additionally, the Commission directed the staff to minimize overlap in the specialties represented on the committee. Therefore, one medical physicist position will be eliminated. The Commission directed that, in the future, the staff should seek nominees from the Agreement states, the non-agreement states, and local government to fill the position of States' representative. The committee expressed regret that the medical physicist position would not be filled. They were especially disappointed that the particular person they believed the staff had nominated was not to join the committee since he had special expertise in radiation biology. He would have been a valuable replacement for Dr. Webster, who is rotating off the committee after this meeting.

6. RADIATION SAFETY OFFICER AND RADIATION SAFETY PROGRAM MANAGEMENT

John E. Glenn, of NRC, provided an overview of NRC staff's actions and concerns regarding radiation safety program management and the conduct of radiation safety officers (RSOs). The staff's concerns include such fundamental issues as the involvement of institutional management with the radiation safety program and the resources devoted to the program, as well as the capability, inclination, and availability of the RSO to oversee the program and enforce program requirements.

To address these concerns, the staff is developing a two-tiered approach that will include the following:

(1) Providing guidance to licensees, and in particular the RSO and licensee management, regarding the duties of the RSO and NRC's expectations of the RSO for program oversight and ensuring compliance with program requirements. The staff has designated a Task Group responsible for developing a NUREG document to serve as a "reference manual" for RSOs.

(2) Increasing accountability of licensee management and the RSO for properly discharging their responsibilities related to oversight of the radiation safety program. Among the items being considered is a requirement that a commitment statement between the RSO and licensee management be submitted during the licensing process, and rulemaking to clarify the RSO's responsibility and liability in 10 CFR Part 35.

The ACMUI provided the following responses to the specific questions posed by the NRC staff:

A. **Is board certification, in and of itself, adequate to prepare a physician for the role of RSO?**

Following substantial discussion, the ACMUI agreed that this may not adequately prepare either a physician or physicist for work as a radiation safety officer. The committee suggested that NRC move away from requiring prescriptive hours and move toward a performance-based assessment. The committee agreed that a syllabus for training RSOs should be developed and that adequate training and proof thereof should be the burden of the licensee. Additionally, the concepts espoused by the committee in relation to the validation of qualifications of authorized users (i.e., the "paradigm shift") apply equally well to validation of qualifications of RSOs. There is no single set of training and experience criteria appropriate for all RSOs because of the great variability in program complexity.

B. **Are the training and experience criteria specified in 10 CFR 35.900, which allow a physician to be designated as an authorized user and, consequently, as RSO, adequate? If not, should physician authorized users be required to obtain additional training in basic health physics and radiation safety practices before they can be designated as radiation safety officer? If so, how much training should be required and in what category?**

The committee agreed that board certification was not necessarily a sufficient criterion for automatic designation of an authorized user as RSO especially for larger programs that involve multiple categories of byproduct material use.

C. **Should NRC modify its regulations to require that RSOs be independent of direct clinical use of byproduct material and report directly to the institution's management for the purposes of radiation safety? (Refer to American College of Medical Physics letter dated April 16, 1993.)**

The committee's consensus opinion, with Dr. Marcus dissenting, was that the RSO's responsibilities should be independent of clinical use whenever possible. It was noted that his may not be possible in small programs.

D. **Should NRC in the initial licensing process and ultimately, in rulemaking, require that the RSO and institution management sign a commitment to ensure that the RSO possesses appropriate and sufficient training in radiation safety for the responsibilities imposed by the type of medical procedures being performed and has the necessary experience in radiation safety in the medical environment to manage the radiation safety program in a safe and efficient manner? (Refer to American College of Medical Physics letter dated April 16, 1993.)**

The ACMUI could not reach consensus on this issue and the members' opinions were evenly split. Those in favor noted that this additional commitment may serve to emphasize to management and the RSO the responsibilities incumbent upon the RSO. Those against noted that "it was just a piece of paper" and that the current regulations already quite adequately detailed the responsibilities of the RSO.

E. Is the 1-year experience requirement specified in 10 CFR 35.900(b)(2) adequate or appropriate?

The committee responded that it would depend on several things: the type and scope of the license; the familiarity of the RSO with the modalities of use; and the willingness of the RSO to learn and perform his/her duties.

7. Update Reports on Proposed Rulemakings:

Prior to the discussions of the update reports on three NRC rulemaking efforts, Dr. Siegel announced that Dr. Marcus had agreed to recuse herself from the two rulemakings with which she is involved.

A. Update on the current rulemaking efforts for patient release criteria

Donald Cool, of NRC, provided an update regarding proposed amendments to 10 CFR 35.75, regarding the release of patients containing radiopharmaceuticals or permanent implants. The staff hopes to complete this rulemaking effort by December 1993. The ACMUI was generally supportive of the approach formulated by staff in response to the advice provided by the committee at its November, 1992 meeting. Ms. Brown expressed concern that written instructions to be provided to patients when exposures to others are expected to be in excess of 100 mrem should be clearly written and readily available.

B. Update on the ACNP/SNM Radiopharmaceutical Petition Rulemaking

Anthony Tse provided a very brief update to the committee. The proposed rule is scheduled to be published in the Federal Register in June, 1993.

C. Assessment of Nursing and Pregnancy Rulemaking

Samuel Jones, of NRC provided a brief status report on the rulemaking to avoid unintended radiation exposure to an embryo, fetus, or breast-fed child. NRC expects to have a proposed rule ready by September 1993. The committee suggested that, in addition to the professional societies that had already been contacted for information pertaining to use of non-radioactive drugs in pregnant or breast-feeding women, the NRC also should contact the American Medical Association and the American Society of Hospital Pharmacists.

Prior to the close of the meeting, Dr. Siegel and Dr. Glenn presented plaques to four retiring members in appreciation of their service to the NRC. CAPT. William Briner, Steven Collins, Dr. Gerald Pohost, and Dr. Edward Webster are completing their tenures on the ACMUI. The committee agreed that they will be sorely missed.

Dr. Glenn declared that the meeting was closed at 11:15 a.m.

Barry A. Siegel, M.D., Chairman

11 June 1993

(Date)