BRIEFING BOOK

Advisory Committee on the
Medical Uses of Isotopes

October 20, 1999

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 20, 1999
2:00 - 5:00 p.m.

U.S. Nuclear Regulatory Commission
Two White Flint Building - T2D3
Rockville, Maryland

AGENDA

2:00 p.m. - 2:15 p.m.	Opening Remarks - Dr. Donald Cool, Director, Division of Industrial and Medical Nuclear Safety Overview and Status of the Rulemaking - Cathy Haney, Chairman, Part 35 Working Group
2:15 p.m. - 2:45 p.m.	Self Evaluation of the ACMUI
2:45 p.m. - 3:00 p.m.	BREAK
3:00 p.m. - 5:00 p.m.	Preparation for the October 21, 1999 Commission Briefing on the Revision of Part 35, Medical Use of Byproduct Material

UNITED STATES NUCLEAR REGULATORY COMMISSION CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES (Pursuant to Section 9 of Public Law 92-463)

1. Advisory Committee on the Medical Uses of Isotopes:

   (Committee's Official Designation)

2. Committee's objectives, scope of activities and duties are as follows:

   The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The appointed Chairman of the Committee will conduct all meetings and will prepare minutes summarizing the deliberations of each meeting. The minutes will include the Committee's recommendations for future actions. Subcommittees may be convened to address specific problems when it is not necessary for the full Committee to be present.

3. Time period (duration of this Committee):

   From April 4, 1998, to April 4, 2000

4. Official to whom this Committee reports:

   Donald A. Cool, Director
   Division of Industrial and Medical Nuclear Safety
   Office of Nuclear Material Safety and Safeguards
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. Agency responsible for providing necessary support to this Committee:

   U.S. Nuclear Regulatory Commission

6. The duties of the Committee are set forth in Item 2 above.

7. Estimated annual direct cost of this Committee:

   a. $160,466.00 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.3 FTE

8. Estimated number of meetings per year:

   Three meetings per year except when active rulemaking is conducted, then five meetings per year.

Charter, ACMUI

9. The Committee's termination date, if less than two years, from the date of establishment of renewal:

April 4, 2000

10. Filing date:

April 13 1998

Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the
Commission

III. Current Actions

The Department of Labor is developing an Equal Opportunity Survey in order to improve its implementation of the laws enforced by OFCCP: Executive Order 11246, as amended; Section 503 of the Rehabilitation Act of 1973, as amended; and the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended, 38 U.S.C. 4212. The three-part survey, as currently envisioned, would collect general information on the status of the federal contractor's affirmative action plan and aggregated personnel and compensation data, with a breakdown by gender and minority status.

Each year, OFCCP will collect survey data from federal contractors who are subject to the laws enforced by the agency. DOL's goals for the survey are: to increase compliance with equal employment opportunity requirements by improving contractor self-awareness; to improve the deployment of scarce federal government resources toward contractors more likely than not to be in noncompliance; and to increase agency efficiency by building on the tiered-review process already accomplished by OFCCP's regulatory reform efforts, thereby allowing better resource allocation.

In consultation with the Office of Management and Budget (OMB), DOL has developed a plan for phasing in the implementation of the Equal Opportunity Survey. As part of the developmental process, the instrument first is being tested using procedures established by the Bureau of Labor Statistics to assure that it is structured in a manner that respondents understand and that the data OFCCP is seeking are readily available.

Once the survey development process has been completed, the survey will be phased in using two mailings in FY 2000. The phase-in process will allow updating of the flagged contractor list with the new EEO–1 data expected in the summer of 2000. It will also permit modifications to be made to data processing procedures to assure timely processing.

Phase I—Survey Instrument Development

During this phase the survey instrument will be put in final form and tested for clarity; the analytical model will be developed; and, initial consultation with an outside contractor on survey processing procedures will take place.

The draft survey instrument has been tested and evaluated using the facilities of the Bureau of Labor Statistics Behavioral Science Research Center. This assures that the definitions and instructions are clearly written and can be readily understood. Suggestions for improving the clarity of the form have been incorporated into the current version. This part of the process began in August 1999 and was completed in September 1999.

Between October 1999 and January 2000 the Department will field test the survey instrument. This field test, conducted on a voluntary basis, will be designed to test the procedures used when the survey is implemented and will include a follow-up component for both respondents and nonrespondents. The field test will be conducted by OFCCP with the assistance of BLS. Following the field test, appropriate revisions will be made to the survey instrument. The final report of the results of the field test and the survey in final form will be included with the final ICR submission to OMB in January 2000.

Phase II—Survey

At this time OFCCP intends to send the survey to contractor establishments that are "flagged" by OFCCP's Equal Employment Data System (EEDS) as being potentially out of compliance with Executive Order 11246. An initial mailing of the survey will be made to respondents selected from those establishments that were flagged in 1999. Approximately 7,000 of the flagged establishments will be surveyed in April 2000. This number was chosen to provide a sufficient sample to test the data intake and processing procedures. Flagged establishments will be selected for the survey based on geographic location and size.

The survey data from the initial mailing will be processed and analyzed and the results used to identify establishments for compliance evaluations. The analytical model will result in a ranking of contractors based on the nature and number of adverse indicators. Compliance evaluations will be scheduled beginning with those establishments with the highest rankings on the indicator scale. As part of the compliance evaluation process, survey responses will be validated for a sample of establishments to assure that accurate data are being submitted. Establishments where compliance evaluations are not initiated may be notified of areas that require additional self-analysis.

The second mailing will be sent to the flagged establishments that were not previously surveyed in the first mailing (i.e., about 53,000 establishments). These surveys will be mailed in late FY 2000, and will be used to select establishments for compliance evaluations during FY 2001. Thereafter OFCCP intends to survey contractors on an annual basis.

Type of Review: New Collection.
Agency: Employment Standards Administration.
Title: Equal Opportunity Survey.
Affected Public: Businesses or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.
Total Respondents: 60,000.
Frequency: Annually.
Total Responses: 60,000.
Estimated Time Per Response: 12 hours.
Estimated Total Burden Hours: 720,000.
Total Burden Cost (capital/startup): 0.
Total Burden Cost (operating/maintenance): $60,000.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: September 30, 1999.

Margaret J. Sherrill,

Chief, Branch of Management Review and Internal Control, Division of Financial Management, Office of Management, Administration and Planning, Employment Standards Administration.

[FR Doc. 99–25811 Filed 10–4–99; 8:45 am]

BILLING CODE 4510–27–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 20, 1999. The meeting will take place at the address provided below. All sessions of the meeting will be open to the public. Topics of discussion will include: (1) the revision of the NRC's medical regulations, in preparation for the Committee's participation in the October 21, 1999, Commission briefing on 10 CFR Part 35 (64 FR 44965); and (2) the Committee's self-review, using the criteria previously developed to evaluate the performance of the Committee.

DATES: The meeting will be held from 2 to 5 p.m. on October 20, 1999.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Room T2B3, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION CONTACT: Diane Flack, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Mail Stop T–9–F31, Washington DC 20555, Telephone (301) 415–5681.

Conduct of the Meeting

Manuel D. Cerqueira, M.D., will chair the meeting. Dr. Cerqueira will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Diane Flack (address listed previously), by October 12, 1999. Statements must pertain to the topics on the agenda for the meeting.

2. At the meeting, questions from members of the public will be permitted at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection, and copying for a fee, at the NRC Public Document Room, 2120 L Street, NW, Lower Level, Washington DC 20555, telephone (202) 634–3273, on or about November 22, 1999. Minutes of the meeting will be available on or about December 20, 1999.

4. Seating for the public will be on a first-come, first-served basis.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, Part 7.

Dated: September 29, 1999.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 99–25796 Filed 10–4–99; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (HyperFeed Technologies, Inc., Common Stock, $.001 Par Value) File No. 1–11108

September 29, 1999.

HyperFeed Technologies, Inc. ("Company") has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act") and Rule 12d2–2(d) promulgated thereunder, to withdraw the security specified above ("Security") from listing and registration on the American Stock Exchange LLC ("Amex" or "Exchange").

The Security has been listed for trading on the Amex and, pursuant to a Registration Statement filed with the Commission on Form 8–A, became designated for quotation on the Nasdaq Stock Market, Inc. ("Nasdaq") on September 17, 1999. Trading in the shares of the Security on the Nasdaq commenced at the opening of business on September 23, 1999.

In making the determination to transfer the trading of shares of its Security from the Amex to the Nasdaq, the Company, whose primary business relates to technology, has stated its belief that there exist greater potential benefits to its shareholders from trading on the Nasdaq.

The Company has complied with the rules of the Amex by filing with the Exchange a certified copy of the preambles and resolutions adopted by its Board of Directors authorizing the withdrawal of the Security from listing on the Amex, and by setting forth in detail to the Exchange the reasons and supporting facts for such proposed withdrawal. The Amex has in turn informed the Company that it would not interpose any objection to the Company's application to withdraw its Security from listing and registration on the Exchange.

The Company's application relates solely to withdrawal of its Security from listing and registration on the Exchange and shall not affect the Security's designation for quotation on the Nasdaq. By reason of Section 12(g) of the Act and the rules and regulations of the Commission thereunder, the Company shall continue to be obligated to file reports under Section 13 of the Act with the Commission.

Any interested person may, on or before October 20, 1999, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–25828 Filed 10–4–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Investment Company Act Release No. 24060; 812–11740]

J.P. Morgan Securities Inc.; Notice of Application

September 29, 1999.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (the "Act") for an exemption from section 12(d)(1) of the Act, under section 6(c) of the Act for an exception from section 14(a) of that Act, and under section 17(b) of the Act for an exemption from section 17(a) of the Act.

SUMMARY OF APPLICATION: J.P. Morgan Securities Inc. ("J.P. Morgan") requests an order with respect to the MEDS trusts ("MEDS Trusts") [1] and future trusts that are substantially similar to the MEDS Trusts and for which J.P. Morgan will serve as a principal underwriter (collectively, the "Trusts") that would (i) permit other registered investment companies, and companies excepted from the definition of investment company under section 3(c)(1) or (c)(7) of the Act, to own a greater percentage of the total outstanding voting stock (the "Securities") of any Trust than that permitted by section 12(d)(1), (ii) exempt the Trusts from the initial net worth requirements of section 14(a), and (iii) permit the trusts to purchase U.S. government securities from J.P. Morgan at the time of a Trust's initial issuance of Securities.

FILING DATES: The application was filed on August 6, 1999. Applicants have agreed to file an amendment to the application, the substance of which is reflected in this notice, during the notice period.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing tot he SEC's Secretary and serving J.P. Morgan with a copy of the request, personally or by mail. Hearing request should be

[1] "MEDS" is an acronym for Mandatory Enhanced Dividend Securities.

SUMMARY MINUTES
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MARCH 24-25, 1999

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a meeting in Rockville, Maryland on March 24-25, 1999. 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., Chair

Manuel Cerqueira, M.D.
Nikita Hobson
Ruth McBurney, M.S., CHP
Dennis P. Swanson, M.S., B.C.N.P
John Graham (3/24 only)
Andrew Kang, M.D.
William B. Nelp, M.D. (3/25 only)
Louis K. Wagner, Ph.D.

Invited guests present at the meeting:

Bruce Bower, M.D., representing endocrinology perspectives
Larry Holder, M.D., representing nuclear medicine perspectives
Richard Vetter, Ph.D., representing Radiation Safety Officer perspectives
Jeffrey F. Williamson, Ph.D., representing medical physicists perspectives

Nuclear Regulatory Commission staff present at the meeting:

Cathy Haney, Section Leader, Rulemaking and Guidance Branch (RGB), IMNS, NMSS and Chair of the Part 35 Working Group (Designated Federal Official for the Committee)
Donald Cool, Ph.D., Director, Division of Industrial and Medical Nuclear Safety, NMSS
Robert Ayres, Ph.D., Materials Safety and Inspection Branch, INMS, NMSS

Part 35 Working Group Members present at the meeting:

Marjorie Rothschild, Office of the General Counsel
Penny Lanzisera, Region 1
Diane Flack, RGB
Sam Jones, RGB
Tony Tse, RGB
Tom Young, Region III
Barry Siegel, M.D., medical consultant to the Part 35 Working Group

OPENING REMARKS

Ms. Cathy Haney officially opened the meeting at 9:05 a.m. with general comments on the meeting agenda and the function of the ACMUI. Ms. Haney stated that she 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. Ms. Haney stated that any ACMUI member who becomes aware of a potential conflict of interest during the course of the meeting should inform her or Dr. Judith Stitt. Ms. Haney noted that the meeting was announced in the Federal Register on March 3, 1999.

Donald A. Cool, Ph.D., made opening remarks to the Committee. Dr. Cool discussed the importance of the Part 35 rulemaking to the Commission as an effort to move in the direction of more risk-informed and performance-based regulations. He also expressed thanks to three members of the Committee whose terms are ending later in 1999, Dr. Stitt, Mr. Dennis Swanson, and Dr. William Nelp.

PREVIOUS ACMUI SUBCOMMITTEE RECOMMENDATIONS

Ms. Haney updated the Committee on the activities of the Part 35 Working Group since the ACMUI diagnostic and therapeutic subcommittee meetings in February 1999. She asked the Committee members to review the minutes of the subcommittee meetings to ensure that the minutes adequately captured the recommendations of the subcommittees. She indicated that the Working Group had incorporated most of the recommendations of the subcommittees into the revised draft final rule that was provided to the ACMUI in advance of this meeting (hereafter referred to as "draft final rule"). In a few cases, the Working Group wanted further information or dialogue with the Committee about certain recommendations.

TIMELINE FOR REVISION OF 10 CFR PART 35 AND ASSOCIATED ACTIVITIES

Ms. Haney summarized the Part 35 rulemaking activities leading up to the present meeting. She also explained that following this meeting the NRC staff and the ACMUI would brief the Commission on the draft final rule. Following the briefing, the rule would be revised to incorporate any ACMUI recommendations, unless the Commission had previously stated a position that was not consistent with the ACMUI recommendations, e.g., patient notification. This version of the rule would then be provided to the other NRC offices for review and concurrence. Comments from the other NRC offices would be returned by early May. She indicated that the final rulemaking package was due to the Commission by June 1999. Finally, she indicated that during the summer and fall of 1999, the Part 35 Working Group expects to focus on finalizing the guidance document associated with Part 35 (NUREG 1556) and the Medical Policy Statement.

REVIEW OF KEY ISSUES IN PART 35 WORKING GROUP'S DRAFT FINAL RULE

Ms. Haney explained that the Working Group had identified specific issues where they would like ACMUI review and comment. This review would assist the Working Group in finalizing the draft final rule for Commission consideration & approval and in writing the Statements of Consideration.

Section 35.292, Training for imaging and localization. (Note that this section was changed to 35.290 in version being forwarded to the Commission)

Ms. Haney indicated that the training and experience requirements in the proposed rule were focused on radiation safety. The duration of the training and experience program needed for individuals to become authorized users (AUs) for imaging and localization studies (§ 35.200) was significantly reduced from the current rule (1,200 hours to 120 hours). In addition, requirements for an examination in radiation safety and a preceptor affirmation of competence was added to the training requirements for AUs, as well as for the authorized nuclear pharmacist (ANP), authorized medical physicist (AMP), and Radiation Safety Officer (RSO).

Ms. Haney explained that the examination requirement was not included in the draft final rule, but a provision was added for NRC to review and approve training programs. She also explained that the duration of the training program for use of byproduct material for imaging and localization studies (§ 35.200) was increased from 120 hours to 700 hours. (The training and experience requirements in the proposed rule are presented in Attachment 1. The training and experience requirements in the draft final rule are presented in Attachment 2.)

A physician member of the public expressed concern that the training and experience requirements for this category of AUs had been increased since the last public meeting. Ms. Haney explained that the classroom and laboratory training (80 hours) and supervised practical experience (40 hours) would be considered a component within the 700 hours so the actual increase was 580 hours. Dr. Cerqueira stressed that it was important to ensure that the required hours of training could be done concurrently (i.e., 120 within the 700).

Dr. Siegel suggested that eliminating the words "in basic radionuclide handling techniques" would help to clarify that the requirement for 700 hours includes the 120 hours (80 hours of didactic and 40 hours of handling [80/40 split]). Mr. Swanson suggested that the specificity of 80 hours and 40 hours within the 700 hours was too prescriptive, and recommended instead that the requirement be made more flexible by saying "700 hours of training and experience applicable to the medical use of unsealed byproduct material." Dr. Siegel argued that this would provide insufficient information to training organizations on the breakdown between classroom training and practical work experience. Mr. Swanson then modified his recommendation to specify 700 hours of training "that includes 120 hours of training in the following areas: (1) didactic and (2) supervised practical experience."

Ms. McBurney suggested that specifying an 80/40 split in the 120 hours would allow Agreement States to make a determination on the adequacy of the alternate training program. Mr. Graham suggested that without such specification, the entire 120 hours could be provided in a classroom. Dr. Siegel agreed with Mr. Graham and suggested retaining the 80/40 specification. Dr. Williamson also agreed with the split. Dr. Wagner suggested that the requirement say "at least 80 and at least 40." Mr. Swanson moved to leave the proposed final rule language as written, retaining the 80/40 split, that is to leave (c)(1) and (c)(2) of this section with respect to the required hours, unchanged.

Motion 1.1: Leave § 35.292(c)(1) and (c)(2), with respect to the required hours, unchanged.

Vote: 6 in favor, none opposed.

Mr. Swanson expressed concern about the requirements for "supervised practical experience under an authorized user." He recommended instead that the reference should be to "experience under the preceptor," since in some cases, such as a centralized nuclear pharmacy, the work would not be done under the supervision of an authorized user. He also questioned whether supervision was the same as preceptorship. Dr. Siegel suggested that the program director would be providing the supervision, while possibly delegating some of the responsibility for training to other persons.

Dr. Vetter supported the requirement for a preceptor. He was concerned that too narrow a restriction would make it impossible for an individual to go elsewhere to obtain specific elements of training. Dr. Wagner suggested that the requirement might be for supervised practical experience approved by a preceptor. Dr. Cerqueira also expressed concern that a cardiologist might obtain clinical training and experience in an Accreditation Council for Graduate Medical Education (ACGME) program, but go outside for didactic training. In that case, the clinical preceptor would have little authority or supervision over the outside program and two preceptor signatures might be needed. Ms. Haney explained that the preceptor will be required to certify that the individual is competent to function independently as an AU and, therefore, two signatures would not be needed.

Dr. Williamson supported revising the definition of preceptor in §35.2. Dr. Siegel thought that changing § 35.292(c)(2) to specify "under the direction of a preceptor" would be sufficient, because the preceptor would be taking the overall responsibility of ensuring that the individual had mastered the necessary material, and "direction" rather than "supervision" is a looser term. Mr. Graham asked if a medical physicist or pharmacist could serve as a preceptor, and was referred to the requirement that the preceptor must meet either §35.292 or § 35.390, which means he or she must be an AU. Dr. Cerqueira recommended using the term "preceptor authorized user" in §35.292(c)(2) and (c)(3) for clarity.

Mr. Swanson suggested that the term "radioactive drug" in the introductory statement to § 35.292 should be retained. Ms. Haney explained that the term radiopharmaceutical did not include

biologics, and therefore "radioactive drug" was more appropriate. However, she noted, the FDA definition of radioactive drug could not be used because Part 35 only addresses use of byproduct material. Mr. Swanson noted that in some contexts, even in Part 35, the term should not be limited to byproduct material. For example, the 700 hours of training and experience received by an individual should not be limited to byproduct material because it could include accelerator-produced material, such as thallium. He also noted that in other contexts, use of the broad term "radioactive drug" may not be appropriate unless it is modified by "containing byproduct material."

Mr. Graham moved to revise § 35.292(c). He moved that the phrase "in basic radionuclide handling techniques" be deleted and the term "radioactive drugs" be substituted for the term "unsealed byproduct material" in the introductory sentence of (c). He also moved that the word "direction" be substituted for the word "supervision" and the term "authorized user" be replaced with the term "preceptor authorized user" in paragraph (c)(2).

Dr. Vetter was concerned that nuclear pharmacists and RSOs may come to an institution having already had their didactic training, and, therefore, the preceptor could not have "directed" that training. Dr. Wagner noted that it is a question not only of direction, but also of approval of the training. Mr. Graham argued that the preceptor does not have to direct all the training, but only must be satisfied that all the training is acceptable. Dr. Cerqueira was concerned that the certifying preceptor could not always verify competence in any training received outside the program. Therefore, more than one preceptor statement might be necessary for individuals who do not obtain board certification, but instead seek AU status via the alternative pathway. Dr. Siegel noted that even medical boards do not require multiple program directors to attest to satisfactory completion of training. Dr. Wagner noted that the rule language should be revised to state: "under the direction of a preceptor" rather than "under the direction of the preceptor." This change would clarify that the preceptor who signs the certification does not need to direct all of the training. Secondly, he recommended replacing the phrase "under the direction of" with the phrase "approved by" to add flexibility.

Drs. Cerqueira and Siegel discussed the likelihood that an individual would plan his or her training in advance and use training programs approved by NRC or whether he or she would receive training in different places at different times. Dr. Siegel suggested an individual using a non-traditional approach could seek advance NRC approval. Dr. Cerqueira questioned if a mechanism existed for such approval. Ms. Haney noted that ACMUI assistance would be requested in approving training programs. She also asked whether NRC needed to approve the 120 hours of classroom and laboratory training and the balance of the 700 hours. Dr. Siegel believed that NRC does need to approve the entire 700, just as it would for an ACGME-approved program.

Mr. Graham argued that an individual should have the flexibility of obtaining training under the direction of multiple preceptor AUs. He moved to amend the pending motion to delete the term "authorized user physician" as preceptor and instead use the term "preceptor authorized user."

Motion 1.2:

1. Section 35.292(c), introductory sentence - The phrase "in basic radionuclide handling techniques" should be deleted and the term "radioactive drugs" should be substituted for the term "unsealed byproduct material."
2. Section 35.292(c)(2) - The word "direction" should be substituted for the word "supervision" and the term "authorized user" be replaced with the term "preceptor authorized user."
3. Section 35.292(c)(3) - The phrase "an authorized user" should be replaced with the phrase "preceptor authorized user" and the word "physician" should be deleted.

Vote: 7 in favor, none opposed.

Section 35.392, Training for use of sodium iodide I-131 for which a written directive is required. (Note that this section was divided into 35.392 and 35.394 in the version being forwarded to the Commission.)

Mr. Swanson expressed concern that an individual who is authorized under § 35.392 for the use of I-131 could prepare I-131 capsules with only 80 hours of training. Dr. Siegel pointed out that the individual could not prepare the capsules because they are neither an ANP nor an AU under § 35.292. He indicated that an individual licensed under § 35.392 can only use a drug that is received from an organization licensed under § 32.72 or prepared by an ANP or an AU who meets the requirements in § 35.292. Dr. Siegel indicated that an AU who only meets the requirements of § 35.392 cannot direct anything be done to a drug received from a § 32.72 supplier. Mr. Swanson then moved that § 35.300(b) be amended to say: "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "

Ms. McBurney noted that the Conference of Radiation Control Program Director's, Inc., (CRCPD) working group developing State regulations had expressed concern to her about inconsistency between the training and experience requirements in §§ 35.292 and 35.390. They were concerned that the draft final training requirements for individuals that would like to use I-131 for treatment of hyperthyroidism and thyroid cancer were insufficient. Dr. Bower noted that I-131 dosages are administered orally, and have a low risk profile. It was also noted that the training and experience requirements in the proposed rule would have resulted in increased training requirements for an individual who would like to be authorized to administer only I-131 for hyperthyroidism or thyroid cancer. Finally, it was noted that the endocrinology community did not think the increase was warranted in light of their impeccable safety record under the current 80 hour training requirement.

Motion 2: Modify § 35.300(b) to state: "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "

Vote: 7 in favor, none opposed.

Intravascular Brachytherapy

Dr. Cerqueira suggested that intravascular brachytherapy should be classified under § 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," as an emerging technology. Ms. Haney noted that intravascular brachytherapy is currently addressed under the requirements for brachytherapy, and that the draft final rule does not explicitly classify intravascular brachytherapy as an emerging technology. She explained that the training and experience requirements for intravascular brachytherapy will be addressed after the completion of the Part 35 rulemaking, and in the meantime will be handled on a case-by-case basis.

Dr. Cerqueira made a motion that intravascular brachytherapy, for the prevention of restenosis in the vascular system, be classified as an emerging technology, pending the results of the ongoing Food and Drug Administration (FDA)/broad trials. Mr. Graham suggested that the implications for intravascular brachytherapy would be better understood if the topic was addressed as part of a broader discussion of Subpart K. Ms. McBurney moved to table the motion.

Motion 3: Table the motion to discuss intravascular brachytherapy for prevention of restenosis in the vascular system until discussion of Subpart K.

Vote: 6 in favor, Dr. Cerquiera opposed, believing it appropriate to discuss at this time.

General Discussion - Training and Experience Requirements - Alternative Pathway Chart (Attachment 2)

The Committee reviewed the chart that summarized the training and experience requirements for the alternative pathway to obtain status as an AU, ANP, AMP, or RSO (Attachment 2).

Ms. McBurney expressed concern over the training requirements for an AU that would like to use sodium iodide I-131 for hyperthyroidism and thyroid carcinoma. Dr. Wagner suggested, and Dr. Siegel agreed, that explicitly stating that the requirements pertained only to oral administration of I-131 would be desirable.

Motion 4: Approve the training and experience requirements - Alternative Pathway (Attachment 2).

Vote: 7 in favor, none opposed.

Section 35.24, Authority and responsibility for the radiation protection program.

<u>Radiation Safety Committee (RSC)</u>

Ms. Flack explained under § 35.24(b) that an RSC is required if the institution has two or more different types of uses of byproduct material under Subparts E, F, and H. The ACMUI therapy

subcommittee had suggested inserting "or." Ms. Flack asked whether the different types of uses would have to be in different Subparts, or whether an RSC should be required if there are different types of machines that are included in the same subpart, e.g., is an RSC needed if a licensee only has a remote afterloader and a teletherapy unit.

Mr. Graham explained that an RSC should not be required if there was only one type of use. Ms. Haney noted that "type of use" is used to reference use of byproduct material as specified in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. As proposed in the draft final rule, if a licensee only used unsealed byproduct material in quantities that required a written directive (§ 35.300), it would not be required to have an RSC. However, a licensee that used unsealed byproduct material in quantities that require a written directive (§ 35.300) and manual brachytherapy (§ 35.400) would be required to have an RSC.

Dr. Williamson noted that two units under § 35.600 would not be covered by the term "types of use." Dr. Wagner suggested adding a reference to two or more units under § 35.600, so that even two of the same type of units would require a RSC. Dr. Williamson advocated making the criterion two or more uses under § 35.600. Dr. Stitt suggested that the distinction between "units" and "uses" should be clear.

Mr. Graham moved that § 35.24(b) be amended to read that licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, or H or two or more types of units under Subpart H should be required to have an RSC. Dr. Siegel suggested that uses under Subpart K should also be included. Ms. Haney said that the need for an RSC under Subpart K should be addressed on a case-by-case because it could involve a low risk activity. Ms. McBurney moved to modify the motion to state "two or more uses under E, F, and H."

Motion 5.1: That § 35.24(b) be amended to state "Subparts E, F, and H or two or more types of units under Subpart H."

Vote: 7 in favor, none opposed.

Dr. Siegel commented that the RSC's duties should be clarified, to specify that the RSC is not just responsible for the activities that mandate the RSC, but also for all other activities involving the use of byproduct materials in the institution. For example, he explained, if an RSC is required because both Subpart E and Subpart H activities are permitted by the license, the intent is that Subpart D activities at the institution would also be covered by the RSC. Mr. Graham moved to change § 35.24 to read: "establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee."

Motion 5.2: That § 35.24 be amended to "establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee."

Vote: 7 in favor, none opposed.

Temporary Radiation Safety Officer (RSO)

Ms. Flack noted that the Working Group is revising § 35.24 to allow multiple temporary RSOs. The Committee made no specific comments on this item.

Section 35.27, Supervision.

Ms. Flack stated that the Working Group considered it important to retain the requirements in § 35.27. Mr. Graham noted that ultimately the chief executive officer is responsible for the actions of everyone who is carrying out any activity that is in any way covered by the hospital's license. He indicated that the draft final rule is correct - licensees are responsible for the acts and omissions of the supervised individual. The Committee had no other comments on this item.

Section 35.40, Written Directives.

Ms. Flack asked the Committee to review § 35.40(b) that lists the information that must be included in written directives. Dr. Williamson recommended that the rule should be revised to state that a written directive for gamma stereotactic radiosurgery include the treatment site, total dose, and number of gamma stereotactic shots for each anatomically distinct treatment site. Other specifications, such as gamma angles and coordinates, should be placed in the treatment plan description. In addition, the written directive should specify number of target coordinate settings, not the target coordinate settings themselves. Dr. Stitt agreed.

Dr. Siegel asked whether the term "anatomically distinct treatment site" was consistent with the definition of treatment site in § 35.2. Dr. Williamson clarified that "distinct" in treatment planning means that the dose contribution from site one is not considered in planning the dose to site two. Dr. Stitt agreed that the language was consistent and would not be burdensome. Dr. Williamson also stated that, to the best of his knowledge, the gamma stereotactic radiosurgery device is only used for single fraction radiosurgery.

Dr. Siegel asked if § 35.40(b) should specify route of administration. Dr. Vetter pointed out that § 35.392 already specifies oral administration, although for sources of I-131 other than sodium iodide, the route of administration should be specified. Mr. Swanson argued that under (b)(1), the written directive could contain a dosage but not the identity of the radiopharmaceutical. Dr. Siegel explained that a form would generally be used to identify the radiopharmaceutical as I-131 sodium iodide. Mr. Graham was unwilling to rely on a form, and argued in favor of adding the radiopharmaceutical name to the minimum requirements for a written directive. The Committee determined that the rule should be modified to address these concerns. Specifically § 35.40(b)(1) should be revised to state: "for an administration of a radiopharmaceutical: the radiopharmaceutical, dosage, and route of administration." The Committee also agreed that the balance of the list of items to be included in the written directive was acceptable.

Dr. Williamson noted that for remote afterloading brachytherapy, the written directive must

include the radionuclide, treatment site, dose per fraction, number of fractions, and total dose. He did not believe the requirements for a low dose-rate (LDR) remote afterloader were appropriate, since the logistics of loading the sources, and doing the treatment planning before the treatment is complete, are identical to the requirements for manual brachytherapy. He believed the requirements should be modified to group the requirements for manual brachytherapy with the requirements for pulsed dose-rate (PDR), medium dose-rate (MDR), and LDR remote afterloaders. Dr. Stitt agreed.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use.

Ms. Haney indicated that the definition for prescribed dosage, as specified in the proposed rule, did not preclude the AU from prescribing a dosage range. In addition, the requirements for written directive in § 35.40 do not preclude an AU from prescribing a dosage range. She also indicated that § 35.63 provides for a 20% deviation between the prescribed and administered dosage.

Dr. Siegel suggested that the rule allow the AU to prescribe a dosage range. He went on to state that if the dosage is specified as a range, the administered dosage must fall within that range. Whereas if the dosage is specified as a single number, the administered dosage should be within 20% of the prescribed dosage. Dr. Vetter questioned whether such a broad latitude would be wise from a radiation safety perspective. Dr. Siegel noted that a physician has latitude to prescribe a dosage range.

Dr. Wagner questioned whether the requirement that administered dosages be within 20% of the prescribed dosage was limited to administrations that require a written directive. He believed a 20% range was acceptable for diagnostic dosages but might not be acceptable for therapeutic doses or dosages. Dr. Williamson noted that the practice was not to prescribe dose ranges when using sealed therapy sources. Typically, the radiation oncologist specifies a single dose. Dr. Williamson was concerned that allowing AUs to specify a range would cause an increase in treatment delivery errors. Dr. Stitt agreed that a specific dose was desirable for therapeutic uses, although flexibility for diagnostic uses made sense.

Mr. Swanson moved to amend § 35.63(d) to allow a licensee to administer dosages that do not differ from the prescribed dosage by more than 20% or dosages that fall within the prescribed dosage range, unless otherwise directed by the AU.

The Committee discussed at length whether a dosage range should be allowed for unsealed byproduct material that requires a written directive. Dr. Wagner moved to make the distinction according to whether or not a written directive is required.

Mr. Swanson argued that this approach directly interfered with the practice of medicine and implied a level of accuracy and dosage determinations with unsealed byproduct material that does not exist. Dr. Wagner agreed that the issue is defining the boundary between radiation

safety and interference with good medical practice. Dr. Williamson was concerned that by allowing a range for certain modalities, an incentive could be created for practitioners to abandon time-honored practices of prescribing a single number in order to avoid potential problems of regulatory enforcement.

Dr. Wagner sought to clarify the motion. He wanted to specify that ranges should not be allowed for the medical use of byproduct material where a written directive is required. Drs. Wagner and Siegel noted examples of situations in which a 20% range could be too narrow. In some cases, administrations could fall outside this range but still be within acceptable medical limits.

Ms. Haney summarized the motion as follows:

Motion 6: NRC regulations should reflect the following:

1. An authorized user may prescribe a dosage range for material administered under §§ 35.100, 35.200, and 35.500.
2. An authorized user may not prescribe a dosage range for material administered under §§ 35.300, 35.400, and 35.600.
3. Administered activities can deviate from a prescribed dosage by 20%.

The Committee decided not to address the issue of a dose range for material used under §§ 35.400 or 35.600.

Vote: Motion withdrawn.

Motion 7: Amend § 35.63(d) to state that unless otherwise directed by the AU, a licensee shall not use a dosage if (a) the dosage differs from the prescribed dosage by more than 20% or (b) the dosage does not fall within the prescribed dosage range.

Vote: 7 in favor, none opposed.

Section 35.3045, Reports of medical events.

Ms. Flack summarized the requirements for medical event reporting, noting that the Working Group revised the requirement to exclude reporting of events that occur as a result of patient intervention, unless a physician determines that the event resulted in permanent function damage to an organ or a physiological system. Ms. Flack also explained that wrong treatment site now involves a dose to the skin or an organ or tissue, other than the treatment site, that exceeds 50 rem to an organ or tissue or 50% of the dose expected from the administration.

Dr. Williamson suggested that the Working Group completely revise the definition of medical event to say it is "an administration of byproduct material in which a technical error on the part of the care giver or device malfunction results in a dose that . . ." Ms. Haney noted that the phrase "technical error" would need to be defined. Drs. Stitt and Wagner agreed that it would be

difficult to define "technical error." Dr. Siegel noted that even with the proposed definition, patient intervention would need to be defined. Dr. Stitt concluded that the proposed final rule was a definite improvement over the current requirements.

Mr. Swanson requested that the Statements of Consideration contain a clear statement that subcutaneous infiltration of a dose that was put into a vein is not considered wrong route of administration.

Ms. Haney requested comments on the phrase "or is expected to result." She explained that the Working Group used the abnormal occurrence reporting policy, which used similar language, in developing the rule text. Mr. Graham and Dr. Siegel suggested using the phrase "results or will result" rather than the phrase "or is expected to result." Dr. Stitt agreed with this approach.

Dr. Wagner noted that the phrase "dose to the skin" could mean dose to a point on the skin or dose to all or a large area of the skin as an organ. He moved that all references to "skin, organ, or tissue" be revised to reference "tissue" only.

Motion 8: In § 35.3045, references to "skin, organ, or tissue" should be revised to reference "tissue" only.

Vote: 7 in favor, none opposed.

The Committee agreed, by consensus, to accept the remainder of the editorial rule changes to this section.

Mr. Swanson moved that the Committee go on record as opposing the patient notification requirements in §§ 35.3045 and 35.3047. Dr. Stitt agreed with the statement that the ACMUI does not support any regulation for required notification of physicians and patients, because the requirement is redundant to existing State laws and medical ethics. Ms. Hobson also noted the possible cruelty in notifying patients unnecessarily and frightening them if negative effects of the event were not anticipated. Ms. Haney noted that the Commission believes the requirement to notify patients recognizes the right of individuals to know information about themselves and provides the opportunity for patients to consult with their personal physicians to make timely decisions about their health care. Drs. Stitt and Siegel noted that providing the patient with a copy of the official letter citing Federal regulations harms the physician-patient relationship. Mr. Graham moved to modify the motion to add that notification is redundant to existing State laws and medical ethics.

Motion 9: ACMUI reaffirms that it does not support any regulation requiring notification of physicians and patients as this is redundant to existing State laws and medical ethics.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official

Committee member during the initial discussion.

Dr. Siegel proposed adding the words "if any" to paragraphs (d)(1)(v), (vi) and (vii). Dr. Stitt agreed, since in some cases there will be no effect on the patient; no improvements are necessary in the program; and no actions need to be taken. The Committee approved the change.

Section 35.3047, Report of a dose to an embryo/fetus or a nursing child.

Ms. Flack indicated that the Working Group had not made any changes to the draft final rule since the subcommittee meetings. However, it has been considering whether the requirement should be removed from the Part 35 rulemaking and instead become the subject of a Part 20 rulemaking that would apply to all NRC licensees. She also indicated that the majority of the Working Group members believed that the reporting threshold for reports should be 50 mSv (5 rem) rather than 5 mSv (500 mrem). Ms. Flack noted that based on information contained in a recent study (Joy R. Russell, et al.,"Radiation absorbed dose to the embryo/fetus from radiopharmaceuticals," *Health Physics Journal*, 73:5 (November 1997) pp. 756-769), a 5 mSv (500 mrem) level could result in a large number of reports being submitted to NRC. Dr. Siegel noted that if the Agreement States adopted the rule, the number of reports would be substantially larger because of gallium and thallium use. Ms. Haney noted that representatives from the CRCPD SR-6 Committee indicated to her that they preferred the 5 mSv (500 mrem) level.

Ms. McBurney moved that the requirement be placed in Part 20.

Motion 10: The reporting requirements for unintended exposures to an embryo/fetus or nursing child that are currently in § 35.3047 should be moved to Part 20.

Vote: 7 in favor, none opposed.

Dr. Siegel stated that the 5 mSv (500 mrem) limit could impact use of byproduct material in diagnostic nuclear medicine. He indicated that a number of nuclear medicine procedures could approach the 5 mSv (500 mrem) limit and would impose either a de facto pregnancy testing requirement or a de facto diversion of women of childbearing age away from needed nuclear medicine procedures. Dr. Wagner stressed the importance of the issue, arguing that the 5 mSv (500 mrem) level would lead to a great amount of patient anxiety and stress. He agreed that the rule would require pregnancy testing for a large number of diagnostic nuclear medicine patients. He supported the 50 mSv (5 rem) reporting level. Mr. Graham moved that the ACMUI endorse the subcommittee recommendation that the reporting threshold be 50 mSv (5 rem).

Motion 11: The reporting threshold in § 35.3047 should be 50 mSv (5 rem).

Vote: 7 in favor, none opposed.

Dr. Wagner noted that the only action a physician can do to protect the nursing child is to

properly notify and instruct the mother about the precautions to be taken to minimize exposure to the child. He moved that the notification requirements in § 35.3047, that pertain to a nursing child, be restricted to events in which the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Motion 12: The reporting requirements in § 35.3047 should be limited to only those events where the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion. (Mr. Graham no longer present.)

Dr. Siegel proposed adding the words "if any" to paragraphs (d)(1)(v) and (vi). The Committee agreed.

Mr. Swanson moved that the ACMUI state that it does not support any regulation requiring notification of physicians, mothers, or pregnant women as this is redundant to existing State laws and medical ethics.

Motion 13: ACMUI does not support any regulation requiring notification of physicians, mothers, or pregnant women as this is redundant to existing State laws and medical ethics.

Vote: 5 in favor, none opposed, 1 abstention. Ms. McBurney abstained, because NRC's reasons for the requirement may be valid. (Mr. Graham no longer present.)

Dr. Siegel suggested and Dr. Wagner moved that the language on unintended permanent functional damage be added.

Motion 14: The following phrase should be included with regards to the embryo/fetal reporting requirement in § 35.3047(a): "Has resulted or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician."

Vote: 6 in favor, none opposed (Mr. Graham no longer present).

Dr. Siegel raised the question of how the phrase "specifically approved in advance by the authorized user" will be interpreted, when a dose is given to a patient based on the belief that she is not pregnant, especially during the period when pregnancy is undetectable. Ms. Haney requested advice on what the Statements of Consideration should say on this subject. Dr. Wagner noted that if the threshold is placed at 500 millirem, a large number of reports would be generated concerning doses to individuals within the first two weeks after conception. Dr. Williamson expressed concern that the medical community will be forced to give pregnancy tests to every woman of childbearing age who receives a diagnostic procedure. Dr. Wagner noted that

even pregnancy tests would not be effective early in the pregnancy. The Committee concluded that the Statements of Consideration should acknowledge that there is no need to report an exposure to an embryo/fetus if the exposure occurred while the pregnancy was not medically detectable.

The meeting recessed at 5:33 p.m. on March 24, 1999.

The meeting reconvened at 8:08 a.m. on March 25, 1999.

REVIEW OF ISSUES RAISED BY NRC GENERIC ASSESSMENT PANEL

Dr. Bob Ayres explained that the NRC Generic Assessment Panel had two issues requiring ACMUI advice. First, an Agreement State licensee had used an ultasound device to place iodine-125 (I-125) seeds in a patient's prostate. The ultrasound device did not have the necessary resolution to image the ends of the implant needle. As a result, 31 seeds were placed in the patient's bladder. Dr. Williamson suggested that the problem was a failure of the device quality assurance program, noting that there are standard tests that are done to ensure contrast resolution. Dr. Holder thought the problem was due to inadequate operator training. Specifically, operators should know what they are looking at and be obligated to not proceed if they cannot see properly. Dr. Siegel asked if this event was considered to be a misadministration or an example of malpractice. If a physician performed the actions, he suggested, it might be malpractice and not require NRC involvement. Dr. Ayres said it was a misadministration, since the intended dose was not given. He asked ACMUI to advise whether NRC should describe this event to its licensees as a generic issue. Ms. McBurney did not believe it was a generic issue since this was the only instance known to have occurred. Dr. Cerqueira thought that it was a malpractice issue and no NRC action was needed. Dr. Stitt indicated that the staff needed to provide additional, more detailed information to the ACMUI prior to any further action.

Second, an Agreement State licensee was giving written instructions to I-125 prostate implant patients that directed the patients to strain their urine for at least the first few days, after source implantation, to capture any I-125 seeds. The instructions directed the patient to return the seeds to the hospital. The licensee indicated that the purpose of the instructions was to ensure that the patient is receiving the "correct dose." Dr. Ayres indicated that the Generic Assessment Panel was concerned that patients would not handle the seeds properly. He requested ACMUI advice on actions, if any, that should be taken by NRC. Dr. Williamson thought that it could be within the medical purview of the physician to ask that the seeds be counted, but he believed the patient should be instructed to then flush them down the toilet rather than collecting and retaining them or transferring them to someone else. Dr. Nelp thought the instruction given to the patient was a matter of medical practice and ACMUI or NRC involvement was not needed. No further recommendations were made.

CONTINUED REVIEW OF KEY ISSUES IN WORKING GROUP'S DRAFT FINAL PART 35 RULE

Section 35.2, Definitions.

Ms. Rothschild questioned whether the duties of the AU, ANP, AMP, and RSO should be placed in the rule or in the guidance document. The Committee agreed that the list of duties should be placed in the guidance rather than in the rule, provided the list did not place any additional requirements on the individuals.

The Committee agreed with the following actions:

1. The definition of diagnostic clinical procedures manual and reference to it should be deleted from the rule.

2. MDR remote afterloaders should be defined.

3. The definition of prescribed dosage should be revised to state: "the quantity or range of radiopharmaceutical activity, as documented in . . ."

4. Ms. Haney and Drs. Stitt and Williamson should develop a definition of manual brachytherapy.

5. The term "radioactive drug" rather than "radiopharmaceutical" should be used generically in the rule. They noted some places where it may be necessary to use the phrase "radioactive drug containing byproduct material."

6. The definition for a unit dosage should be revised to reference dosages prepared "by or under the supervision" of an ANP or AU. The definition should also clearly state that a unit dosage is a dosage intended for medical use, without subsequent manipulation, in a single patient."

Section 35.12, Application for license, amendment, or renewal.

The Committee was asked whether NRC should only review and approve the procedures required in Subpart H as part of the license or amendment process. Mr. Swanson and Dr. Siegel noted that Subpart K should require a more detailed review of procedures for an emerging technology. Dr. Williamson supported the change, but asked why it was necessary for NRC to review the procedures required by Subpart H. Ms. Haney explained that at present only one procedure is required by Subpart H (full calibrations and spot checks).

Drs. Wagner and Williamson suggested that the review of procedures was unnecessarily burdensome and resulted in a situation where the licensee could only change a protocol by a license amendment. Ms. McBurney noted that Agreement States prefer the review to be done by the license reviewer rather than by an inspector.

Dr. Cerqueira moved that NRC should not require license applicants to provide any procedures, including Subpart H procedures, to NRC for review prior to NRC issuance of the license or amendment and, therefore, should not tie licensees to those procedures via license conditions. Dr. Wagner noted that the real issue was whether licensees must follow the procedures unless they apply for and receive a license amendment that allows use of a revised procedure. He suggested the motion should say that the licensee is free to amend the procedures as needed, without prior approval.

Motion 15: ACMUI believes that NRC should not require license applicants to provide any procedures (including Subpart H procedures) to NRC for review prior to NRC issuance of the license (or amendments) and therefore should not tie licensees to these procedures via license conditions.

Vote: 5 in favor; 1 opposed, 1 abstention. Ms. McBurney opposed because States and many licensees want review of procedures. Dr. Nelp abstained because he disliked how the motion was phrased.

Section 35.60, Possession, use and calibration of instruments to measure the activity of unsealed byproduct materials.

The Committee agreed with the proposed revisions to § 35.60. Mr. Swanson recommended that the identity and serial number of any radionuclide standards used in calibrating the instruments be included in the recordkeeping requirement in § 35.2060.

Section 35.63, Determination of dosages of unsealed byproduct material for medical use.

Dr. Siegel noted that § 35.63 needed to be revised to address the issue of tritiated and carbon-14 compounds used in research, which may be obtained from a manufacturer who is not a § 32.72 licensee, radiopharmacist, or AU, but whose activity cannot be directly measured by a licensee without altering the dosage. Dr. Stitt suggested additional work by the Working Group to address the issue.

Section 35.400, Use of sealed sources for manual brachytherapy.

The Committee agreed with the addition of the phrase "in accordance with an effective investigational device exemption application accepted by the FDA" in § 35.400. The ACMUI believed this phrase addresses use of sources not listed in the Sealed Source and Device Registry.

Section 35. 410, Safety Instructions.

The Committee agreed with the revision to § 35.410 that requires an AU to be notified if a patient or human research subject has a medical emergency or dies.

Section 35.432, Calibration measurements of brachytherapy sealed sources.

The Committee agreed with allowing a licensee to accept a manufacturer's calibration of manual brachytherapy sources.

Subpart H, Use of a Sealed Source in Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

The Committee agreed with limiting Subpart H to photon-emitting devices.

Section 35.600, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

The Committee agreed with the addition of the phrase "in accordance with an effective investigational device exemption application accepted by the FDA" in § 35.600. The ACMUI believed this phrase addresses use of sources not listed in the Sealed Source and Device Registry.

Section 35.615, Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Dr. Williamson noted that the requirements for qualified individuals to be present during initiation and ongoing treatments with MDR and HDR afterloaders should not be identical. He believed that requirements for MDR, LDR, and PDR remote afterloaders should be similar.

The Committee reached agreement on the following items:

1. The draft final language in § 35.615 for "an authorized medical physicist and an authorized user or an individual under the supervision of the authorized user who has been trained to remove the applicators in the event of an emergency, to be immediately available during continuation of all patient treatments," during initiation and ongoing treatments with an MDR afterloader provides needed flexibility.

2. Only a physician designee is needed at the initiation of a treatment with a PDR remote afterloader.

3. Paragraph (b) should be revised to delete the requirement to "immediately" shield the radioactive source for gamma stereotactic radiosurgery, because time is needed to withdraw the patient.

Section 35.632, Full calibration measurements on teletherapy units.
Section 35.633, Full calibration measurements on remote afterloader units.
Section 35.635, Full calibration measurements on gamma stereotactic radiosurgery units.

The Committee agreed with the requirements for calibration in §§ 35.632, 35.633, and 35.635.

Section 35.642, Periodic spot-checks for teletherapy units.
Section 35.643, Periodic spot-checks for remote afterloader units.
Section 35.644, Periodic spot-checks for low dose-rate remote afterloaders.
Section 35.645, Periodic spot-checks for gamma stereotactic radiosurgery units.

The Committee agreed with the removal of the redundancies in §§ 35.642, 35.643, 35.644, and 35.645. Dr. Williamson recommended changing the check on source transfer tubes from quarterly to annually. He also recommended NRC clarify whether LDR remote afterloader licensees need to possess a calibration system if they rely on the manufacturer's calibrations.

Section 35.657, Therapy-related radiosurgery units.

The Committee suggested that Dr. Williamson review the requirements in § 35.657 directly with the Working Group.

Preparation of Commission Briefing Materials

The Committee members developed a list of issues that they wished to bring to the attention of the Commission and identified the members of the Committee who would present particular parts of the briefing.

10 CFR Part 32, Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

Mr. Swanson noted that Part 32 contains similar requirements to the current Part 35. In particular, § 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35," requires that the licensee have instrumentation to measure the radioactivity of drugs and have procedures for use of the instrumentation. Mr. Swanson made a motion that, following completion of the Part 35 rulemaking, the NRC review § 32.72 and make it consistent with the requirements in the final Part 35.

Motion 16: Subsequent to publication of the final Part 35 rule, NRC should review Part 32 for items of consistency.

Vote: 6 in favor, none opposed.

ACGME and NRC Approval of Training Programs

Dr. Cerqueira indicated that only the nuclear medicine program, as described in the ACGME Directory, meets the requirements to be ACGME accredited. The description of the radiology program is general; the cardiology program does not specify details about the hours of training; and the endocrinology program does not specify requirements.

Dr. Cerqueira was concerned that all cardiology, radiology, and endocrinology programs will have to apply to NRC for approval. He noted that there are over 400 cardiology training programs. He was uncertain how quickly programs could make the necessary changes to the ACGME Directory. Dr. Holder suggested that all of the 400 programs would not involve nuclear cardiology and so only a portion of them would seek approval. Dr. Siegel argued that programs, such as radiology, would be able to make the necessary changes in the program description within the two-year rule implementation period.

Mr. Swanson suggested that the cardiology and endocrinology societies should seek information on what would be involved in obtaining ACGME approval of the nuclear cardiology and nuclear endocrinology programs. Dr. Siegel noted that programs have cross-departmental training, so potentially cardiologists or endocrinologists could obtain the necessary training as part of a radiology or nuclear medicine program, as an elective in their cardiology or endocrinology training. The necessary training could be an elective component of an ACGME-approved training program, rather than an essential component of all programs, but the requirements of the program would need to be specified for that elective.

At 12:17 p.m. Ms. Haney adjourned the meeting.

SUMMARY OF MOTIONS

Motion 1.1: Leave § 35.392(c)(1) and (c)(2), with respect to the required hours, unchanged.
Vote: 7 in favor, none opposed.

Motion 1.2:

1. Section 35.292(c), introductory sentence - The phrase "in basic radionuclide handling techniques" should be deleted and the term "radioactive drugs" should be substituted for the term "unsealed byproduct material."
2. Section 35.292(c)(2) - The word "direction" should be substituted for the word "supervision" and the term "authorized user" be replaced with the term "preceptor authorized user."
3. Section 35.292(c)(3) - The phrase "an authorized user" should be replaced with the phrase "preceptor authorized user" and the word "physician" should be deleted.
Vote: 7 in favor, none opposed.

Motion 2: Modify § 35.300(b) to state "who meets the requirements specified in §§ 35.292, 35.390, or an individual under the supervision . . . "
Vote: 7 in favor, none opposed.

Motion 3: Table the motion to discuss intravascular brachytherapy for prevention of restenosis in the vascular system until discussion of Subpart K.
Vote: 6 in favor, Dr. Cerquiera opposed, believing it appropriate to discuss at this time.

Motion 4: Approve the training and experience requirements - alternative pathway (chart)
Vote: 7 in favor, none opposed.

Motion 5.1: That § 35.24(b) be amended to state "Subparts E, F, and H or two or more types of units under Subpart H."
Vote: 7 in favor, none opposed.

Motion 5.2: That § 35.24 be amended to "establish a radiation safety committee to oversee all uses of byproduct material permitted by the licensee."
Vote: 7 in favor, none opposed.

Motion 6: NRC regulations should reflect the following:

1. An authorized user may prescribe a dosage range for material administered under §§ 35.100, 35.200, and 35.500.
2. An authorized user may not prescribe a dosage range for material administered under §§ 35.300, 35.400, and 35.600.
3. Administered activities can deviate from a prescribed dosage by 20%.
Vote: Motion withdrawn.

Motion 7: Amend § 35.63(d) to state that unless otherwise directed by the AU, a licensee shall not use a dosage if (a) the dosage differs from the prescribed dosage by more than 20% or (b) the dosage does not fall within the prescribed dosage range.

Vote: 7 in favor, none opposed.

Motion 8: In §35.3045, references to "skin, organ, or tissue" should be revised to reference "tissue" only.

Vote: 7 in favor, none opposed.

Motion 9: ACMUI reaffirms that it does not support any regulation requiring notification of physicians and patients as this is redundant to existing State laws and medical ethics.

Vote: 6 in favor, None opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion.

Motion 11: The reporting threshold in § 35.3047 should be 5 rem.

Vote: 7 in favor, none opposed.

Motion 12: The reporting requirements in § 35.3047 should be limited to only those events where the mother was not properly instructed in accordance with § 35.75 prior to release from the facility.

Vote: 6 in favor, none opposed, 1 abstention. Ms. McBurney abstained, on the grounds that NRC's reasons for retention of the requirement may be valid, and because she was not an official Committee member during the initial discussion. (Mr. Graham no longer present.)

Motion 13: ACMUI does not support any regulation requiring notification of physicians, mothers or pregnant women as this is redundant to existing State laws and medical ethics.

Vote: 5 in favor, none opposed, 1 abstention. Ms. McBurney abstained, because NRC's reasons for the requirement may be valid. (Mr. Graham no longer present.)

Motion 14: The following sentence should be included with regards to the embryo/fetal reporting requirement in § 35.3047(a), "Has resulted or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician."

Vote: 6 in favor, none opposed (Mr. Graham no longer present).

Motion 15: ACMUI believes that NRC should not require license applicants to provide any procedures (including Subpart H procedures) to NRC for review prior to NRC issuance of the license (or amendments) and therefore should not tie licensees to these procedures via license conditions.

Vote: 5 in favor; 1 opposed, 1 abstention. Ms. McBurney opposed because States and many licensees want review of procedures. Dr. Nelp abstained because he disliked how the motion was phrased.

Motion 16: Subsequent to publication of the final Part 35 rule, NRC should review Part 32 for items of consistency.

Vote: 7 in favor, none opposed.

Attachment 1

Proposed Rule - August 1998
Training and Experience Requirements
Alternative Requirements to Certification by Board Approved by NRC

	Structured Educational Program		Other
	Didactic (hrs)	Practical (hrs)	
35.100, Unsealed - uptake, dilution, excretion	40	20	Physician, preceptor, exam
35.200, Unsealed - imaging and localization	80	40	Physician, preceptor, exam
35.300, Unsealed - written directive required	80	40	Physician, preceptor, exam, 5 cases
35.400, Manual brachytherapy	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
35.500, Sealed sources for diagnosis	8		Physician, Dentist, Podiatrist
35.600, Therapeutic medical devices	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
RSO	200		Preceptor, exam, 1 yr or AU
AMP			Preceptor, exam, MS, 2 yrs
ANP	700		Preceptor, exam

Attachment 2
TRAINING AND EXPERIENCE REQUIREMENTS - Alternative Pathway

	Requirements*
§ 35.290 - Training for uptake, dilution, and excretion studies *(Written Directive is not required - § 35.100)*	- 40 hours classroom and laboratory - 20 hours supervised practical
§ 35.292 - Training for imaging and localization studies *(Written Directive is not required - § 35.200)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment
§ 35.390 - Training for use of unsealed byproduct material *(Written directive is required - § 35.300)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment - 3 cases each use category requested
§ 35.392 - Training for use of sodium iodide I-131 for which a written directive is required	- 80 hours classroom, laboratory and supervised practical - 3 cases each use category requested
§ 35.490 - Training for use of manual brachytherapy sources (§ 35.400)	- 200 hours didactic - 500 hours practical - 3 years ACGME program
§ 35.590- Training for use of sealed sources for diagnosis (§ 35.500)	- 8 hours classroom and laboratory
§ 35.690 - Training for use of remote aferloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.600)	- 200 hours didactic - 500 hours practical - 3 years ACGME program

§35.50 - Radiation Safety Officer	- OPTION 1
	  - 200 hours didactic
	  - 1 year supervised experience
	- OPTION 2
	  - Authorized user for type of use

§35.51 - Authorized Medical Physicist	- MS - 2 years experience
§ 35.55 - Authorized Nuclear Pharmacist	- 700 hours structured educational program

* Training must be in NEC or A/S approved program. An AU under §§ 35.290, 35.292, 35.390, 35.392, 35.490, 35.690 must be a physician. An AU under § 35.590 may be a physician, dentist, or podiatrist. An AU, AMP, and ANP must also have a preceptor statement.

Attachment 1

Proposed Rule - August 1998
Training and Experience Requirements
Alternative Requirements to Certification by Board Approved by NRC

	Structured Educational Program		Other
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Jordan, AEOD/
Morrison, RES

Cys: Taylor
Milhoan
Thompson
Blaha

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

August 21, 1986

OFFICE OF THE
SECRETARY

MEMORANDUM TO: James L. Milhoan
Co-chairperson, Strategic Assessment and
Rebaselining Steering Committee

James W. Johnson
Co-chairperson, Strategic Assessment and
Rebaselining Steering Committee

James M. Taylor
Executive Director for Operations

John T. Larkins
Executive Director/ACRS/ACNW

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-028 -
STRATEGIC ASSESSMENT ISSUE PAPER:
INDEPENDENT OVERSIGHT (DSI 19)

The Commission does not believe that this issue is direction setting and believes that it should not be included in the set of issue papers for public comment. In addition to the Strategic Assessment and Rebaselining Steering Committee, the Advisory Committee on Reactor Safeguards, Advisory Committee on Nuclear Waste, and the EDO are requested to respond to the actions described below. Furthermore, this issue paper should be given normal distribution associated with SECY papers. The issue paper does not require revision prior to release.

The Commission continues to believe that independent technical oversight is essential in order to ensure that NRC's products are of the highest technical quality and the Commission's decisions have the public's confidence. But considering the changing environment, the reduction of workloads in a number of areas under the purview of several of the referenced independent oversight committees, the duplication of the activities between committees in some areas, and the cost in funds and FTE's associated with all the agency's committees, the Commission's decision on this DSI is modified versions of options 2 (Continue Current Independent Technical Oversight; Conduct Comprehensive, Periodic Review of Committee Charters) and 1 (Establish Criteria to Articulate the Threshold for the Need and Type of Independent Technical Oversight) as summarized below:

1. (Modified Option 2) The ACRS should remain as the

Commission's primary independent technical oversight committee. The Commission believes that the committee's charter should be given a comprehensive review to evaluate what adjustments in the scope and depth of the committee's charter are needed in light of the changing external and internal factors discussed in the DSI paper.

Even though the ACNW is experiencing a decrease in its activities and there are also many uncertainties about the agency's future activities associated with HLW and LLW programs, the Commission continues to believe that issues presently being addressed by the ACNW will continue to exist in one form or another; therefore, the Commission believes that some form of independent technical oversight should be retained for the areas under the purview of the ACNW. The Commission requests that ACNW retain its current form in the interim but the staff should examine the pros and cons of having ACNW remain in its current form or as a stand alone subcommittee of ACRS. Either option would allow the Commission to retain independent technical oversight of both areas, i.e., reactors and waste. This also preserves the option of having an active body of expertise available should the activities under the purview of both the ACRS and the ACNW increase in the future.
(ACRS/ACNW) (SECY Suspense: 1/2/97)

2. The Commission believes that the role of the ACMUI should be re-examined and addressed after the determination is made on the NRC's role in the materials/medical program area.
(~~EDO~~/ACMUI) (SECY Suspense: 180 days after final Commission decision on medical program) 9600117
NMSS

3. (Modified Option 1) The Commission believes that the activities of the NSRRC should be revisited. This committee played an important role in its first few years of existence in ensuring the effectiveness of the research program in addressing the evolving regulatory needs.
(~~EDO~~/NSRRC) (SECY Suspense: 9/30/96) 9600118
RES

4. The Commission believes that CRGR should be retained but its scope should be revisited. While the Commission continues to believe the scope should be expanded to include NMSS activity, it also believes consideration should be given to including reactor inspection guidance within the scope of CRGR.
(~~EDO~~/CRGR) (SECY Suspense: 11/29/96) 9600119
AEOD

In general, for the independent oversight committees that remain, as well as the CRGR, the Commission supports Option 2 but believes that the periodic reviews should not be limited to only the committee charters. Each committee should be evaluated to determine what value it is contributing to achieving the agency's

mission, but the committee should also be directly involved in this evaluation. That is, each committee is requested to produce a set of criteria, for Commission consideration, under which the performance of the committee would be evaluated in the future. Each committee should then periodically review itself against these criteria and provide the results of this evaluation to the Commission.

		(ACRS/ACNW)	(SECY Suspense: 1/2/97)
9600120	RES	(~~EDO~~/NSRRC)	(SECY Suspense: 6/30/97)
9600121	AEOD	(~~EDO~~/CRGR)	(SECY Suspense: 11/29/96)
9600122	NMSS	(~~EDO~~/ACMUI)	(SECY Suspense: One year after final decision on medical program)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
K. Cyr (OGC)
D. Rathbun (OCA)
H. Bell (OIG)

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

April 9, 1998

MEMORANDUM TO: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS MEMORANDUM DATED AUGUST 21, 1997, COMSECY-96-028, "STRATEGIC ASSESSMENT ISSUE PAPER: INDEPENDENT OVERSIGHT (DSI 19)"

The Commission, in a Staff Requirements Memorandum dated August 21, 1996, COMSECY-96-028, "Strategic Assessment Issue Paper: Independent Oversight (DSI 19)," discussed its continuing belief in the value, to the Commission, of independent technical oversight committees to the Commission in order to ensure that Nuclear Regulatory Commission's (NRC) products are of the highest technical quality and that the Commission's decisions have the public's confidence. Furthermore, the Commission stated that each committee should be evaluated to determine what value the committee is contributing to achieving the Agency's mission, and that the committee should also be directly involved in the evaluation. The Commission requested that each of the independent oversight committees produce a set of criteria, for Commission consideration, under which the performance of the committee should be evaluated in the future.

The staff discussed COMSECY-96-028, as it relates to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), with the ACMUI members during the ACMUI meeting held on March 1-2, 1998. The ACMUI members, in conjunction with the staff, developed the self-evaluation criteria outlined in the attachment , for Commission consideration. The staff considers the criteria sufficiently comprehensive to adequately assess the ACMUI's value to the Commission.

The ACMUI will periodically review itself against these criteria and provide the results of this evaluation to the Commission during its annual meeting with the Commission, commencing with the 1999 annual meeting. Typically, the annual briefing is scheduled during the second quarter of the calendar year.

The staff will independently conduct an annual evaluation of the ACMUI, using the attached criteria, and will provide the results of this evaluation, in writing, to the Commission during the second quarter of the fiscal year, commencing with the second quarter of calendar year 1999.

...: 3

NRC FILE CENTER COPY 98-80

Attachment 2

The staff's evaluation will include an observation concerning if the ACMUI is effective in proposing solutions to problems as opposed to simply raising new, unresolved questions.

Attachment: Self-Evaluation Criteria
for the ACMUI

CONTACT: Patricia Vacherlon, NMSS/IMNS
(301) 415-6376

cc: SECY
OPA
OIP
OCA
OIG
OGC
CFO
CIO

SELF-EVALUATION CRITERIA FOR
THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACUMI)

1. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the Committee?

2. Do the Committee members clearly define issues for staff and provide timely, useful 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 the medical community to the attention of NRC staff?

7. Does the committee facilitate/foster communication between the public/medical community and NRC?

Attachment

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

COMMISSIONER

To: Paperiello, NMSS

cys: Callan
Thadani
Thompson
Norry
Blaha

May 26, 1998

MEMORANDUM TO: John C. Hoyle
Secretary

FROM: Edward McGaffigan, Jr.

SUBJECT: EDO MEMO DATED APRIL 9, 1998 REGARDING AN SRM DATED AUGUST 21, 1997 (COMSECY-96-028) AND THE ACMUI

I have reviewed the self-evaluation criteria developed by the Advisory Committee on the Medical Uses of Isotopes in conjunction with the staff and offer the following comments for the staff's consideration.

The memorandum states that "the staff's evaluation will include an observation concerning if the ACMUI is effective in proposing solutions to problems as opposed to simply raising new, unresolved questions." This statement implies that new, unresolved questions raised by the ACMUI may be of little value to the staff. While I agree that it is desirable and more efficient for the staff if ACMUI proposed solutions for every problem identified, this is not always possible. I would also argue that it is equally important for the ACMUI to feel free to raise new, unresolved questions since its members bring their day-to-day experiences in the medical community to the table for discussion and consideration by the staff.

I offer the following edits to the current questions in the attachment to the EDO memorandum:

Question 2 should be edited to add the word, "objective," after the word, "useful."
Question 6 should be edited to add the phrase, "all elements of," after the words, "issues from."

I also offer three additional questions for the self-evaluation criteria:

Does the Committee consider current resource constraints of the NRC when recommending new or enhanced regulatory programs?
Does the Committee make effective use of subcommittees to assist the staff on specific tasks or projects?
Does the scope and size of the Committee meet the current needs of NRC?

Finally, the self-evaluation criteria should be periodically re-evaluated by the staff and the ACMUI to ensure that it is effective in evaluating the performance of the Committee.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
EDO
OGC

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

July 29, 1999

MEMORANDUM TO: Chairman Dicus
Commissioner McGaffigan
Commissioner Diaz
Commissioner Merrifield

FROM: William D. Travers
Executive Director of Operations

SUBJECT: EVALUATION OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

In Staff Requirements Memorandum (SRM) "COMSECY-96-028 - Strategic Assessment Issue Paper: Independent Oversight (DSI 19)," (Attachment 1) the Commission requested that each Advisory Committee develop a set of criteria, for Commission consideration, under which the performance of the Committee would be evaluated. The Commission also requested that each Committee should then periodically review itself against the criteria and provide the results of the evaluation to the Commission.

In response to the SRM, the ACMUI members, in conjunction with the staff, developed self-evaluation criteria. These criteria were forwarded to the Commission in April 1998 (Attachment 2). At that time, we indicated that the ACMUI would periodically review itself against these criteria and provide the results to the Commission during its annual meeting with the Commission. This was to commence with the 1999 annual meeting. In addition, we indicated that the staff would independently conduct an annual evaluation of the ACMUI, using the same criteria, and would provide the results of this evaluation to the Commission. The first evaluation was to have been provided during the second quarter of calendar year 1999.

Since early 1998, the ACMUI's full resources have been devoted to the extensive revision undertaken on 10 CFR Part 35, "Medical Uses of Byproduct Material." As a result, the Committee has not been able to devote resources to its self-evaluation. The next meeting of the ACMUI (November 1999 or slightly later) will again be focused on Part 35 and, any supporting documentation for the Part 35 rulemaking. However, the Nuclear Regulatory Commission staff will schedule time during this meeting for the ACMUI to conduct the self-evaluation.

Similarly, the staff has not performed its evaluation of the ACMUI because those staff members in the best position to evaluate the Committee's performance have been devoting their full attention to the Part 35 rulemaking. We estimate that the final rule, with supporting documentation, will be submitted to the Commission in late December 1999.

CONTACT: Stephen Lewis, NMSS/IMNS
(301) 415-6478

For these reasons, the ACMUI's self-evaluation and the staff's evaluation of the ACMUI will be provided to the Commission in March 2000. This will allow the staff and the Committee to devote their full resources to the completion of the rulemaking and related documents. It will also enable both the Committee and the staff to reflect in their evaluations the experience with the Part 35 rulemaking.

Attachments:
1. SRM - COMSECY-96-028
2. Memorandum, dated April 9, 1998, from L. Joseph Callan to the Commission

cc: OGC
OCA
OIP
CFO
CIO
SECY
OPA

ACMUI ANNUAL COMMISSION BRIEFING

Manuel D. Cerqueira, M.D.
John Graham
Nekita Hobson
Ruth McBurney, M.S., CHP
Louis Wagner, Ph.D.

October 21, 1999

Briefing Outline

- General Comments
- Radiation Safety Committee
- Training and Experience
- Medical Event
- Unintentional Exposure to Embryo/Fetus/Nursing Child
- Notifications
- Implementation Challenges

General Comments

- Draft final rule is risk-informed, more performance based
  - Occupational, public, and patient safety maintained
  - Focus on higher risk procedures
  - Reduces unnecessary regulatory burden for low-risk procedures
- Stakeholder involvement
  - ACMUI, subcommittees
  - Regulated community

Radiation Safety Committee (§35.24)

- ACMUI endorses the draft final rule that requires 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
  - Provides the licensee flexibility in program management in environment of consolidating resources

Training and Experience

- NRC focus is on radiation safety
  - Training should be obtained in a clinical environment
- ACMUI endorses alternative pathway for training and experience requirements for AU, AMP, ANP, and RSO
  - Importance of preceptor statements
  - NRC recognition of specialty boards
    - Initiate recognition process immediately
- Encourages uniform national standards for training and experience
- T&E for emerging technologies

Medical Event (§30.3045)

- ACMUI endorses dose thresholds in draft final rule
  - Adequately capture events of concern
  - Dose thresholds will help to reduce unnecessary regulatory burden (wrong treatment site, patient intervention)
- Events occurring as result of patient intervention should not be reported to NRC unless unintended permanent functional damage to an organ or physiological system

Unintentional Exposure to Embryo/Fetus/Nursing Child (§35.3047)

- ACMUI endorses 50 mSv (5 rem) as an appropriate ***reporting*** threshold
  - Technical implications
  - Minimal impact on the patient/physician relationship
  - Minimal impact on current standard of care and cost

Notification Following Medical Event or Exposure to Embryo/Fetus/Nursing Child

- ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing standards of care
- Alternative rule language provided by staff preferred over existing requirements

Implementation Challenges

- Early recognition of medical specialty boards
- Focusing NRC license reviewers and inspectors on licensee performance and high risk procedures
- Use of guidance document

Revision of 10 CFR Part 35 Medical Use of Byproduct Material

October 21, 1999

Catherine Haney

Briefing Outline

- Background
- Purpose of SECY-99-201
- Key issues for Commission decision
- Implications for licensing, inspection, and enforcement programs
- Resources and timetable for completion of rulemaking

Background

- SRM-COMSECY-96-057, March 20, 1997, Commission directed the revision and restructuring of Part 35 into a risk-informed, more performance-based regulation
- Continuous interaction with public, stakeholders, Agreement States, non-Agreement States, and ACMUI

Purpose of SECY-99-201

- Provide draft final rule language for 10 CFR Part 35
- Summarize public comments and staff's draft responses to the comments
- Provide comparison of current rule to draft final rule
- Achieve closure on outstanding issues from previously issued SRMs
- Provide proposed Agreement State compatibility designations
- Provide CRCPD SR-6 Committee view on draft revision
- Request approval to complete final rulemaking package
- Request approval to begin notification process for specialty boards

Key Issues for Commission Decision

- Need for formal risk assessment
- Radiation Safety Committee
- Training and experience requirements
- Reporting threshold for unintended exposure to embryo/fetus/nursing child
- Notification following a medical event or exposure to embryo/fetus/nursing child
- Additional CRCPD SR-6 Committee concerns

Risk Assessment

- Issue - need to perform a formal risk assessment (SRM-SECY-98-263)
- Pros
  - Additional information
  - Responsive to public and Agreement State comments
- Cons
  - Significant delay in final rule
  - Resource intensive
  - Data necessary to perform a formal risk assessment may be either not available or be problematic
- Staff recommendation - proceed with Commission's direction to develop a risk-informed rule that is focused on radiation safety
- Draft final rule risk informed: reduction in unnecessary regulatory burden, especially in low risk diagnostic area

Radiation Safety Committee

- Issue - impact of the proposed deletion of the RSC on the licensees' effectiveness in carrying out radiation protection programs
- Considerations - risk, public comment
- Staff resolution - RSC only required 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 Requirements

- Issue - establish appropriate T&E requirements
- Considerations - public comments; risk; misadministration history
- Global recommendations
  - Focus on radiation safety
  - Reliance on preceptor statement vs. requirement for an examination or NRC approval of training program
  - NRC recognition of specialty boards

Training and Experience Requirements (cont)

- Changes in specific T&E since March 1999
  - Use of unsealed byproduct material
    - Requirement for total hours of training and experience versus breakdown of hours for classroom and laboratory training and supervised work experience
    - Requirements for oral administration of NaI (I-131) based on quantities used
  - Use of sealed byproduct material
    - Requirements added for ophthalmic use of Sr-90
- CRCPD SR-6 Committee concerns

Reporting Threshold for Unintended Exposure to an Embryo/Fetus/Nursing Child

- Issue - need for NRC to meet AO reporting criteria
- Considerations - impact on medical practices; public comments; reporting threshold, not dose limit; recommendations of radiation protection organizations; include reporting threshold in Part 35 or develop rulemaking plan to revise Part 20 or Parts 30, 40, and 70

Reporting Threshold for Unintended Exposure to an Embryo/Fetus/Nursing Child (cont)

- Staff resolution
  - Embryo/fetus - report any unintentional dose that exceeds 50 mSv (5 rem) dose equivalent
  - Nursing child - report any dose that is greater than 50 mSv (5 rem) TEDE; or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician

- CRCPD SR-6 Committee concerns

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child

- Issue - revision of the requirements to notify the patient, responsible relative, or mother
- Considerations - public comments; risk; alternative regulatory text provided in SRM
  - Verbal notification
  - Written documentation in patient's file
  - Written certification stating patient was notified

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child (cont)

- Pros of alternative text
  - More consistent with medical policy goals
  - Greater reliance on physician-patient relationship
  - Consistent with another Federal patient notification requirement
  - Responsive to SRM direction to be risk-informed and to public comments
- Cons of alternative text
  - Does not ensure patient is fully informed
  - Not consistent with other NRC requirements

Notification Following a Medical Event or Exposure to Embryo/Fetus/Nursing Child (cont)

- Resolution - current requirements retained in draft final rule; alternative rule text provided for Commission consideration

Additional CRCPD SR-6 Committee Concerns

- Criteria for releasing individuals containing unsealed byproduct material or implants containing radioactive material
- Safety precautions associated with brachytherapy treatments

Implications for Licensing, Inspection, and Enforcement Programs

- Specific vs. general licensing
- Information to be submitted in support of licensing actions
- Inspection - review of procedures
- Revisions to the Enforcement Policy

Resources and Timetable for Completion of Rulemaking

- 3 FTE to complete rulemaking, MPS, and NUREG

- SRM will drive final due date - estimate final rule, including OMB approval, mid 2000; effective date early 2001

Back-up Slides

Proposed 10 CFR Part 35
Table of Sections Applicable to
Diagnostic and Therapeutic Nuclear Medicine

Section No. and Title		All Uses	35.100	35.200	35.300
Subpart A--General Information					
35.1	Purpose and scope.	✔			
35.2	Definitions.	✔			
35.5	Maintenance of records.	✔			
35.6	Provisions for the protection of human research subjects.	✔			
35.7	FDA, other Federal, and State requirements.	✔			
35.8	Information collection requirements: OMB approval.	✔			
35.10	Implementation.	✔			
35.11	License required.	✔			
35.12	Application for license, amendment, or renewal.	✔			
35.13	License amendments	✔			
35.14	Notifications.	✔			
35.18	License issuance.	✔			
35.19	Specific exemptions.	✔			

Section No. and Title		All Uses	35.100	35.200	35.300
Subpart B--General Administrative Requirements					
35.24	Authority and responsibilities for the radiation protection program.	✔			
35.26	Radiation protection program changes.	✔			
35.27	Supervision.	✔			
35.40	Written directives.				✔
35.41	Procedures for administrations requiring a written directive				✔
35.50	Training for Radiation Safety Officer.	✔			
35.55	Training for an authorized nuclear pharmacist.	✔			
35.57	Training for experienced RSO, teletherapy or medical physicist, authorized user, and nuclear pharmacist.	✔			
35.59	Recentness of training.	✔			
Subpart C--General Technical Requirements					
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.	✔			
35.61	Calibration of survey instruments.	✔			
35.63	Determination of dosages of unsealed byproduct material for medical use.	✔			
35.65	Authorization for calibration, transmission, and reference sources.	✔			
35.69	Labeling of vials and syringes.	✔			
35.70	Surveys of ambient radiation exposure rate.				✔

Section No. and Title		All Uses	35.100	35.200	35.300
35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material.	✔			
35.80	Provision of mobile medical service.	✔			
35.92	Decay-in-storage.	✔			
Subpart D--Unsealed Byproduct Material - Written Directive Not Required					
35.100	Use of unsealed byproduct material for uptake, dilution, and excretion.		✔		
35.190	Training for uptake, dilution, and excretion studies.		✔		
35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.			✔	
35.204	Permissible molybdenum-99 concentration.			✔	
35.290	Training for imaging and localization studies.			✔	
Subpart E--Unsealed Byproduct Material - Written Directive Required					
35.300	Use of unsealed byproduct material for which a written directive is required.				✔
35.310	Safety instruction.				✔
35.315	Safety precautions.				✔
35.390	Training for use of unsealed byproduct material for which a written directive is required.				✔

Section No. and Title		All Uses	35.100	35.200	35.300
35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).				✔
35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).				✔
Subpart L--Records					
35.2024	Records of authority and responsibilities for radiation protection programs.	✔			
35.2026	Records of radiation program changes.	✔			
35.2040	Records of written directives.				✔
35.2045	Records of medical events.	✔			
35.2047	Record of a dose to an embryo/fetus or a nursing child	✔			
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.	✔			
35.2061	Records of radiation survey instrument calibrations.	✔			
35.2063	Records of dosages of unsealed byproduct material for medical use.	✔			
35.2070	Records of surveys for ambient radiation exposure rate.				✔
35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.	✔			
35.2080	Records of administrative and technical requirements that apply to the provision of mobile medical services.	✔			

Section No. and Title		All Uses	35.100	35.200	35.300
35.2092	Records of decay-in-storage.	✔			
35.2204	Records of molybdenum-99 concentrations.			✔	
35.2310	Records of instruction and training.	✔			
Subpart M--Records					
35.3045	Report and notification of a medical event.	✔			
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child.	✔			
Subpart N--Enforcement					
35.4001	Violations.	✔			
35.4002	Criminal penalties.	✔			

TRAINING AND EXPERIENCE REQUIREMENTS ON DRAFT FINAL RULE

	Requirements*
§ 35.190 - Training for uptake, dilution, and excretion studies *(Written directive is not required - § 35.100)*	- 60 hours training and experience (classroom and laboratory training and supervised work experience)
§ 35.290 - Training for imaging and localization studies *(Written Directive is not required - § 35.200)*	- 700 hours training and experience (classroom and laboratory training and supervised work experience)
§ 35.390 - Training for use of unsealed byproduct material *(Written Directive is required - § 35.300)*	- 700 hours training and experience (classroom and laboratory training and supervised work experience) - 3 cases for each use category for which AU status is requested
§ 35.392 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)	- 80 hours classroom and laboratory training - supervised work experience (including 3 cases involving administration of less than or equal to 33 millicuries)
§ 35.394 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)	- 80 hours of classroom and laboratory training - supervised work experience (including 3 cases involving administration of greater than 33 millicuries)
§ 35.490 - Training for use of manual brachytherapy sources (§ 35.400)	- 200 hours classroom and laboratory training - 500 hours supervised work experience - 3 years supervised clinical experience in radiation oncology**

§ 35.491 - Training for ophthalmic use of strontium-90	- 24 hours classroom and laboratory training - supervised clinical training that includes treatment of 5 individuals
§ 35.590 - Training for use of sealed sources for diagnosis (§ 35.500)	- 8 hours classroom and laboratory training
§ 35.690 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.600)	- 200 hours classroom and laboratory training - 500 hours supervised work experience - 3 years supervised clinical experience in radiation oncology**
§ 35.50 - Training for Radiation Safety Officer	- 200 hours didactic training - 1 year supervised experience; similar types(s) of use(s)
§ 35.51 - Training for an authorized medical physicist	- Master's or Doctor's degree - 1 year training - 1 year supervised experience
§ 35.55 - Training for an authorized nuclear pharmacist	- 700 hours structured educational program

* An AU under §§ 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.690 must be a physician. An AU under § 35.590 may be a physician, dentist, or podiatrist. An AU, RSO, AMP, and ANP must also have a preceptor statement.

** May be obtained concurrently with supervised work experience.

Recommendations on Exposure to Embryo/Fetus/Nursing Child

- Threshold level is consistent with recommendations in
  - NCRP #54, Medical Radiation Exposure of Pregnant and Potentially Pregnant Women (1977)
  - AAPM TG #36, Fetal Dose from Radiotherapy with Photon Beams (1995)
  - NCRP Commentary #9, Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child (1994)
    - At a reporting threshold of 50 mSv (5 rem), there are no deterministic effects, and the risk of stochastic effects is less than 1%
    - Concluded that "setting requirements for action ... at some level below an effective dose of 100 mSv (10 rem) to allow for a margin of safety should enable all such incidents with the potential for harm to be dealt with appropriately

Projected Schedule

October 1999	Commission briefing on draft final rule
November 1999	SRM on preparation of final rule
February 2000	Submission of final rulemaking package for Commission approval
TBD	Commission approval of final rule
TBD + 90 days	OMB approval of publication of final rule in FR
6 mos after pub	Effective date of final rule