THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

PUBLIC MEETING

U.S. NUCLEAR REGULATORY COMMISSION HEADQUARTERS

NOVEMBER 12-13, 2003

MEMBERS OF THE PUBLIC SIGN IN SHEET
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ACMUI Meeting
November 12-13, 2003
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3
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NOVEMBER 12, 2003

PRINTED NAME	PRINTED NAME
1 Paul Turlo	19
2 Lynne Fairobent	20
3 Nancy R Doty	21
4 JAMES BOXALL	22
5 Roger WB Rosen	23
6 TOMAS HERRERA	24
7 Angela Lee	25
8 Bill Uffelman	26
9 William D. Kelligan	27
10 Gerald A. White	28
11 ALBERT RAIZNER	29
12 JAMES E. MORRIS	30
13 CRAIG REED	31
14 Adam Lowe	32
15 Andrew Kaug	33
16 David Tiktinsky	34
17 DONNA-Beth Howe	35
18 VIJAYA S. BHATIA	36

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NOVEMBER 13, 2003

PRINTED NAME	PRINTED NAME
1 Roshunda Drummond	19
2 Lynne Fairobent	20
3 Bill Uffelman	21
4 Gregg White	22
5 Raymond Horn	23
6 KRISTIN SWENSON	24
7 Nancy R Daly	25
8 Downs-Beth Howe	26
9 Angela Lee	27
10 Jackie King	28
11	29
12	30
13	31
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15	33
16	34
17	35
18	36

ACMUI SPEAKERS and PARTICIPATING STAFF
November 12 & 13, 2003

Manuel D. Cerqueira, ACMUI Chairman

John Szabo, OGC

Charlie Cox, NMSS/IMNS/MSIB

Bernard Stapleton, NSIR

Thomas Essig, NMSS/IMNS/MSIB, Designated Federal Official

Michael Markley, NMSS/IMNS/MSIB

Keith McDaniel, NMSS/IMNS/RGB

Roger Broseus, PhD, NMSS/IMNS/RGB

Richard Vetter, PhD, ACMUI

Donna-Beth Howe, PhD, NMSS/IMNS/MSIB

Angela Williamson, NMSS/IMNS/MSIB

Roberto Torres, NMSS/IMNS/MSIB

Sami Sherbini, PhD, NMSS/IMNS/MSIB

Ronald Zelac, PhD, NMSS/IMNS/MSIB

Charles L. Miller, PhD, NMSS/IMNS

ACMUI MEMBERS

MEMBER	SPECIALTY
Manuel D. Cerqueira, M.D. Georgetown University Medical Center Division of Cardiology (5-PHC) 3800 Reservoir Rd. NW Washington, DC 20007-2197	**Nuclear Cardiology** Email: cerqm@concentric.net Phone: 202-444-7190 FAX: 202-444-4593
David A. Diamond, M.D. Florida Oncology Network Walt Disney Memorial Cancer Institute Florida Hospital - Orlando 2501 N. Orange Ave., Suite 181 Orlando, FL 32804	**Radiation Oncologist** Email: dagdmail@yahoo.com Phone: 407-303-2030 FAX: 407-303-2042
Douglas F. Eggli, M.D. Dept. of Radiology, H066 Penn State University Hospital The Milton S. Hershey Medical Center Room # HG300Z P.O. Box 850 500 University Drive Hershey, PA 17033	**Nuclear Medicine Physician** Email: deggli@psu.edu Phone: 717-531-8940 FAX: 717-531-5596
Nekita Hobson National Association of Cancer Patients 2070 Ridgeline Avenue Vista, CA 92083	**Patient Advocate** Email: nohobson@aol.com Phone: 760-598-8289 FAX: 760-598-7304
Maureen Hess U.S. Food and Drug Administration 5600 Fishers Lane HFD - 160, Parklawn Building Rockville, MD 20857	**FDA Representative** The choice of FDA appointees is made by FDA. Ms. Hess chooses the FDA representative for each meeting. Email: hessm@cder.fda.gov Phone: 301-594-5461

ACMUI Members
Updated: October 20, 2003

MEMBER	SPECIALTY
Ralph P. Lieto St. Joseph Mercy Hospital Radiation Safety Office 5301 E. Huron River Dr. PO Box 995 Ann Arbor, MI 48106-0995	**Medical Physicist, Nuclear Medicine** Email: lietor@trinity-health.org Phone: 734-712-8746 FAX: 734-712-5344
Leon S. Malmud, M.D. Dean Emeritus, Temple University School of Medicine Temple University Health System 3401 N. Broad St Philadelphia, PA 19140	**Health Care Administrator** Email: martinp@tuhs.temple.edu or Malmudls@tuhs.temple.edu Phone : 215-707-7078 (Pat Martin) Phone: 215-885-0756 FAX: 215-707-3261
Ruth McBurney Division of Licensing, Registration and Standards Bureau of Radiation Control Texas Department of Health 1100 West 49th Street Austin, TX 78756-3189	**State Representative** Email: ruth.mcburney@tdh.state.tx.us Phone: 512-834-6689 FAX: 512-834-6716
Subir Nag, M.D. Division of Radiation Oncology Department of Radiology Arthur G. James Cancer Hospital and Research Institute Ohio State University 300 W. Tenth Avenue Columbus, OH 43210	**Radiation Oncologist** Email: nag.1@osu.edu Phone: 614-293-8415 FAX: 614-293-4044
Sally Wagner Schwarz Division of Nuclear Medicine Mallinckrodt Institue of Radiology Washington University School of Medicine 510 south Kingshighway Blvd. St. Louis, MO 63310	**Nuclear Pharmacist** Email: schwarzs@mir.wustl.edu Phone: 314-362-8426 FAX: 314-362-9940

MEMBER	SPECIALTY
Richard J. Vetter, Ph.D. Mayo Clinic Medical Sciences B-28 *or* 200 1st St. SW Rochester, MN 55905	**Radiation Safety Officer** Email: vetter.richard@mayo.edu Phone: 507-284-4408 FAX: 507-284-0150
Jeffrey F. Williamson, Ph.D. **(NEW 09/01/02)** MCV Radiation Oncology 401 College Street, Basement B-129 PO Box 980058 Richmond, VA 23298-0058	**Therapy Physicist** Phone: 804-828-8451 Fax: 804 827-1670 E-mail jfwilliamson@vcu.edu Donna Manion dmanion@hsc.vcu.edu

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

November 12-13, 2003
U.S. Nuclear Regulatory Commission
Two White Flint North Building, Room T2B3
Rockville, Maryland 20852-2738

AGENDA

NOVEMBER 12, 2003

CLOSED SESSION

8:00 – 8:30	Ethics Briefing – John Szabo, NRC/OGC
8:30 – 9:00	ACMUI Accomplishments and Challenges – Charles Miller, NRC/NMSS
9:00 – 9:40	Safeguards Training & Update on NRC Activities to Address Security and Control in the Materials Arena – Charles Cox, NRC/NMSS and ~~Bernard~~ Michael Layton ~~Stapleton~~, NRC/NSIR
9:40 – 9:45	Add Vice Chair - ACMUI
9:45 –10:00	**BREAK**

OPEN SESSION

10:00 –10:05	Opening Remarks – Thomas H. Essig, NRC/NMSS
10:05 – 10:20	Update: National Materials Program Pilot Project on Operating Experience – Michael Markley, NRC/NMSS
10:20 – 12:00	The Rulemaking Process – Keith McDaniel, NRC/NMSS
12:00 – 1:00	**LUNCH**
1:00 – 2:00	Implementation of Proposed Revisions to Part 35; Recognition of Board Certifications – Roger Broseus, PhD, NRC/NMSS
2:00 – 3:00	Discussion: Possible Licensee Implications Associated with the Training and Experience Recommendations in SECY 03-0145 – Richard Vetter, PhD, ACMUI
3:00 – 3:15	**BREAK** - call office
3:15 – 5:00	Novoste IVB Event Analysis – ACMUI
5:00	**ADJOURN**

NOVEMBER 13, 2003

ACMUI Meeting
Agenda

8:00 – 9:00	SeedSelectron and 35.1000 - Donna-Beth Howe, PhD, NRC/NMSS
9:00 – 10:00	Update: Listing Sources by Model/Serial Number on Licenses – Donna-Beth Howe, PhD, NRC/NMSS
10:00 – 10:15	**BREAK**
10:15 – 11:00	Dose Reconstruction in Unplanned Exposures/Extremity Monitoring at Materials Facilities –Sami Sherbini, PhD, NRC/NMSS
11:00 – 11:45	Radioiodine Activity Threshold for Treatment of Hyperthyroidism – Angela Williamson, NRC/NMSS
11:45 – 1:00	**LUNCH**
1:00 – 1:30	ACMUI Access to NMED Event Data – Thomas Essig, NRC/NMSS ✓
1:30 – 2:00	Discuss Draft Information Notice Re: Issuance of Identification Cards to Patients Released after Treatment with Radiopharmaceuticals – Roberto Torres, NRC/NMSS ✓
2:00 – 2:15	**BREAK**
2:15 – 3:15	NMSS Update: Emerging Technologies - Donna-Beth Howe, PhD, NRC/NMSS ✓
3:15 – 3:45	Update: Interpretation of 10 CFR 35.61(b) – Ronald Zelac, PhD, NRC/NMSS ✓
3:45 – 4:15	Update: Recommendations from Spring 2003 ACMUI Meeting – Angela Williamson, NRC/NMSS ✓
4:15 – 5:00	Administrative Conclusion: Next Meeting Date Agenda Topics Meeting Summary
5:00	**ADJOURN**

NOTICE OF CLOSED SESSION AGENDA TOPICS

The following agenda topics are for the closed session and must not be distributed to, nor discussed with members of the public:

- Ethics Briefing
- Safeguards Training and Update on NRC Activities to Address Security and Control in the Materials Arena
- Add Vice Chair

ETHICS BRIEFING: CLOSED SESSION
BRIEFING FOR ACMUI ONLY

NO HANDOUTS PROVIDED

Safeguards Training and Update on NRC Activities to Address Security and Control in the Materials Arena

CLOSED SESSION
BRIEFING FOR ACMUI ONLY

HANDOUTS PROVIDED AT MEETING

Add ACMUI Vice Chair

CLOSED SESSION
FOR ACMUI ONLY

NO HANDOUTS PROVIDED

NMP PILOT 3: OPERATING EXPERIENCE EVALUATION

Marcia Howard, Ohio
mhoward@gw.odh.state.oh.us
Michael Markley, NRC/IMNS
mtm@nrc.gov

USE OF OPERATING EXPERIENCE INFORMATION

- Domestic and foreign event data
- Inspections, special studies, and generic reviews
- Industry-wide analyses
- Risk insights and metrics
- Performance indicators
- Feedback for regulatory action

MAY 2003 ACMUI MEETING

- Recommended consideration of studies and trending done by the University of Texas
- Suggested that the views, regarding operating experience evaluation, of both Agreement States and non-Agreement States be considered

PILOT ACTIVITIES

- Revised charter and issued work product plan
- Conducting bi-weekly working group teleconferences
- Participated in NMSS Operating Experience Committee deliberations
- Briefed Organization of Agreement States
- Obtained information from University of Texas and conducted teleconference

REGULATORY EFFECTIVENESS

- Generic communications that do not work
- Refining data versus developing trends and insights
- Studies that are not applied to oversight programs – inspection, licensing, etc.
- Attention to risk evaluation - priorities, resources, and methods
- Means to address human error consistently

INCIDENT AND WORKING GROUP REPORTS

- Evaluating common root causes, generic issues, and communications
- Examining for trends and common themes
- Assessing the effectiveness of regulatory actions and follow-up
- Considering opportunities for expanded use of risk insights

PILOT 3 SURVEY

- Interviews/questionnaires of managers, inspectors, and reviewers to assess:
  - Information needs
  - Regulatory decisions
  - Communications practices, tools, and methods
- OAS Meeting participants
  - Test cases

TEST CASES

- Intravascular brachytherapy - item of current interest in medical events
  - Training
  - Devices
  - Data on malfunctions
- Portable gauges – optimize State experiences in common NRC/AS program
  - Trends and oversight
  - Rules, generic communications, and results

RECOMMENDATIONS

- Regulatory framework for use by NRC and Agreement States
  - Procedures
  - Sources of information
  - Evaluation criteria
- Integrated decision making
  - Organizational interfaces
  - Methods to better communicate

WORKING GROUP MEMBERS

- Marcia Howard, Ohio (Co-chair)
- Michael Markley, NRC/IMNS (Co-chair)
- Debbie Gilley, Florida
- Duncan White, NRC/RI

National Materials Program Pilot Project 3
Operating Experience Evaluation

Charter

Objectives

The objective of the Operating Experience Evaluation Pilot is to optimize the common use of operating experience information from licensed facilities and trending in integrated NRC and Agreement State review, assessment, and decision-making processes. The pilot should develop and test a structured process for evaluating cumulative licensee data and performance, identify gaps in NRC and Agreement State processes, and develop strategies and tools to make the programs more scrutable, predictable, and transparent. The revised process should produce consistent analyses and results when implemented by the NRC or Agreement States.

Scope of Activities

The pilot will examine NRC and Agreement State processes for collecting, reviewing, analyzing, and disseminating concerns and lessons learned from operating experience. Operating experience information may include: domestic and foreign event data, major team inspections and special studies leading to generic reviews and/or generic communications, industry-wide analyses of performance and trends, insights and metrics amenable to risk-informed decision making, and performance indicators and associated thresholds for increased regulatory attention.

This pilot should: (1) examine the process for evaluating a collective set of Agreement State and NRC licensee events for generic implications and possible additional regulatory action, (2) consider the proposed process, in SECY-02-0216, for providing information on significant nuclear materials issues and adverse licensee performance, and (3) address applicable recommendations identified in incident or working group reports (e.g., Schlumberger Augmented Inspection Team, Davis-Besse Lessons Learned Task Force report, etc.).

The pilot is expected to identify gaps in NRC and Agreement State regulatory processes and opportunities for improvement in program effectiveness. The pilot should develop a set of evaluation tools and metrics to be tested using cumulative data, a standard format, and decision criteria. The pilot should examine and implement lessons learned from past operating experience and associated root cause analyses, risk insights, and corrective actions. Of particular importance are precursor events that provide leading indication of change/problems and/or highlight weakness in regulatory oversight programs. The pilot should also examine methods to advance materials-related contributions to the annual report to the Commission on performance trends in the materials area.

The pilot should develop a proposed regulatory framework and associated program recommendations for consideration by the NRC and Agreement States. The framework should propose enhancements to procedures, organizational review and evaluation methods, sources of information, and methods to better communicate operating experience information. This pilot should provide recommendations for enhanced efficiency and effectiveness of materials oversight programs, including matters related to duplication of effort and/or burden reduction, particularly with regard to the allocation and use of inspection resources.

The pilot should seek broad stakeholder input including the views of the Organization of Agreement States (OAS), Committee of Radiation Control Program Directors (CRCPD),

Advisory Committee on the Medical Use of Isotopes (ACMUI), and from open-public meetings with licensees and members of the public, as appropriate.

Work Products

The pilot should prepare: (1) an overall work product plan for developing and testing methods to systematically evaluate operating experience information, and (2) a final work product and associated recommendations for improving the efficiency, effectiveness, and consistency of operating experience evaluation.

Organization

The Working Group (WG) should comprise Co-Chairpersons from both NRC (Mike Markley, NMSS/IMNS) and Agreement States (Marcia Howard, State of Ohio), at least one additional Agreement State representative, and one NRC representative from an NRC Regional Office materials program. NRC membership shall not exceed Agreement State participation.

Schedule

The updated schedule for completion of this pilot is provided in the Work Product Plan consistent with the National Materials Program Pilot Projects, Implementation Plan.

Level of Effort

Approximately two person-days per month will be required of participants. The Working Group Chair will require, on average, eight person-days per month for this effort. Actual Working Group travel should not exceed three meetings per year. Teleconferencing and video technology will be used to limit costs.

National Materials Program Pilot Project 3
Operating Experience Evaluation

Work Product Plan

Review Plan

The Working Group (WG) will focus on identifying enhancements to NRC and Agreement State (AS) processes for collecting, reviewing, analyzing, and disseminating concerns and lessons learned from operating experience. The WG will evaluate regulatory processes and methods to address the following questions:

1. How operating experience information can be better communicated between NRC and Agreement States?

2. How can operating experience information and trending optimize NRC and Agreement State resource utilization?

3. How can risk insights be better integrated into regulatory decision making?

Review Process, Evaluation Criteria, and Documentation

The WG will conduct reviews, interviews/surveys, and analyses to identify constraints, impediments, and efficiencies in existing regulatory processes:

7/03 Review pilot evaluation criteria in SECY-02-0074, reexamine periodically

7/03 Review regulatory guidance for evaluating operating experience information, including applicable items in Attachment A:

1. Domestic and foreign event data

2. Major team inspections and special studies

3. Generic reviews and/or generic communications

4. Industry-wide analyses of performance and trends

5. Insights and metrics amenable to risk-informed decision making

6. Performance indicators and associated thresholds for increased regulatory attention

Emphasis on evaluating diverse perspectives of AS and NRC headquarters and regional roles and responsibilities

8/03 Conduct interviews with regulatory personnel to assess end-user decisions (inspectors, reviewers, managers):

1. Information needs and who needs to be informed

2. Regulatory decisions desired

   a. Prompt regulatory action
   b. Increased regulatory attention
   c. Evaluation and handling of potential generic issues
   d. Efficiencies through trending and potential leading indicators of change
   e. Use of risk insights in decisions

3. Communication practices, tools, and methods

   a. Organizational interfaces
   b. Data versus evaluation
   c. Dissemination of insights and results
   d. Licensee relocation across State/regional boundaries

4. Impacts on resource allocation

5. Feedback for guidance, licensing, guidance and rulemaking

6. Successes and failures

8/03 Evaluate recommendations in incident or working group reports (e.g., Mallinkrodt Phase I Report, Schlumberger Augmented Inspection Team, St. Joseph Mercy Hospital, Davis-Besse Lessons Learned Task Force report, etc.). The WG should evaluate:

1. Safety issues including root causes, corrective actions, and actions to preclude reoccurrence

2. Communication of emergent issues, generic issues, trends, and safety insights

3. Use of information of event reports and information in NMED

4. Licensee follow-up to generic communications

5. Regulatory use of and follow-up to (e.g., use of temporary instructions) to generic communications, Generic Safety Issues, and IMPEP findings

6. Use of risk information in regulatory decision making

9/03 Develop proposal for test case and criteria for evaluation. The WG should evaluate:

1. Candidate areas to test based on consequences (e.g., industrial radiography, intravascular brachytherapy, portable gauges, diagnostic nuclear medicine, etc.)

2. Criteria using cumulative data, inspection insights, a standard format, and integrated decision making

3. Regulatory decisions desired

   a. Prompt regulatory action
   b. Increased regulatory attention
   c. Evaluation and handling of potential generic issues

d. Efficiencies through trending and potential leading indicators of change
e. Use of risk insights in decisions

4. Communication practices, tools, and methods

a. Organizational interfaces
b. Data versus evaluation
c. Dissemination of insights and results
d. Licensee relocation across State/regional boundaries

5. Proposed process for providing information on significant nuclear materials issues and adverse licensee performance (NRC Strategic Plan and SECY-02-0216)

6. Impacts on resource allocation

9/03 Evaluate and incorporate insights from NRR/RES Operating Experience Task Force, as appropriate

10/03 OAS meeting (Illinois)

1. Present status and test case

2. Conduct poster session, if supported by other pilots

3. Conduct survey to solicit feedback

10/03 ACMUI meeting on status/proposal, as appropriate

11/03 Develop draft framework proposal and associated recommendations for consideration by the NRC and Agreement States.

1. Propose enhancements to procedures, organizational review and evaluation methods, and sources of information

2. Methods to better communicate operating experience information.

3. Recommendations for enhanced efficiency and effectiveness of materials oversight programs, including matters related to duplication of effort and/or burden reduction

12/03 Solicit public comments on framework proposal/recommendations (e.g., electronic, FRN, etc.)

1/04 Reconcile comments. Complete draft pilot report

2/04 Public meeting on Pilots results and NMP direction (tentative)

3/03 Input/review progress report to the Commission

4/04 Complete final pilot project report. Submit for review/approval.

5/04 CRCPD meeting

6/04 Review and reconcile comments. Participate in development of draft Commission report.

8/04 Complete draft Commission report. Begin concurrence.

9/04 Pre-brief key NRC and Agreement State managers and reconcile comments.

11/04 Submit final report to Commission. Participate in briefing, as needed.

Level of Effort

Approximately two person-days per month will be required of participants. The Working Group Chair will require, on average, eight person-days per month for this effort. Actual Working Group travel should not exceed three meetings per year. Teleconferencing and video technology will be used to limit costs.

ATTACHMENT A
KEY REGULATORY GUIDANCE DOCUMENTS

1. Policy and Procedures Letter 1-57, "Generic Assessment Process"

2. Policy and Procedures Letter 1-80, "NMED Events: Searches, Certification, and Updates to the Monthly Licensing and Statistics Report and Budget Estimate and Performance Report"

3. NRC Inspection Manual Chapter, 2800, "Materials Inspection Program"

4. Temporary Instruction 2800/033 Revision 02, "Revised Materials Inspection Program"

5. SA-100, Implementation of the Integrated Materials Performance Evaluation Program"

6. SA-101, "Reviewing Common Performance Indicator #1, Status of Material Inspection Program"

7. SA-105, Reviewing Common Performance Indicator #5, Response to Incidents and Allegations"

8. SA-300, Reporting Materials Events"

9. Management Directive 6.4, "Generic Issues Program"

10. Management Directive 8.3, "NRC Incident Investigation Manual"

11. Management Directive 8.5, "Operational Safety Data Review"

12. Management Directive 8.10, "NRC Medical Event Assessment Program"

13. Management Directive 8.13, "Reactor Oversight Process"

14. Management Directive 8.14, "Agency Action Review Meeting"

15. NUREG-1614, "U.S. Nuclear Commission Strategic Plan"

16. NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems"

17. NUREG-1631, "Source Disconnects Resulting From Radiography Drive Cable Failures"

ATTACHMENT B
HISTORICAL DOCUMENTS AND PILOT PROJECT REVIEW CRITERIA

1. SECY-99-0250, "National Materials Program: Request Approval of the Formation of a Working Group on the Increase in the Number of Agreement States and Impacts on NRC Materials Program"

2. SECY-01-0112, "National Materials Program: Transmittal of Final Working Group report Presenting Options for a National Materials Program"

3. SECY-02-0074, "National Materials Program: Pilot Projects"

4. SECY-02-0107, "Addendum to SECY-02-0074, National Materials Program: Pilot Projects"

5. SECY-02-0216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse Licensee Performance"

6. SECY-03-0036, "Report to Congress on Abnormal Occurrences for Fiscal Year 2002"

7. SECY-03-0044, "Update of the Risk-Informed Regulation Implementation Plan"

8. Memorandum dated January 29, 2003, from P. Lohaus, STP, to J. Funches, CFO, K. Cyr, OGC, M. Virgilio, NMSS, H. Miller, RI, L. Reyes, RII, J. Dyer, RIII, E. Merschoff, RIV, Subject: Request for Working Group Members for National materials Program Pilot Projects

9. National Materials Program Pilot Project 3, Operating Experience Evaluation, Charter, March 2003

10. Nuclear Materials Events Database, Quarterly Reports

11. Memorandum dated January 3, 2003, from William D. Travers, EDO, to Chairman Meserve and Commissioners Dicus, Diaz, McGaffigan, and Merrifield, Subject: Senior Management's Review of the Davis-Besse Lessons Learned Task Force Report

THE RULEMAKING PROCESS

ACMUI Meeting
November 12, 2003

Keith McDaniel
NRC/NMSS/IMNS

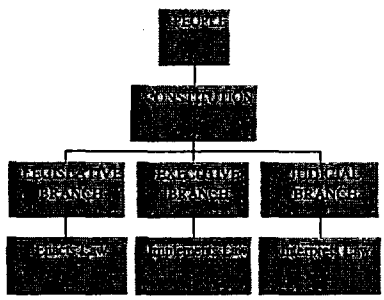
1

Discussion Topics

- NRC's Place in Government
- Rulemaking & Guidance
- Standard Rulemaking Process
- Organization Responsibilities
- Working Group Membership/Responsibilities
- Rulemakers Website
- Reference Documents
- Suggested Courses

2

NRC IN GOVERNMENT



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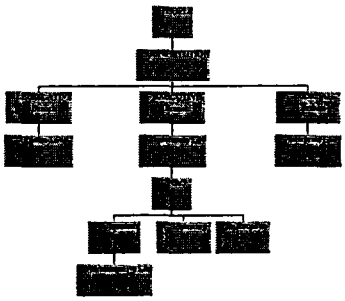
NRC IN GOVERNMENT



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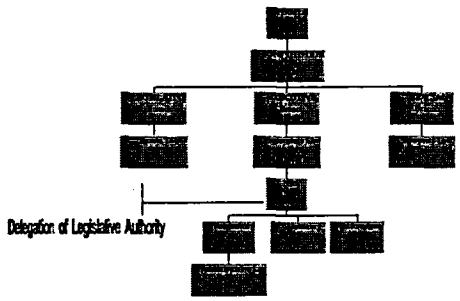
NRC IN GOVERNMENT



5

ACTS

- Delegated Authority
  - Atomic Energy Act, as amended by the Energy Reorganization Act (42 U.S.C. 2201) delegates rulemaking authority to the NRC Commission.
- Procedural Requirements
  - Administrative Procedure Act of 1946 (5 U.S.C. 551-553), as amended, gives the minimum procedural requirements that Federal agencies must follow.

6

Rulemaking & Guidance

- RULEMAKING
  - developing and amending regulations that **licensees** must meet to obtain or retain a license or certificate to use nuclear material or operate a nuclear facility.
- GUIDANCE
  - developing and revising guidance documents, such as regulatory guides, standard review plans, and NRC's Inspection Manual to aid **licensees** in meeting the regulations.

7

Several Types of Rulemaking Processes

- Notice & Comment rulemaking (standard process)
- Enhanced Public Participation rulemaking
- Direct Final rulemaking
- Certificate of Compliance rulemaking

8

Standard Rulemaking Process

- Identified need for rulemaking
- Rulemaking Plan
- Proposed Rule - Public Comment
- Final Rule

9

Need for Rulemaking

- User-need memo from NMSS/NSIR programmatic divisions
- EDO or Commission directive
- Petition for rulemaking (10 CFR 2.802)
- Congressional mandate/Executive Branch order

10

Rulemaking Plan

- What is the regulatory problem?
- Do any legal objection exists - OGC analysis?
- Will the rulemaking be cost-effective?
- Will it be a major rule?
- Are there any Agreement State issues?
- Will we need supporting documents?
- What resources are needed?
- Who makes up the Working Group?

11

Rulemaking Plan

- RGB has the lead and assigns a Task Leader.
- Task Leader forms a Working Group (WG).
- Task Leader/WG prepare a Plan.
- Agreement States review Plan, if needed.
- Plan approved by EDO or Commission.
- About a 30-week process.

12

Rulemaking Plan

References

- Management Directive 6.3, "The Rulemaking Process", Section 04
- Regulations Handbook, NUREG/BR-0053, Section 3.3
- NMSS Policy and Procedures Letter 1-63, Appendix A

13

Proposed Rule

- RGB has overall responsibility.
- Package includes the Federal Register notice and other supporting documents.
- To Advisory committees during Office review.
- Agreement States review, if needed.
- Goes out for public comment.
- Regulatory History is prepared.
- About a 1-year process.

14

Proposed Rule

References

- Regulations Handbook, NUREG/BR-0053, Part 5
- NMSS Policy and Procedures Letter 1-63, Appendix B

15

Final Rule

- RGB has overall responsibility.
- Approved by the Commission or EDO.
- Includes FRN and supporting documents.
- FRN contains responses to public comments.
- Agreement States review, if needed.
- About a 1-year process.

16

Final Rule

References

- Regulations Handbook, NUREG/BR-0053, Part 7
- NMSS Policy and Procedures Letter 1-63, Appendix C

17

Advisory Committees

- Information copies of rulemakings provided to advisory committees.
- Proposed rule forwarded to advisory committees when rule is sent out for office concurrence.
- Committee may request a meeting on a specific rulemaking or staff may recommend review by a committee.
- Committee comments require a response.

18

Organizational Responsibilities

- IMNS/RGB - Overall responsibility for rulemaking for NMSS
- Other Divisions - Responsibility for programmatic and technical input in area of expertise and responsibility
- Other Offices - Coordinate with RGB on any package that discusses or references the need for rulemaking

19

Working Group Membership

- RGB Task Leader
- Member from NMSS/NSIR with programmatic responsibilities related to the rulemaking
- Member from OGC
- Staff from other Divisions and Offices, as appropriate - extent of involvement is typically limited to specific input area

20

Working Group Responsibilities

RGB Task Leader

- Develops schedules, milestones, and resource estimates
- Identifies need for, and obtains contractor support
- Prepares rulemaking documents and addresses comments received during review
- Schedules and prepares briefing for Division Directors and Office Directors
- Estimates information collection burden and prepares OMB clearance package
- Ensures task is on schedule

21

Working Group Responsibilities

WG Members

- Works with RGB Task Leader to prepare rule package, address comments, estimate information collection burden, assist in preparation of briefing materials
- Review contractor reports
- WG Member keeps their management apprised of status and obtains Office/Division position on issues
- Prepare associated guidance, as appropriate, and develop milestones to complement rulemaking schedule

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Rulemakers Website

- Researching and drafting rules, supporting documents, and Federal Register Notices
- Tracking the status of NRC rulemakings and petitions for rulemaking
- Finding the latest guidance on rulemaking policies and procedures
- http://www.internal.nrc.gov/ADM/DAS/cag/RM01/

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Reference Documents

- Code of Federal Regulations, Title 10, Energy
- Regulations Handbook NUREG/BR-0053, Rev. 5
- Management Directive 6.3, The Rulemaking Process
- NMSS Policy and Procedures Letter 1-63

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Suggested Courses

- Rulemaking 101
  - NRC staff
- The Regulatory Drafting & Process Course
- The Advanced Regulation Drafting Course
- The Regulatory Process
  - The Regulatory Group, Inc. - www.reg-group.com

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Things to Remember

- Regulations are Administrative Laws.
- Regulations & Guidance are for applicants and licensees to use nuclear materials.
- RGB has lead for NMSS rulemaking.
- Rulemaking is a 4-step process.
- Rulemaking is a marathon, not a sprint.
- NRC Rulemaker website is a good resource.

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LIST OF ACRONYMS

- CFR - Code of Federal Regulations
- EDO - Executive Director for Operations
- FRN - Federal Register notice
- IMNS - Division of Industrial and Medical Nuclear Safety
- NMSS - Office of Nuclear Material Safety and Safeguards-

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LIST OF ACRONYMS

- NSIR - Office of Nuclear Security and Incident Response
- OGC - Office of the General Counsel
- OMB - Office of Management and Budget
- RGB - Rulemaking and Guidance Branch
- WG - Working Group

September 4, 2001

MEMORANDUM TO: Director and Deputy Director, IMNS
Director and Deputy Director, FCSS
Director and Deputy Director, DWM
Director and Deputy Director, SFPO
Branch Chiefs, IMNS, FCSS, DWM, and SFPO

FROM: Martin J. Virgilio, Director
Office of Nuclear Material Safety /RA/
and Safeguards

SUBJECT: NMSS POLICY AND PROCEDURES LETTER 1-63, PROCEDURES FOR PREPARATION AND REVIEW OF RULEMAKING PACKAGES, REVISION 1

Policy and Procedures Letter 1-63, Revision 1 (attached) provides the Office of Nuclear Material Safety and Safeguards (NMSS) procedures for preparation and review of rulemaking packages. The revision incorporates changes to the rulemaking process and provides additional detail for some of the steps.

The attached procedure was previously issued in draft for comment in a memorandum dated May 7, 2001, from Patricia K. Holahan to NMSS Division Directors and to other NRC offices. Comments received regarding the draft were reviewed and incorporated into the procedure as appropriate.

All addresses should review the attached procedures to familiarize themselves with the procedures and disseminate the information to the staff, as appropriate. The procedure is to be implemented immediately, and will remain in effect until further notice.

Attachment: NMSS Policy And Procedure Letter 1-63, Revision 1

cc w/encl.: H. T. Bell, OIG
J. Larkins, ACRS & ACNW
H. Miller, Region I/ORA
L. Reyes, Region II/ORA
J. Dyer, Region III/ORA
E. Merschoff, Region IV/ORA
C. Trottier, RES
M. Federline, NMSS
W. Beecher, OPA
J. Murphy, CRGR
J. Funches, CFO
C. Carpenter, NRR
B. Shelton, OCIO
S. Treby, OGC
F. Congel, OE
M. Lesar, ADM
P. Lohaus, OSTP

CONTACT: Merri Horn, NMSS/IMNS
(301) 415-8126

September 14, 2001

MEMORANDUM TO: Director and Deputy Director, IMNS
Director and Deputy Director, FCSS
Director and Deputy Director, DWM
Director and Deputy Director, SFPO
Branch Chiefs, IMNS, FCSS, DWM, and SFPO

FROM: Martin J. Virgilio, Director */RA/*
Office of Nuclear Material Safety
and Safeguards

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F. Congel, OE
M. Lesar, ADM
P. Lohaus, OSTP

Distribution:Ticket IMNS 7950
RGordon r/f
RGB staff

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ADDRESSEES

Donald A. Cool, Director, IMNS
Susan M. Frant, Dep. Dir., IMNS
Patricia K. Holahan, Chief, RGB
John W. Hickey, Chief, MSIB

John T. Greeves, Director, DWM
Josephine M. Piccone, Dep. Dir., DWM
Thomas H. Essig, Chief, EPAB
Larry W. Camper, Chief, DCB
William C. Reamer, DWM

Michael F. Weber, Director, FCSS
Robert C. Pierson, Dep. Dir., FCSS
Catherine Haney, Chief, SSSB
Melvyn Leach, Chief, FCLB
Eric J. Leeds, Chief, SPB

E. William Brach, Director, SFPO
Wayne M. Hodges, Dep. Dir., Technical Review Directorate
Charles L. Miller, Dep. Dir., Licensing & Inspection Directorate

NMSS PROCEDURES FOR PREPARATION AND REVIEW OF RULEMAKING PACKAGES

CONTENTS

ACRONYMS

ACMUI	Advisory Committee on Medical Use of Isotopes
ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee on Reactor Safeguards
ADM	Office of Administration
ANPR	Advance Notice of Proposed Rulemaking
CRGR	Committee to Review Generic Requirements
EA	Environmental Assessment
EDO	Executive Director for Operations
EIS	Environmental Impact Statement
FRN	Federal Register Notice
IMNS	Division of Industrial and Medical Nuclear Safety
MD	Management Directive
NMSS	Office of Nuclear Material Safety and Safeguards
NRR	Office of Nuclear Reactor Regulation
OCA	Office of Congressional Affairs
OCFO	Office of the Chief Financial Officer
OCIO	Office of the Chief Information Officer
OE	Office of Enforcement
OFR	Office of the Federal Register
OGC	Office of the General Counsel
OIG	Office of the Inspector General
OMB	Office of Management and Budget
OPA	Office of Public Affairs
OSTP	Office of State and Tribal Programs
PBPM	Planning, Budgeting, Performance Management
PM	Project Manager
PMDA	Program Management, Policy Development and Analysis Staff
PRM	Petition for Rulemaking
RA	Regulatory Analysis
RAP	Rulemaking Activity Plan
RES	Office of Nuclear Regulatory Research
RGB	Rulemaking and Guidance Development Branch
SFPO	Spent Fuel Project Office
SBREFA	Small Business Regulatory Enforcement Fairness Act
SRM	Staff Requirements Memorandum
TL	Task Leader
TSSI	Transportation and Storage Safety and Inspection Section
WG	Working Group

NMSS PROCEDURES FOR PREPARATION AND REVIEW OF RULEMAKING PACKAGES

PURPOSE:

It is the policy of the NRC to develop quality rules that are consistent with the requirements of all applicable laws and regulations and to promote increased efficiencies in its rulemaking process. The Office of Nuclear Material Safety and Safeguards (NMSS) is responsible for conducting its rulemaking activities in an orderly and systematic manner and in accordance with Agency policies and procedures, and with due attention to schedules and resources. Rulemaking activities include resolving petitions for rulemaking and developing or participating in the development of rulemaking plans, advance notices of proposed rulemaking, proposed rules, final rules, Paperwork Reduction Act submissions, and regulatory histories, as appropriate. Within NMSS, the Rulemaking and Guidance Branch (RGB) within the Division of Industrial and Medical Nuclear Safety (IMNS) has the primary responsibility for rulemaking activities.

This letter establishes more detailed procedures for initiating, conducting, and managing rulemakings. The procedures in this letter define the role and responsibilities of the NMSS headquarters divisions in initiating rulemaking activities, developing rulemaking packages, and in subsequent review and approval of the packages. This letter also includes procedures for obtaining input, review, and concurrence by other NRC offices and the regions, as appropriate. The Appendices to this letter contain descriptions and explanation of the steps in the rulemaking process to provide additional guidance for each major rulemaking activity (i.e., rulemaking plan, proposed rule, final rule, direct final rule, and petitions). The procedures in this letter were based on Management Directive (MD) 6.3, "The Rulemaking Process,"[1] and on NUREG/BR-0053, "The NRC Regulations Handbook."[2]

NEED FOR RULEMAKING:

A request for a rulemaking action is generally made in one of the following ways.

1. Petition for rulemaking.

   A request for a rulemaking action may come from submittal of a petition for rulemaking from an interested person under 10 CFR 2.802 (e.g., an individual, a private organization or company, an NRC licensee, a government agency, etc.). Procedures for handling a petition for rulemaking are described in Part 11 of the Regulations Handbook. RGB is responsible for handling petitions related to NMSS areas of responsibility.

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[1]Management Directive 6.3, "The Rulemaking Process," Revised June 2, 2000.

[2]NUREG/BR-0053, "Regulations Handbook," Revision 5, March 2001.

2. Congressional mandate/Executive Branch order.

   Rulemaking may be initiated in response to Congressional promulgation of a new statute requiring new regulatory requirements.

3. EDO or Commission directive.

   A rulemaking action may be initiated as directed by either the EDO or by the Commission, as for example, in a Staff Requirements Memorandum (SRM).

4. User-need memo from an NMSS programmatic division.

   The need for a rulemaking action may be indicated by a user-need memo from the director of an NMSS programmatic division to the IMNS Division Director. The NMSS programmatic division should obtain office level approval of the need for rulemaking and discuss the proposed action with IMNS prior to sending the user-need memo. The user need memo should indicate the priority for the rulemaking in light of the NMSS performance goals and should also provide sufficient technical basis for the rulemaking. If the technical basis is not developed, the programmatic division should send a user-need memo to the Office of Nuclear Regulatory Research (RES) requesting them to develop the technical basis.

5. User-need memo from another Office or the Regions

   The need for a rulemaking action may be indicated by a user-need memo from another office or from the Regions to the NMSS Office Director. The user need memo should indicate the priority for the rulemaking and should also provide sufficient technical basis for the rulemaking.

Once a request for a rulemaking is received, the rulemaking is prioritized in accordance with the planning, budgeting, performance management (PBPM) process to identify which, if any, actions need to be shed or deferred. The rulemaking process generally consists of preparation of a rulemaking plan and, if the plan is approved, preparation and issuance of proposed and final rules.

RESPONSIBILITIES:

General organizational responsibilities in the rulemaking process for the various NRC offices are described in MD 6.3, Section 03. RGB has the overall responsibility for preparation of rulemaking plans and proposed and final rule packages for NMSS programmatic areas. This includes developing and preparing the rulemaking plan and the rulemaking packages (proposed/final rule, OMB clearance package, petition denials, etc.) needed for each step of the rulemaking process, coordinating input from other divisions and offices, obtaining necessary concurrences, and maintaining schedules. RGB ensures that all rulemaking activities are budgeted and prioritized, and included in the Rulemaking Activity Plan (RAP). RGB tracks all rulemaking activities in the Operating Plan for the nuclear materials safety arena. Programmatic divisions are responsible for the preparation of any guidance documents

necessary to support the rule. Programmatic divisions and branches are also responsible for coordinating with RGB anytime a document is in preparation which discusses or references the need for rulemaking.

Other divisions in NMSS and other NRC offices have responsibility for programmatic and technical input in their respective areas of expertise and responsibility, and for review and concurrence in the rule packages, as appropriate. These responsibilities are described in MD 6.3, Sections 032 - 0315 and include providing key staff to assist in developing rulemaking documents as well as an office representative to coordinate rulemaking actions and to provide office concurrence.

To aid in carrying out the responsibilities noted above, a working group (WG) is typically established early in the rulemaking process. Use of a WG approach should make the preparation of rulemaking plans and packages, including the process of obtaining concurrences, more efficient. WG members will assess the tasks needed to prepare the necessary rulemaking documents and the specific WG members who should undertake those tasks, appropriate to their programmatic responsibilities and expertise. Based on that assessment, the NMSS divisions and other offices are responsible for providing necessary resources for the WG members to carry out their functions. For the WG to be most useful, it should be made up of members as follows:

1. a Task Leader from RGB;

2. a WG member from the NMSS branch with programmatic responsibilities related to the rulemaking;

3. a WG member from the Office of the General Counsel (OGC); and

4. staff from other divisions and offices, as appropriate. Where the input of a division or office to the rule packages is very specific (e.g., input on matters of regulatory flexibility, information collection, Agreement State compatibility, or enforcement), a WG member may be named, but the extent of involvement in preparation of rulemaking documents and the attendance at WG meetings can be limited to the specific input area, thus limiting the level of resources needed.

For some rulemakings, a Steering Group may be used. The Steering Group provides direction and guidance to the WG and facilitates the concurrence process. The Steering Group meets periodically and is briefed on the status of activities. A Steering Group would be used primarily for controversial rulemakings for which the implementation would cut across several divisions or offices. The Steering Group should be made up as follows:

1. IMNS Division Director or designee;

2. NMSS Programmatic Division Director or designee;

3. Assistant General Counsel for Rulemaking and Fuel Cycle; and

4. Senior management representatives from other offices, as appropriate.

Responsibilities for preparing rulemaking activities are as follows:

RGB Management

RGB has overall responsibility for preparing the rule packages and for coordinating input from other divisions and offices. RGB also has responsibility for tracking rulemaking actions to ensure that these actions are on schedule. RGB management is responsible for:

1. Assigning a task leader from RGB to the WG.
2. Arranging for representation of appropriate internal stakeholder organizations in the WG.
3. Determining the priority of the rulemaking using the PBPM process.
4. Ensuring that the rulemaking action is on schedule.
5. Notifying IMNS Division Director about potential problems that would cause a slip in the schedule.
6. Ensuring that all rulemaking activities are tracked in operating plans.
7. Scheduling monthly meetings with IMNS management and programmatic division management to review status of rulemakings.

NMSS Programmatic Branch Management

NMSS programmatic branch management is responsible for:

1. Ensuring that the rulemaking action is technically sound and can be implemented.
2. Identifying needed guidance for implementation.
3. Meeting due dates for input.

IMNS Division Management

IMNS division management is responsible for:

1. Notifying the NMSS Office Director about potential problems that would cause slippage in the schedule.

NMSS Programmatic Division Management

NMSS programmatic divisions are responsible for:

1. Obtaining NMSS Office Director approval for the user-need memo.

2. Assigning a staff member to the WG to work on the rule package with the RGB Task Leader (TL). In order for the WG to function effectively, assigned staff should be allotted sufficient time to carry out their functions on the WG.

3. Ensuring that the rulemaking action is consistent with the division goal and mission.

4. Providing key staff to develop necessary guidance concurrently with the rule package. The Programmatic Division is responsible for developing any guidance documents.

NMSS Office Management

NMSS office management is responsible for:

1. Ensuring that the rulemaking action is consistent with NRC policy.

Other Offices

Other headquarters offices, regional offices, and advisory committees are responsible for:

1. Reviewing the rule package in accordance with their responsibilities. Specific responsibilities of the Office of the General Counsel (OGC), the Office of the Inspector General (OIG), the Office of Administration (ADM), the Office of State and Tribal Programs (STP), and the Advisory Committee on Reactor Safeguards (ACRS), the Advisory Committee on Nuclear Waste (ACNW), the Committee to Review Generic Requirements (CRGR), and the Advisory Committee on the Medical Use of Isotopes (ACMUI) are listed in MD 6.3, Sections 036, 035, 0310, 0312, and 0313, respectively.

   Responsibilities of offices that concur in the rulemaking package are listed in MD 6.3, Section 0314. A summary of those responsibilities is as follows:

   OGC - legal sufficiency and consistency with current rules and agency policy.

   STP - consistency with NRC policy regarding Agreement State compatibility and technical content in areas of STP expertise.

   OCIO - ensuring that impacts related to information technology and information management implications have been properly addressed, including whether there are information collection requirements that will require submittal of a package to the OMB.

   ADM - ensuring that implications related to regulatory flexibility and small businesses are addressed and that the Federal Register notices meet the requirements of the Office of the Federal Register.

OE - ensuring that the rulemaking plan is consistent with, or will require modification of, the enforcement policy.

OCFO - ensuring that resource impacts have been properly addressed.

NRR - consistency and technical content in areas where NRR would be affected.

RES - development and consistency of implementation of the technical basis in areas where the technical basis is provided by RES.

Regions - ensuring that the requirements in the rulemaking are sufficient to allow clear licensing and inspection activities.

Advisory Committees - review and provide comment on the rule packages, as appropriate.

Committee to Review Generic Requirements - review and provide comment on the rule packages, at the recommendation of the Director, NMSS or at the EDO's request.

2. Providing key staff to participate in the WG to assist in the development of the rule package. In order for the WG to function effectively, assigned staff should be allotted sufficient time to carry out their functions on the WG.

3. Responding to the lead office within 20 calendar days of the office concurrence memo with questions or concerns regarding technical analysis of information or data which may invalidate or raise doubts about the rule proposal.

4. Reviewing rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of agency policy.

RGB Task Leader

The responsibilities of the RGB Task Leader include:

1. Explaining the expectations for the WG to the WG members. The RGB TL can use Attachment 1 as a tool to explain the expectations for participation in the WG. A copy of Attachment 1 should also be provided to the WG member's management.

2. Obtaining the rulemaking number from ADM and the TAC number from PMDA.

3. Developing the schedule for preparing the rulemaking plan. Assessing the scope of the rulemaking action, identifying the tasks necessary to complete the rulemaking action, identifying the WG member who will be responsible for completing these tasks, and developing schedules and resource estimates for preparing the proposed and final rule packages.

In estimating the time needed to prepare the rule package, consideration should be given to such factors as whether contractor effort is needed, the extent of enhanced public participation, whether Agreement State coordination is necessary, whether advisory committee or CRGR review is necessary, whether an environmental assessment (EA) or environmental impact statement (EIS) will be prepared, etc. Consideration should also be given to other assigned programmatic and office responsibilities of the WG members. In addition, if associated guidance (including licensing, inspection, and enforcement guidance) is to be prepared along with the rule, consideration should be given to the time needed to prepare the guidance so that final guidance will be available at the time the rule is implemented.

4. If associated guidance (i.e., regulatory guides, inspection guidance, etc.) is to be prepared with the rule, the RGB Task Leader assists WG members, as appropriate, in preparing the guidance.

5. Identifying the need for contractor support where IMNS has lead contract responsibility. Monitoring resulting task orders and reviewing contractor reports. If another division or office has lead contract responsibility, the RGB Task Leader provides review of contractor reports.

6. In coordination with the STP WG member, developing the compatibility level(s) of the rule.

7. Preparing, along with WG members, the rule package and addressing comments received during review of the rule package.

8. Scheduling, preparing, and delivering briefings, as necessary, for Steering Groups, Division Directors, and Office Directors to discuss the rulemaking package.

9. Estimating the information collection burden and sending it to the Office of the Chief Information Officer (OCIO) for review, and, when needed, developing the OMB clearance package (supporting statement and Federal Register notice) in coordination with OCIO.

10. Documenting the risk screening and the high level performance guidelines in the rulemaking package.

11. Ensuring that the task is on schedule, and notifying the RGB Section Leader or Branch Chief about potential problems that could cause a slip in the schedule.

12. Monitoring the progress of the rule package as it goes to NMSS or the EDO.

13. Updating the RGB rule status chart on a biweekly basis with the current status of the rulemaking action.

14. Preparing the RAP and Regulatory Agenda input.

15. Placing and maintaining all rule documents on the 'O' drive.

16. Preparing material for public meetings.

17. Preparing information for posting on the website (if a unique site is being used).

18. Preparing the Regulatory History.

19. Preparing an item of interest when a rule is published in the Federal Register.

WG Members

Responsibilities of WG members from other divisions or offices are as follows:

1. Working with the RGB Task Leader to assess the tasks needed to prepare the rule package, address comments, estimate information collection burden, assist in preparing briefing materials, and complete rule package.

2. Keeping branch managers apprised of the rulemaking action and obtaining comments and input on policy decisions from branch managers. Notifing branch managers of potential problems or policy issues.

3. Ensuring that management opinion is understood and presented to the WG.

4. Reviewing contractor reports (where IMNS has lead contractor responsibility) or monitoring contractor efforts (where WG member's division or office has lead contractor responsibility).

5. Preparing associated guidance (including licensing, inspection, and enforcement guidance), as appropriate, and developing milestones for its preparation so that final guidance will be available at the time the rule is implemented. The NMSS Programmatic Division has the lead for preparing guidance documents.

6. Facilitating the rulemaking concurrence process by keeping their management informed of significant issues of concern and assisting in developing an appropriate resolution of those issues.

7. Supporting any public meetings.

Steering Group

Responsibilities of the Steering Group are as follows:

1. Providing guidance and direction to the WG.

2. Mediating major issue resolutions.

3. Resolving significant questions of policy.

4. Facilitating office concurrence.

5. Keeping office management apprised of policy issues, schedules, and status of activities.

RULEMAKING PROCESS:

Once a request for a rule is received, a plan for the rulemaking is developed. A rulemaking plan may not be necessary in certain situations, in particular if the Commission specifically directs the initiation of a rulemaking action, if the rule is purely administrative, if there is sufficient urgency to proceed to preparation of a rule package, or if the issue is addressed through issuance of a direct final rule. See MD 6.3, Paragraph 042 and Section 1.5e of the Regulations Handbook. Such a determination would be made based on discussion between RGB and the NMSS programmatic division. In determining the schedule for the rulemaking, the staff should consider the PBPM priority based upon NRC performance goals.

Procedures for developing rulemaking plans, including the contents of the plans, are described in MD 6.3, Section 04, and Part 3, Section 3.3 of the Regulations Handbook. Specific steps for preparing rulemaking plans are described in Appendix A of this letter.

Another tool the NRC can use is the Advance Notice of Proposed Rulemaking (ANPR) or an issues paper. An ANPR or an issues paper are typically used when the NRC does not have adequate information to make a decision to go forward with a rulemaking. In an ANPR or issues paper, the NRC seeks information from the public that is then used to make the decision on whether to go forward with a rulemaking and/or the content of the rulemaking. The ANPR process is more formal than use of an issues paper. Part 11 of the Regulations Handbook contains additional information on the ANPR process. The office review and concurrence process is the same as for a proposed rule.

Generally, the rulemaking process consists of development of a rulemaking plan followed by issuance of a proposed rule for public comment and, following the public comment period, issuance of a final rule. In certain situations NRC may issue what is referred to as a "direct final rule". A description of those situations, including the procedures for issuing a direct final rule, is contained in Part 9 of the Regulations Handbook. Specific steps for preparing a proposed rule package, a final rule package and a direct final rule package are described in Appendices B, C, and D of this letter, respectively. Specific steps for preparing Part 72 Certificate of Compliance rulemakings are described in Appendix E.

The content of a rule package generally includes a Commission paper, Federal Register notice, and Congressional letters, as well as supporting documents, as appropriate, such as a regulatory analysis, a backfit analysis, an EA or EIS, and a package on information collection requirements for submittal to the Office of Management and Budget (OMB). Information on the

procedures for preparing these documents, including their contents, is contained in the following:

1. The Regulations Handbook, which contains information on procedures for, and content of, all of the components of the rule package, including the Federal Register notice, regulatory analysis, Congressional letters, and EA and EIS;

2. NUREG/BR-0058[3], which contains guidelines on preparation of regulatory analyses;

3. 10 CFR Part 51, which contains requirements regarding preparation of an EA and EIS, including determining when an EA or EIS is needed (Parts 51.20 - 51.22), the EIS process (Parts 51.26 - 51.29 and 51.85 - 51.88), and the contents of an EA or EIS (Parts 51.30 - 51.31 and Appendix A of 10 CFR 51);

4. Management Directive 5.9[4] which contains information on Agreement State compatibility issues.

5. Management Directive 3.54[5] which contains guidance on preparing OMB clearance packages.

All Commission Papers and EDO transmittal memorandums that provide a rulemaking plan, proposed or final rule, or petition for rulemaking denial should include a discussion of how the action meets the NMSS performance goals. The NMSS goals are:

1. Maintain safety, protection of the environment, and the common defense and security.

2. Increase public confidence.

3. Make the NRC activities and decisions more effective, efficient, and realistic.

4. Reduce unnecessary regulatory burden on stakeholders.

Additional information on the goals can be found in the Strategic Plan[6].

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[3] NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev 3, July 2000.

[4]Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," February 27, 1998.

[5]Draft Management Directive 3.54, "Collection of Information and Reports Management,"

[6]NUREG-1614, Vol. 2, "U. S. Nuclear Regulatory Commission Strategic Plan," September 2000.

After a decision has been made to release the rulemaking documents, the documents are placed on the rulemaking webpage: http://ruleforum.llnl.gov. The documents are provided to ADM, which then places them on the web page. For some of the larger rulemakings, IMNS may decide to develop a webpage specific to that rulemaking. The IMNS webpage would provide links to documents related to the rulemaking such as a Commission Paper or Issues Paper. Rulemaking documents should be provided to ADM to put on the webpage within 15 days of being made publicly available. The OCIO places proposed and final rules with the associated clearance packages on the website, http://www.nrc.gov/NRC/PUBLIC/OMB/index.html.

Additional stakeholder participation opportunities may be provided for some rulemakings. The need for additional opportunities should be discussed by the WG and RGB management. These can consist of requests for public comment through the Federal Register or through a website or listserver dedicated to the rulemaking. The staff may hold workshops or meetings to obtain public input on a regulatory issue or an area of the regulations that may be a candidate for rulemaking. The staff may solicit input on an issue or on proposed rule language. Input may be sought in developing a rulemaking plan, the proposed rule, or even the final rule.

Advisory Committee Review:

Information copies of all rulemakings are provided to the advisory committees. On occasion, an advisory committee will request a meeting on a specific rulemaking or the staff will recommend review by an advisory committee. This may be on a rulemaking plan or a proposed or final rule. RGB will brief the appropriate advisory committee on the rationale for the rulemaking. Any consensus comments or recommendations that are received from an advisory committee concerning a rulemaking action must receive a response. The response can be in the form of a letter from the EDO or in the Supplementary Information section of a proposed or final rule, as appropriate. If a rulemaking needs to be reviewed by an advisory committee, additional time should be provided in the schedule if possible. The committees typically require about 60 days for committee review before the date by which comments are desired.

CRGR Review:

CRGR will review rulemakings at the recommendation of the Director, NMSS, or at the EDO's request. Rulemakings that require a backfit analysis are potential candidates for CRGR review. Any recommendations that are received from CRGR concerning a rulemaking action must receive a response. The Director, NMSS must submit a close-out memorandum to the CRGR Chairman, describing whether the CRGR recommendations were accepted, and in case of a disagreement, the close-out memorandum will be submitted to the EDO for resolution. If a rulemaking requires CRGR review, additional time should be provided in the schedule. A review request and the rulemaking package must be submitted 2 weeks before the anticipated review date; meeting summaries are issued final within 2 weeks of the review meeting.

ADAMS:

The current NMSS/IMNS procedure for ADAMS requires the document originator (the RGB Task Leader) to fill out NRC Form 665 and provide it, along with the relevant documents, to the document submitter. The submitter will enter the documents into ADAMS, filling out the

minimal profile information, and provide the document to the Document Processing Center (DPC). The profile information should include the RIN number and any ticket numbers. The DPC will then complete the ADAMS profile and declare the document an Official Agency Record. For rule packages being issued for office concurrence, the submitter will enter the documents into ADAMS after the office concurrence memo is signed (within 5 days). Any rule package that requires Commission concurrence or signature (the version after office concurrence) is entered into ADAMS by the submitter prior to the package going to IMNS for concurrence. SECY will complete the profiles and declare the documents as official agency records. Any rule package that requires EDO concurrence or signature (the version after office concurrence) is entered into ADAMS by the submitter prior to going to IMNS for concurrence. the EDO's office will send an e-mail to NMSS indicating concurrence with the document in ADAMS. The submitter will then provide the documents to DPC. The DPC will then complete the profile and declare the document an Official Agency Record. The ADAMS procedure could change in the future; the **RGB Task Leader** should follow the IMNS (or NMSS) procedure that is in place at the time the package is assembled. Table 1 contains a listing of the appropriate ADAMS templates to be used for profiling the various rulemaking related documents. Any reference to a document being publicly available through ADAMS must provide the ADAMS accession number.

REGULATORY HISTORY:

The regulatory history procedures apply to each proposed or final rule submitted for publication in the Federal Register. The regulatory history is necessary to ensure that all documents of central relevance to a rulemaking proceeding are identified and accessible. The Task Leader is responsible for preparing the regulatory history within 60 days of the publication of the proposed rule and the final rule. Guidance is provided in the Regulations Handbook and in the Regulatory History Procedures. There is no need to include markups as part of the regulatory history, unless the comments are considered to be substantive. ADM and OGC will include any substantive comments that need to be included in the regulatory history in a cover memo. The memo will be made part of the regulatory history, however, there is no need to include the editorial markups. E-mail concurrences, including the properties, should be placed in ADAMS and made a part of the regulatory history.

REGULATORY AGENDA:

ADM maintains the Regulatory Agenda which contains descriptions of and schedules for NRC's regulatory activities. It is updated quarterly. The Task Leader provides Regulatory Agenda input to RGB and ADM as requested. The input is usually provided to ADM through the RGB Technical Assistant.

RULEMAKING PROCESS FLOW CHARTS AND TIMELINES:

Figures 1 through 3 show simplified flow charts for the rulemaking process. Detailed schedules are provided in each Appendix.

WEBSITES:

There are several websites that may be beneficial to those involved in rulemaking activities. The primary website is: http://ruleforum.llnl.gov. This site is maintained by ADM. ADM posts all of the Federal Register notices related to rulemaking on this site. ADM also posts the environmental assessments and regulatory analysis documents. In addition, the OCIO places proposed and final rules with the associated clearance packages on the website, http://www.nrc.gov/NRC/PUBLIC/OMB/index.html.

The technical conference website is used to post documents for Agreement State review, such as rulemaking plans and preliminary versions of a proposed rule. The Agreement States may upload their comments directly to the site. ADM coordinates the posting of any documents to this website. The address is: http://techconf.llnl.gov.States/. It is necessary to have a password to access this site.

STP has posted its procedures "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements - SA - 200" on its website. This document is useful for determining the compatibility category for various rule sections. The address is: http://www.HSRD.ORNL.GOV/nrc/procedures/sa200.pdf.

There are several sites available that are useful for searching the Federal Register. Among these sites are: http://www.gpo.ucop.edu/search/fedfld.html; and http://www.access.gpo.gov/su_docs/aces/aces140.html. For searching the contents of or obtaining the effective rule text for the Code of Federal Regulations, the following website is useful: http://www.access.gpo.gov/ecfr. The site (http://www.access.gpo.gov) provides a useful link to the Federal Register, Code of Federal Regulations, Congressional Record, and public laws among other resources. A website that can be used to search the Congressional Record, committee information, legislation, etc is: http://thomas.loc.gov.

In addition to these sites, IMNS may establish a webpage for a specific rulemaking activity. Information on meetings, issue papers, proposed rule text, and links to other documents such as SECY papers are generally provided. The need for a rule-specific webpage is decided on a case-by-case basis.

Attachment 1

WORKING GROUP MEMBER RESPONSIBILITIES

Responsibilities of WG members from other divisions or offices are as follows:

Provide technical input to rule
- Statement of Considerations
- Rule language
- Estimate of information collection burden
- Response to comments
- Monitor/review contractor effort

Keep management apprised of rulemaking
- Notify management of potential problems or policy issues
- Obtain management comments on rule package
- Obtain management input on policy decisions at early stage
- Obtain management concurrence on rulemaking

Support management briefings and any public meetings

Prepare associated guidance
- Make sure final guidance available at the time the rule is implemented (licensing, inspection, enforcement)

General Operating Standards
- Attend WG meetings
- Come prepared to discuss issues
- Provide input on time
- Stay focused to task
- Clearly state your organization's positions/concerns

Table 1 ADAMS TEMPLATES FOR RULE DOCUMENTS

TYPE OF DOCUMENT	TEMPLATE	SPECIAL INSTRUCTIONS
Commission Paper	SECY-012	
EDO Transmittal Memo	NMSS-009	
Office Concurrence Memo	NMSS-010	
Federal Register Notice - Final Rule	ADM-015	
Federal Register - Proposed Rule	ADM-016	
Federal Register - ANPR	ADM-017	
Federal Register Notice - Petition Denial	ADM-018	
Federal Register Notice - Policy Statement	ADM-014	
Federal Register Notice - General	ADM-012	
Rulemaking Plan	ADM-020	
Regulatory Analysis	ADM-031	
Environmental Assessment	ADM-033	
EIS	ADM-032	
Letter to State Liaison Officer	STP-001	
Authority Statement for EDO's Signature	ADM-030	
Notice of Final Rule Signed by EDO	ADM-033	
Notice of Petition Denial Signed by EDO	ADM-033	
Weekly Report to the Commission	ADM-034	
Congressional Letters	OCA-001	
NUREG Document	OCIO-032	

TYPE OF DOCUMENT	TEMPLATE	SPECIAL INSTRUCTIONS
OMB Supporting Statement	OCIO-004	
SBREFA Forms	OCA-001	
Letter to Petitioner	SECY-005 (if signed by SECY) EDO-002 (if signed by EDO) NMSS-010 (if signed by NMSS or IMNS)	
SRMs	SECY-013	
Rulemaking Comments - External	SECY-067	

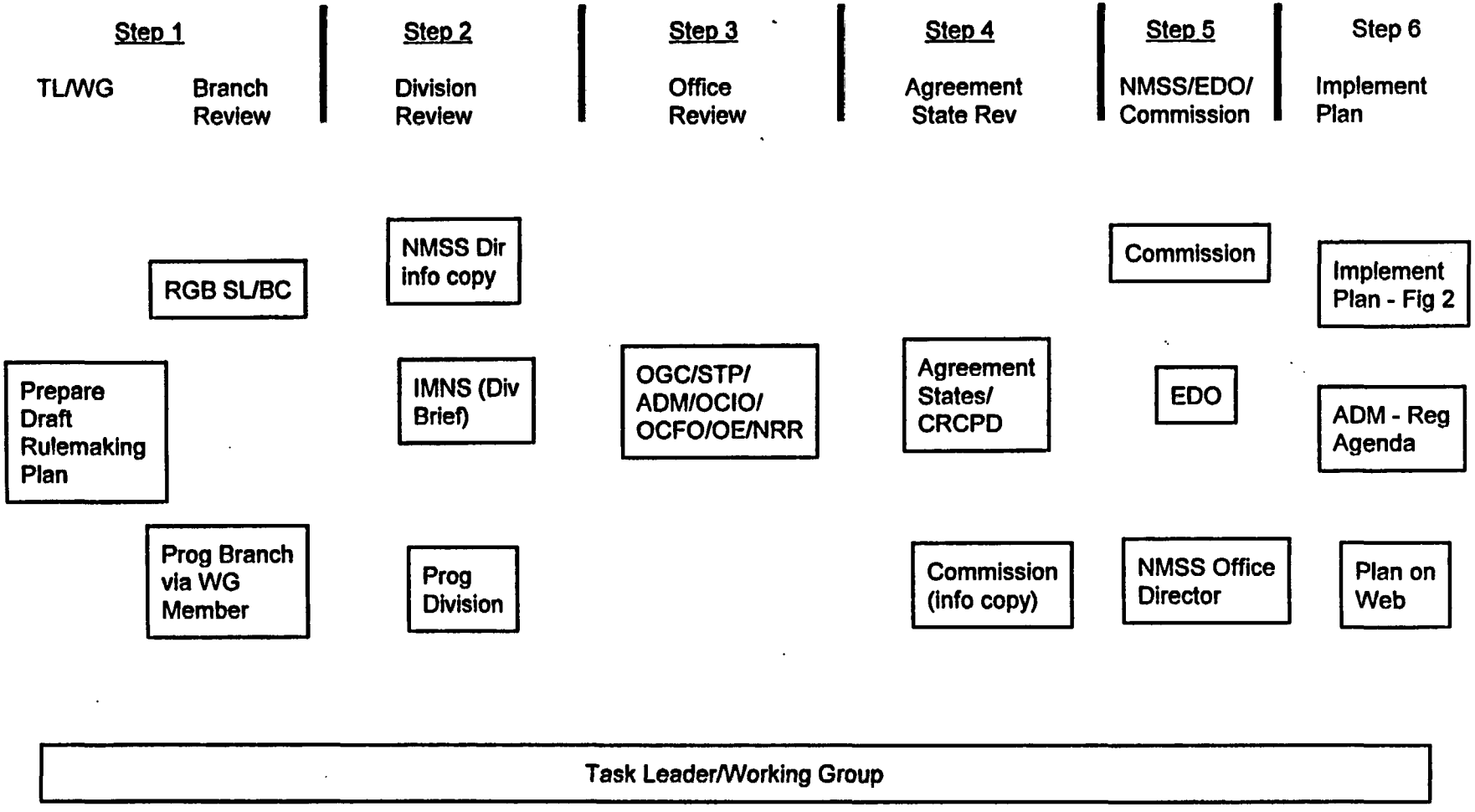


Figure 1 - Procedures for Rulemaking Plans

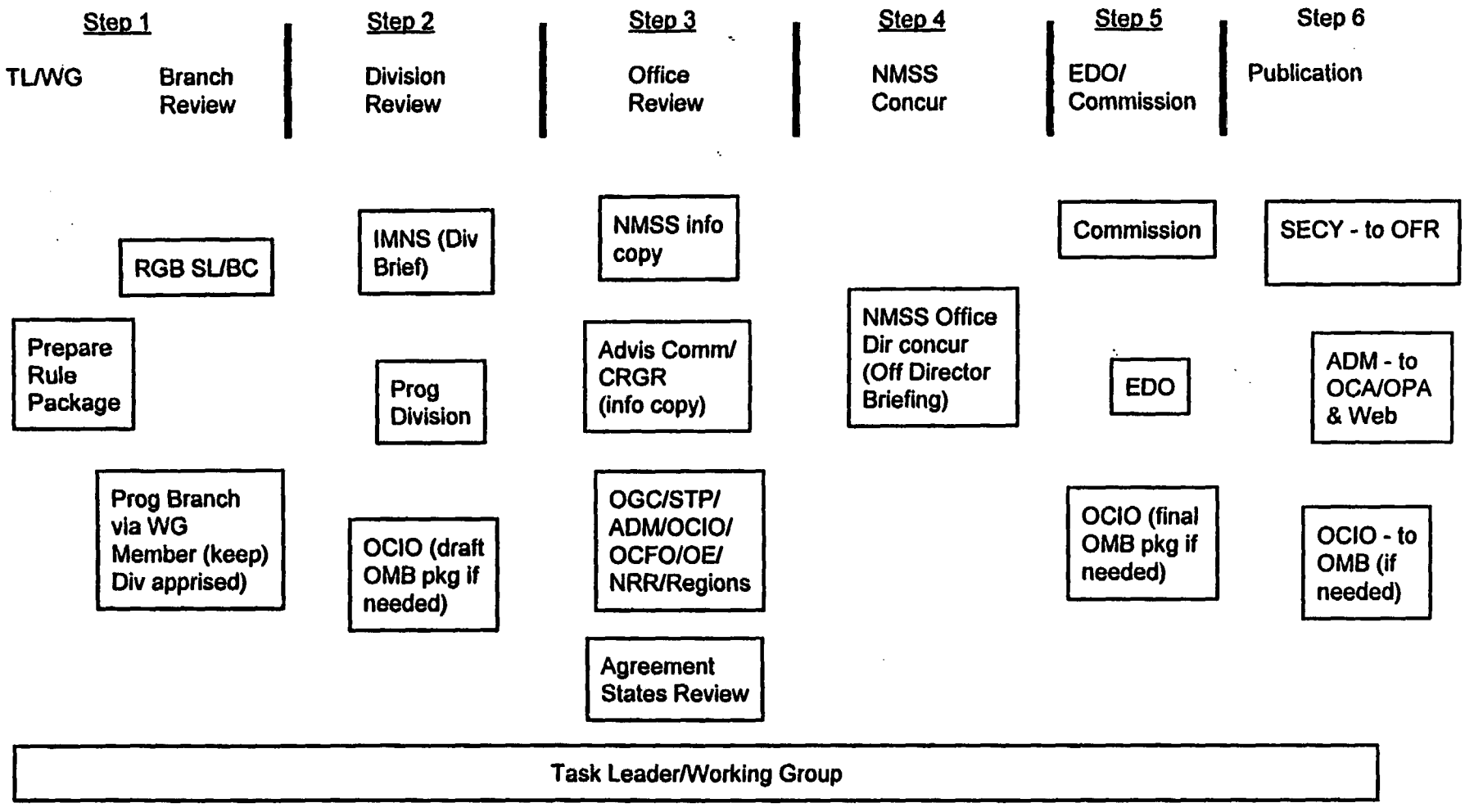


Figure 2 - Procedures for Rule Packages

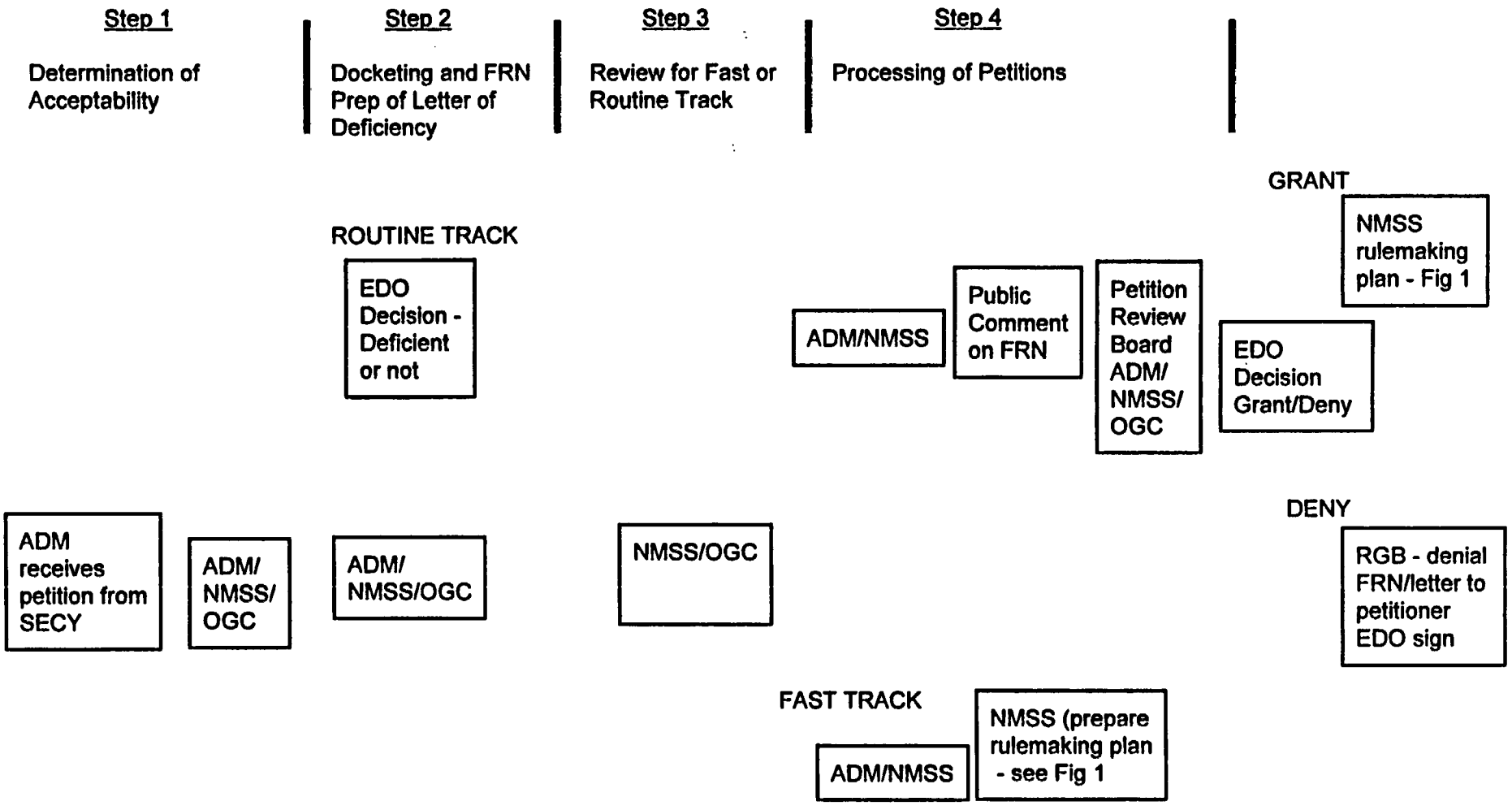


Figure 3 - Procedures for Petitions

APPENDICES

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF RULEMAKING PACKAGES

As discussed in NMSS Policy and Procedures Letter 1-63, rulemaking generally takes place in response to an event or directive that indicates a need for further regulation (e.g., a petition for rulemaking from an interested person). In response to the indicated need, the rulemaking process consists of preparation of rulemaking plans, and preparation and issuance of proposed and final rules. NMSS Policy and Procedures Letter 1-63 contains an outline of overall responsibilities for preparing and reviewing rulemaking plans and proposed and final rule packages.

The Appendices contain descriptions and explanation of the steps in the rulemaking process to give further guidance as to how the responsibilities listed in NMSS Policy and Procedures Letter 1-63 will be carried out as the rulemaking process unfolds. It also describes the need for preparation of certain documents at each step, for example the OMB package, and the rationale for those needs. Appendix A covers the rulemaking plan, Appendix B covers a proposed rule, Appendix C covers a final rule, Appendix D covers a direct final rule, Appendix E covers Certificate of Compliance (CoC) Rulemakings, and Appendix F covers petitions for rulemakings. The specific actions listed under each of the steps in the Appendices are based on Management Directive 6.3 and on the Regulations Handbook. RGB also maintains template documents in the 'O' drive (under the folder "RGB Template Documents" and in a notebook on top of the RGB file cabinets outside T9F55.

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF RULEMAKING PLAN PACKAGES

PREPARATION OF RULEMAKING PLANS

RGB has the overall responsibility for preparation of the rulemaking plan and other NMSS divisions and NRC offices have responsibilities for assisting with preparation of the plan and for review of the plan. The contents of a rulemaking plan are discussed in MD 6.3, Section 04 and in Section 3.3 of the Regulations Handbook.

Attachment 1 contains the schedule template for preparing a rulemaking plan. The discussion below follows the schedule and provides discussion as to what actions need to be taken at each step of the process by the RGB Task Leader, by RGB, IMNS, and NMSS management, and by staff and management in other divisions and offices.

Step 1 - Initiation of Rulemaking

In this step:

a. The **NMSS Programmatic Division** identifies a need for a rulemaking.

b. The **NMSS Programmatic Division** in coordination with IMNS briefs the NMSS Office Director on the need for the rulemaking.

c. Following agreement by the **NMSS Office Director** on the rulemaking concepts, the **NMSS programmatic division** sends a user-need memo to the IMNS Division Director. The user-need memo should indicate the priority in light of the NMSS performance goals and should provide the technical basis for the rulemaking.

d. Rulemakings may also be initiated by a petition for rulemaking (see Appendix F), EDO or Commission directive, Congressional mandate, or Executive Order.

Step 2 - Preparation of Draft Rulemaking Plan

In this step:

a. After receipt of a request for rulemaking action, **RGB management** assigns a RGB Task Leader. Consulting with the appropriate NMSS programmatic division and other offices, staff members from other NMSS divisions and offices are selected as members of a WG.

b. **RGB Task Leader** contacts ADM for a rulemaking number and contacts the PMDA Program Analyst for a TAC number (and RITS code if not yet established).

c. **RGB Management** prioritizes the rulemaking in accordance with the PBPM process.

d. The **RGB Task Leader** prepares input for the RAP and provides it to ADM and rulemaking status chart.

e. The **RGB Task Leader**, in consultation with the **WG and RGB management**, develops the milestone schedule for preparing the rulemaking plan, and as part of the plan, develops schedules and resource estimates for preparing the proposed and final rule packages. The milestones should address preparation of all supporting documents and identify all necessary steps to ensure that NMSS has adequately planned for the complete process. The **RGB Task Leader** provides a copy of the schedule to the RGB Section Leader.

In estimating the time needed to prepare the rule package, consideration should be given to such factors as whether contractor effort is needed, the extent of enhanced public participation, whether Agreement State coordination is necessary, whether advisory committee or CRGR review is necessary, whether an EA or EIS will be prepared, the priority of the rule, etc. Consideration should also be given to other assigned programmatic and office responsibilities of the WG members.

f. The **RG Task Leader** works with the **WG members** to prepare the draft rulemaking plan package (the package includes a Commission paper and the rulemaking plan). All documents should be maintained in the 'O' drive. In preparing the draft rulemaking plan package, the **RGB Task Leader** works with **the WG members** from other divisions or offices in determining the responsibilities of each WG member in preparing the documents that comprise the package. **WG members** may have the lead on preparing specific parts of the rulemaking plan package based on their areas of programmatic responsibility and expertise. The **RGB Task Leader** should also include the **Risk Group** for any rules that involve risk-informing the regulations.

The **WG** should identify whether the rule under consideration can be signed out under the EDO's authority or whether it will require Commission approval. See MD 9.17, "Organization and Functions, Office of the Executive Director for Operations.

The **WG** should determine the suggested compatibility level for the rulemaking.

g. The **RGB Task Leader** assembles the package for the rulemaking plan. The package contains the office concurrence memo, a Commission Paper, and the rulemaking plan.

Step 3 - Branch Review of Draft Rulemaking Plan

In this step:

a. The **RGB Task Leader** submits the draft rulemaking plan package to the **RGB Section Leader/Branch Chief** for review. The **WG members** provide a copy of the draft rulemaking plan package to their respective managements for review. **NMSS programmatic branch** reviews the package to ensure that the rulemaking action is technically sound. **WG members** work to obtain comments from branch managers and notify branch managers of potential problems or policy issues that should be addressed in their comments. If the RGB Section Leader has significant comments, the package is returned to the RGB Task Leader for resolution. Otherwise, the RGB Section Leader provides the package to the RGB Branch Chief.

b. The **RGB Task Leader** addresses any comments from the RGB Section Leader/Branch Chief and any comments received from the programmatic branch.

c. The **RGB Task Leader** provides the Commission Paper to the **NMSS Technical Editor** (or during office concurrence).

Step 4 - Division Review of Draft Rulemaking Plan

In this step:

a. The **RGB Branch Chief** sends the draft rulemaking plan package to IMNS management and to other NMSS Programmatic Divisions. In some cases, RGB may provide the package to the **NMSS Correspondence Analyst** for issuance of an NMSS ticket to the NMSS Programmatic Divisions. The **RGB Task Leader** should discuss this with **RGB Management**.

b. **IMNS management and NMSS Programmatic Divisions** review the draft rulemaking plan package to ensure that the rulemaking action is consistent with division goals and missions. **WG members** in other divisions work to coordinate with their division management.

c. The **RGB Task Leader** prepares briefing sheets and briefs the **IMNS Director and NMSS Programmatic Divisions** on the rulemaking plan package.

d. The **RGB Task Leader** addresses comments from IMNS and NMSS Programmatic Divisions and prepares a revised draft of the rulemaking plan package. In addressing the comments, the **RGB Task Leader** works with **WG members** from other divisions or offices.

e. The **NMSS Programmatic Division** concurs in the rulemaking plan.

f. The **IMNS Division Director** signs the office concurrence memo and sends the draft rulemaking plan package to other NRC offices for concurrence. These offices are **OGC, OE, ADM, STP, OCIO, and OCFO**. The package will go to NRR if the rulemaking impacts Part 20 or Parts 50 - 170.

g. The **IMNS Division Director** also provides an information copy of the draft proposed rule package to **ACMUI, ACRS, ACNW, CRGR, OIG,** and **OPA,** as appropriate, and to the **NMSS Office Director, NMSS Deputy Office Director,** and the **Regional Administrators.**

Step 5 - Office Review of Draft Rulemaking Plan

In this step:

a. **Offices** review the package according to their programmatic responsibilities and the organizational responsibilities listed in MD 6.3, Sections 032 - 0311. The offices are to provide their comments and/or concurrence within 20 days.

b. The **RGB Task Leader** schedules a meeting with the cognizant offices to resolve any outstanding concerns for the day after the due date of the office concurrences. If all concurrences have been received, the meeting will be canceled.

c. The **RGB Task Leader** addresses comments from other NRC offices, as well as any comments received from the NMSS Office Director or Deputy Office Director, and prepares a final draft of the rulemaking plan package. In addressing the comments, the **RGB Task Leader** works with the **WG members** from other divisions or offices.

d. The **RGB Task Leader** submits the final draft of the rulemaking plan package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

e. The **RGB Branch Chief** forwards the rulemaking plan package to **IMNS** for final concurrence. If there are no substantive changes, it is not necessary to send the package back to the NMSS Programmatic Divisions.

Step 6 - Agreement State Review of the Draft Rulemaking Plan (if Appropriate, i.e., if the Rulemaking Would Impact Agreement States)

In this step:

a. The **RGB Task Leader** puts in the Plan of the Week, under the NMSS TA section, that the draft rulemaking plan is being provided to the Agreement States for review and comment.

b. The **IMNS Division Director** provides the draft plan, marked "pre-decisional" to STP via memo. The EDO Assistant for Operations is copied on the memo. The **EDO Assistant for Operations** provides a copy of the rulemaking plan to the **Commission** via a Commission note with an indication that it is being sent to the

Agreement States for comment. In certain instances, as when a rulemaking is particularly controversial or involves a significant policy issue, **NMSS** may decide to send the rulemaking plan to the Commission for negative consent, rather than for information, before it is sent to the Agreement States or the CRCPD.

c. The **RGB Task Leader** provides an electronic copy of the draft rulemaking plan (marked "pre-decisional") to **ADM**. **ADM** will post the draft rulemaking plan on the technical conference forum website for the use of the Agreement States. **STP** will notify the Agreement States of document availability for review and comment.

d. The **RGB Task Leader** notifies the **Council Chair of the Conference of Radiation Control Program Directors (CRCPD) who has responsibility for suggested State regulations (SSRs)** of the rulemaking plan via the NRC's CRCPD SSR point of contact (IMNS Division Director), as applicable.

Note: the rulemaking plan should not be sent to either the Agreement States or the CRCPD until the information copy of the plan is provided to the **Commission**.

e. **The Agreement States** have a 45-day comment period.

f. The **RGB Task Leader**, in concert with **WG members**, addresses comments from the Agreement States and CRCPD and prepares the final rulemaking plan package (if the Agreement States provide substantive comments and/or if the final rulemaking plan has significant changes from the draft, **IMNS** will reissue the package to the appropriate **NMSS divisions and NRC offices** for concurrence in the manner of Steps 4 and 5, above).

The final rulemaking plan package consists of a Commission paper and the rulemaking plan and includes a discussion of the staff's disposition of Agreement State and CRCPD comments.

g. The **RGB Task Leader** submits the final draft of the rulemaking plan package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

h. The **RGB Branch Chief** forwards the rulemaking plan package to **IMNS** for final concurrence.

Step 7 - NMSS Concurrence in Rulemaking Plan Package

In this step:

a. The **RGB Task Leader** schedules briefing of the **NMSS Office Director and/or Deputy Director**, provides draft package prior to the briefing, and prepares briefing sheets. The **RGB Task Leader** conducts the briefing.

b. The rulemaking plan package is forwarded to the **NMSS Correspondence Analyst** for **NMSS Office Director** concurrence.

c. The **NMSS Office Director** concurs in the rulemaking plan package.

Step 8 - EDO/Commission Review of Rulemaking Plan Package

In this step:

a. The rulemaking plan package is sent to the **EDO**.

b. Any comments from the EDO, either editorial or technical, that require return of the package for changes are to be discussed with **RGB management**.

c. After concurrence by the **EDO**, the package is provided to the **Commission**.

Step 9 - Actions Subsequent to EDO/Commission Approval of the Final Rulemaking Plan

In this step:

a. **RGB Task Leader** provides the rulemaking plan electronically to **ADM** (this may be done by ensuring that the current version of the plan is saved on the "O" drive or by providing the ADAMS accession number); **ADM** makes the approved rulemaking plan available on NRC's rulemaking website.

b. **RGB** prepares an entry for the Regulatory Agenda and forwards it to **ADM** for inclusion in the next NRC Regulatory Agenda.

c. **STP** notifies the Agreement States of the Commission's approval (or disapproval) of the rulemaking plan, and the availability of the approved plan on the rulemaking website.

d. **RGB** notifies the CRCPD Council Chair who has responsibility for suggested state regulations of the Commission's approval (or disapproval) of the rulemaking plan so that, if the plan is approved, development of a suggested stae regulation, if desired, may parallel the NRC's rulemaking.

e. **Participating offices** implement the final rulemaking plan as approved by the EDO.

Checklist for Contents of Rulemaking Plan Package

The contents of a rulemaking plan package is the same whether the rulemaking plan is to be approved by the Commission or by the EDO. Commission Paper would be either a Negative Consent or a Notation Vote Paper. A Notation Vote Paper is used for those issues that are not within the EDO's delegated authority and for any issues that would be setting NRC policy.

Document	Commission	EDO
Commission Paper	X	X
Rulemaking Plan	X	X

Attachment 2

Generic Schedule for Preparation of Rulemaking Plan*

Action	Timeframe
Prepare Rulemaking Plan Package	Time varies
Provide to RGB Section Leader for review	1 week
Provide to RGB Branch Chief for concurrence	1 week
Resolve comments	1 week
Division briefings	
Division review and concurrence	1 week
Resolve comments	1 week
IMNS issue for Office concurrence	3 days
Office concurrence	20 days
Resolve office comments	1 -2 weeks
RGB concurrence	1 week
IMNS review and concurrence	1 week
Provide to STP and ADM for Agreement states	1 week
Agreement State comment period	45 days
Resolve Agreement State comments	1 - 2 weeks
RGB concurrence	1 week
IMNS issue for Office concurrence	1 week
Office concurrence**	20 days
Resolve office comments	1 - 2 weeks
RGB concurrence	1 week
IMNS Division final concurrence	1 week
NMSS concurrence	1 week
EDO approval	1 week
Package to Commission	1 week

Forward rulemaking plan to ADM for posting	after receipt of SRM approving plan

*Note that these timeframes are intended as guidance, each rulemaking plan will have its own schedule. The timeframe will depend on the complexity of the rulemaking and on any EDO, NMSS, or IMNS tickets.

**The second round of office concurrence may be shortened depending on the significance of the changes due to Agreement state comments.

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF PROPOSED RULE PACKAGES

RGB has the overall responsibility for the preparation of proposed rule packages. The proposed rule package includes the Federal Register notice (FRN) for the proposed rule, as well as the appropriate supporting documents (e.g., the regulatory analysis, an EA or EIS, a backfit analysis, the OMB package, the Congressional letters, a press release, and regulatory guidance). If the proposed rule is to go to the Commission, the package includes a Commission Paper transmitting the rulemaking from the EDO to the Commission. If the rulemaking is to be signed out by the EDO, the package should contain a transmittal memo from the NMSS Office Director to the EDO, the authority statements for the EDO's signature, and an entry for the weekly report to the Commission. Other NMSS divisions and NRC offices have responsibilities for assisting with preparation of these documents and for their review. RGB has the responsibility for preparing regulatory guidance for those rulemakings for which IMNS has the programmatic lead. However, the NMSS programmatic division is responsible for development of regulatory guidance for those rules for which they have the programmatic lead. Attachment 1 contains a checklist for a proposed rule. Part 5 of the Regulations Handbook discusses the format and content of a proposed rule.

Attachment 2 contains the schedule template for proposed rules. The discussion below follows the schedule and provides discussion as to what actions need to be taken at each step of the process by the RGB Task Leader, by RGB, IMNS, and NMSS management, and by staff and management in other divisions and offices.

Step 1 - Preparation of Proposed Rule Package

In this step:

a. If there was no rulemaking plan, **RGB management** assigns a RGB Task Leader. Consulting with the appropriate NMSS programmatic division and other offices, staff members from other NMSS divisions and offices are selected as members of a WG.

b. The **RGB Task Leader** contacts ADM for a rulemaking number and a regulation identifier number (RIN) and contacts the PMDA Program Analyst for a TAC number and RITS code (if not yet established).

c. **RGB Management** prioritizes the rulemaking in accordance with the PBPM process, if not previously completed.

d. The **RGB Task Leader** prepares input for the RAP and the Regulatory Agenda and provides it to ADM (if this has not been done at the rulemaking plan stage).

e. The **RGB Task Leader** prepares the milestone schedule as prescribed in the rulemaking plan. The schedule should be consistent with any EDO, NMSS, or

IMNS tickets. The **RGB Task Leader** discusses the schedule with the WG members and provides a copy to the **RGB Section Leader**. The milestones should address preparation of all supporting documents and identify all necessary steps to ensure that NMSS has adequately planned for the complete process.

f. The **RGB Task Leader** prepares a draft package for the proposed rule. All of the rule documents should be maintained on the 'O' drive. In preparing the draft rule package, the **RGB Task Leader** works with **the WG members** from other divisions or offices in determining the responsibilities of each WG member in preparing the documents that comprise the proposed rule package. **WG members** may have the lead on preparing specific parts of the rule package based on their areas of programmatic responsibility and expertise (e.g., regulatory text, regulatory analyses, EAs, EISs, etc). The **RGB Task Leader** should also include the **Risk Group** for any rules that involve risk informing the regulations.

Where associated guidance (including licensing, inspection, and enforcement guidance) is to be prepared along with the rule, the **RGB Task Leader** assists the **WG members**, as necessary, in preparing the guidance so that final guidance will be available at the time the rule is implemented. The NMSS Programmatic Division has the lead for guidance documents. The draft guidance document should be published for comment at the same time the proposed rule is out for comment.

g. The **RGB Task Leader** assembles the rulemaking package for the proposed rule. The package contains the office concurrence memo, a Commission Paper and SECY Paper Distribution Form 6 (if signed out by the Commission) or a transmittal memo (if signed out by the EDO); the FRN; the supporting documents (e.g., an RA, EA or EIS, and backfit analysis, if they have been prepared as separate documents and not embedded in the FRN); and as background material, the Congressional letters and a draft press release. The draft press release is prepared by **OPA**. The **RGB Task Leader** should coordinate with OPA so that the press release is part of the package that goes to the EDO or Commission. **OPA** typically prepares the draft press release while the package is out for office concurrence. If OPA determines that a press release is not necessary, this should be stated in either the EDO memo or the Commission Paper. The package should also contain a cover letter for STP to send the states requesting comment on the FRN and the draft EA. If the proposed rule is to be signed out by the EDO, the package also contains the authority statement for the EDO's signature and an entry for the Weekly Report to the Commission. When a Commission Paper is prepared, particular attention should be paid to the recommendations section to ensure that all necessary requirements for publishing a rulemaking are met.

h. Concurrently, the **RGB Task Leader** addresses any information collection requirements in consultation with the **WG** and in coordination with the **RGB OMB Project Manger (PM)**. The **WG** estimates the burden imposed by the proposed information collection requirements contained in the rule. The **RGB Task Leader** may contact OCIO staff for a quick read on the significance of the burden change. If it is believed that the burden from information collection requirements is

insignificant, the RGB Task leader sends a completed Form 670 (containing an estimate of the information collection burden), and the draft proposed rule (marked pre-decisional), via E-mail to **OCIO** or provides a paper copy to the **OCIO** contact. If the information collection requirements are considered significant, the **RGB Task Leader** with the assistance of the **WG** prepares the OMB clearance package and sends the draft supporting statement and draft proposed rule to OCIO. At this stage the draft OMB package may be informally provided to OCIO.

OCIO reviews Form 670 and the draft proposed rule to determine whether the information collection burden (increase or decrease) can be considered insignificant (note that if the information collection requirements in the rule are controversial, an OMB approval package is required even if the burden is insignificant). **OCIO**, after consultation with OMB, notifies the RGB Task Leader and ADM on its decision as follows:

1. If it is determined that the burden is significant, the OCIO notifies the **RGB Task Leader** to complete preparation of the OMB clearance package;

2. If it is determined that the burden is insignificant, the **RGB Task Leader** has no further action regarding preparation of the OMB clearance package other than including appropriate text in the statement of consideration for the rule.

Step 2 - Branch Review of Proposed Rule Package

In this step:

a. The **RGB Task Leader** submits the draft proposed rule package to the **RGB Section Leader/Branch Chief** for review. The **WG members** provide a copy of the draft proposed rule package to their respective managements for review. **NMSS programmatic branch** reviews the rule package to ensure that the rulemaking action and associated guidance is technically sound. **WG members** work to obtain comments from branch managers and notify branch managers of potential problems or policy issues that should be addressed in their comments. If the RGB Section Leader has significant comments, the package is returned to the RGB Task Leader for resolution. Otherwise, the RGB Section Leader provides the package to the RGB Branch Chief.

b. The **RGB Task Leader** addresses any comments from the RGB Section Leader/Branch Chief and any comments received from the programmatic branch.

c. Concurrently, the **RGB Branch Chief** sends the OMB package (containing the draft supporting statement), if needed, to OCIO.

d. **OCIO** reviews the content of the OMB package.

e. The **RGB Task Leader** provides the Congressional letters, Commission Paper or memo to the EDO to the **NMSS Technical Editor** (or during office concurrence).

Step 3 - Division Review of Proposed Rule Package

In this step:

a. The **RGB Branch Chief** sends the draft proposed rule package to IMNS management and to other NMSS programmatic divisions. In some cases, RGB may provide the package to the **NMSS Correspondence Analyst** for issuance of an NMSS ticket to the NMSS programmatic divisions. The **RGB Task Leader** should discuss this with **RGB Management**.

   IMNS management and **NMSS Programmatic Divisions** review the draft proposed rule package to ensure that the rulemaking action is consistent with division goals and missions. **WG members** in other divisions work to coordinate with their division management.

b. The **RGB Task Leader** prepares briefing sheets and briefs the **IMNS Director and NMSS Programmatic Divisions** on the proposed rule package.

c. The **RGB Task Leader** addresses comments from IMNS and NMSS Programmatic Divisions and prepares a revised draft of the proposed rule package. In addressing the comments, the **RGB Task Leader** works with **WG members** from other divisions or offices.

d. The **NMSS Programmatic Division** concurs in the rule.

e. The **IMNS Division Director** signs the office concurrence memo and sends the draft proposed rule package to other NRC offices for concurrence. These offices are **OGC, OE, ADM, STP, OCIO, and OCFO**. The package will go to NRR if the rulemaking impacts Part 20 or Parts 50 - 170.

f. The **IMNS Division Director** also provides an information copy of the draft proposed rule package to **ACMUI, ACRS, ACNW, CRGR, OIG,** and **OPA**, as appropriate, and to the **NMSS Office Director, NMSS Deputy Office Director,** and the **Regional Administrators**.

Step 4 - Office Review of Proposed Rule Package

In this step:

a. **Offices** review the package according to their programmatic responsibilities and the organizational responsibilities listed in MD 6.3, Sections 032 - 0311. The offices should provide any comments and the office concurrence within 20 days.

b. The **RGB Task Leader** schedules a meeting with the cognizant offices to resolve any outstanding concerns for the day after the due date of the office concurrences. If all concurrences have been received, the meeting will be canceled.

c. The **RGB Task Leader** addresses comments from other NRC offices, as well as any comments received from the NMSS Office Director or Deputy Office Director, and prepares a final draft of the proposed rule package. In addressing the comments, the RGB Task Leader works with the **WG members** from other divisions or offices.

d. The **RGB Task Leader** submits the final draft of the proposed rule package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

e. The **RGB Branch Chief** forwards the proposed rule package to **IMNS** for final concurrence. If there are no substantive changes, it is not necessary to send the package back to the NMSS Programmatic Divisions.

Step 5 - Agreement State Review of the Draft Proposed Rule (if Appropriate, i.e., if the Rulemaking Would Impact Agreement States)

In this step:

a. The **RGB Task Leader** puts in the Plan of the week, under the NMSS TA section, that the draft proposed rule is being provided to the Agreement States for review and comment.

b. The **IMNS Division Director** provides the draft proposed rule, marked "pre-decisional" to STP via memo. The **RGB Task Leader** also provides an electronic copy of the draft proposed rule to **ADM**. **ADM** will post the draft proposed rule on the technical conference forum website for the use of the Agreement States. **STP** will notify the Agreement States of the proposed rule availability for review and comment.

c. The **RGB Task Leader** notifies the **Council Chair of the Conference of Radiation Control Program Directors (CRCPD) who has responsibility for suggested State regulations (SSRs)** of the draft proposed rule via the NRC's CRCPD SSR point of contact (IMNS Division Director).

d. **The Agreement States** have a 30-day comment period. For complex rule packages, the comment period may be extended.

e. The **RGB Task Leader**, in concert with **WG members**, addresses comments from the Agreement States and CRCPD and prepares the final proposed rule package (if the Agreement States provide substantive comments and/or if the final proposed rule has significant changes from the draft, **IMNS** will reissue the

package to the appropriate **NMSS divisions and NRC offices** for concurrence in the manner of Steps 3 and 4, above).

The final proposed rule statements of consideration should include a discussion of the staff's disposition of Agreement State and CRCPD comments.

f. The **RGB Task Leader** submits the final draft of the proposed rule package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

g. The **RGB Branch Chief** forwards the rulemaking plan package to **IMNS** for final concurrence.

Step 6 - NMSS Concurrence in Proposed Rule Package

In this step:

a. The **RGB Task Leader** schedules briefing of the **NMSS Office Director and/or Deputy Director**, provides the draft package prior to the briefing, and prepares briefing sheets. The **RGB Task Leader** conducts the briefing.

b. The proposed rule package is forwarded to the **NMSS Correspondence Analyst** for **NMSS Office Director** concurrence.

c. The **NMSS Office Director** concurs in the proposed rule package. If the rule is to be signed by the EDO, the **NMSS Office Director** signs the transmittal memo forwarding the package to the EDO.

d. The **RGB Task Leader**, prepares the final OMB package (containing the supporting statement, Federal Register notice for the clearance package, and Form 620) for submittal to **OCIO** in coordination with the **RGB OMB PM**. In preparing the package, The **RGB Task Leader** works with the **WG members**.

e. No later than the date that the rule package is sent to the EDO, the **RGB Branch Chief** sends the final OMB package (containing the supporting statement, Federal Register notice for the clearance package, and Form 620) to **OCIO** after concurrence by **WG members** and management in the programmatic branch.

Step 7 - EDO/Commission Review of Proposed Rule Package

In this step:

a. The rule package is sent to the **EDO**. The package should include, for Commission consideration where appropriate, proposed licensing and inspection guidance or a synopsis of the planned means of inspection and enforcement. If additional guidance is unnecessary, the package should include a statement to that effect.

Any comments from the EDO, either editorial or technical, that require return of the package for changes are to be discussed with **RGB management.**

b. After concurrence by the **EDO**, the package is provided to the **Commission.** If the rule can be issued under the **EDO's authority**, it is signed by the **EDO** and the weekly item is sent to the Commission. After the proposed rule is signed by the EDO, it is returned to the RGB Task Leader.

Step 8 - Issuance of Proposed Rule

In this step:

a. The **Commission** votes on the rule package. The results of the vote, along with Commission directions regarding changes that should be made to the package, are sent to the **EDO** in a Staff Requirements Memorandum (SRM).

b. **RGB Task Leader** incorporates Commission directions in the SRM and prepares the package for publication.

c. Following incorporation of Commission direction, the **RGB Task Leader** sends the OMB package and a copy of the latest revision of the rule, if needed, to OCIO. **OCIO** sends the OMB package to OMB for approval;

d. The **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the proposed rule package to ADM. The package is submitted to ADM at least 2 working days before the due date established in the SRM. The package to ADM should contain 3 copies of the FRN, a disk copy of the FRN, the Congressional letters, a disk copy of the Congressional letters, and the Press Release, and any supporting documents. **ADM** sends the final proposed rule package to SECY for delivery to the OFR. Upon publication in the Federal Register, ADM places the proposed rule on the rulemaking website along with any supporting documents like the RA, EA or EIS, and any regulatory guidance.

e. If the rule package is being issued under EDO's authority, the **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the proposed rule package to ADM, noting the date that the proposed rule can be forwarded to the OFR. The package should be submitted to ADM within 5 days of the EDO's signature. The package should contain the original signed FRN, 11 copies of the FRN, and a disk copy of the FRN. The package should also contain the Congressional letters, a disk copy of the Congressional letters, the State Liaison Officers letter, the Press Release, and any supporting documents such as the RA and the EA or EIS. **ADM** will forward the proposed rule to the OFR for publication. Upon publication in the Federal Register, **ADM** will place the proposed rule documents on the rulemaking website. **ADM** will coordinate the release of the press release with **OPA**, the issuance of the State Liaison Officers letter with **STP**, and the issuance of the Congressional letters with **OCA**.

f. The transmittal memo to ADM should indicate, as appropriate, any places in the FRN where a date must be inserted before publication. Also note that the disk copy of the FRN should not include the concurrence page.

g. The **RGB Task Leader** prepares an Item of Interest for inclusion in the NMSS Items of Interest once the proposed rule has been published in the Federal Register.

Checklist for Contents of Proposed Rule Package

The package contents is dependent on whether the proposed rule is to be issued by the EDO or the Commission.

Document	Commission	EDO
Commission Paper	X	
Transmittal Memo from NMSS Office Director to EDO		X
Federal Register Notice	X	X
Regulatory Analysis (if a separate one was prepared)	X	X
Environmental Assessment (if a separate one was prepared) or EIS	X	X
Letter to State Liaison Officers forwarding EA and FRN	X	X
Backfit Analysis (if a separate one was prepared)	X	X
Authority statement for EDO's signature		X
Weekly Report to the Commission		X
Congressional Letter (as background)	X	X
Press Release (as background)	X	X

Checklist for Content of OMB Package

A separate package is prepared for those rules requiring OMB clearance. The package is provided to CIO and is necessary for both Commission and EDO issued rules.

Document	Commission	EDO
OMB Supporting Statement	X	X
OMB Federal Register Notice	X	X
Draft Proposed Rule FRN	X	X

Attachment 2

Generic Schedule for Proposed Rule*

Action	Timeframe
Prepare Proposed Rule Package	Time varies
Provide to RGB Section Leader for review	1 week
Provide to RGB Branch Chief for concurrence	1 week
Resolve comments	1 week
Division briefings	
IMNS and Programmatic Division review and concurrence	1 week
Resolve comments	1 week
IMNS issue for Office concurrence	3 days
Office concurrence	20 days
Resolve office comments	1 - 4 weeks
RGB concurrence	1 week
IMNS Division review and concurrence	1 week
Provide to STP and ADM for Agreement states	1 week
Agreement State comment period	30 days
Resolve Agreement State comments**	2 weeks
RGB concurrence	1 week
IMNS Division review and concurrence	1 week
NMSS concurrence	1 week
EDO approval	1 week
Package to Commission	1 week
SRM	
Make SRM changes	as specified in SRM
Forward proposed rule package to ADM	5 days or date in SRM
Publication in FR	3 weeks

Prepare Item of Interest	Upon publication in FR
Prepare Regulatory History	60 days

*Note that these timeframes are intended as guidance, each rule will have its own schedule. The timeframe will depend on the complexity of the rulemaking and on any EDO, NMSS, or IMNS tickets.

**Dependent on significance of changes due to Agreement State comments, may need to reissue for office concurrence.

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF FINAL RULE PACKAGES

RGB has the overall responsibility for the preparation of final rule packages. The final rule package includes the Federal Register notice (FRN) for the final rule, as well as the appropriate supporting documents (e.g., the regulatory analysis, an EA or EIS, a backfit analysis, the OMB package, the Congressional letters, a press release, and regulatory guidance). If the final rule is to go to the Commission, the package includes a Commission Paper transmitting the rulemaking from the EDO to the Commission. If the rulemaking is to be signed out by the EDO, the package should contain a transmittal memo from the NMSS Office Director to the EDO, the authority statements for the EDO's signature, and an entry for a daily staff note to the Commission. The FRN for the final rule includes the response to public comments. Other NMSS divisions and NRC offices have responsibilities for assisting with preparation of these documents and for their review. RGB has the responsibility for finalizing regulatory guidance for those rulemakings for which IMNS has the programmatic lead. However, the NMSS programmatic division is responsible for finalization of regulatory guidance for those rules for which they have the programmatic lead. Attachment 1 contains a checklist for a final rule. Part 7 of the Regulations Handbook discusses the format and content of a final rule.

Attachment 2 contains the schedule template for a final rule. The discussion below follows the schedule and provides discussion as to what actions need to be taken at each step of the process by the RGB Task Leader, by RGB, IMNS, and NMSS management, and by staff and management in other divisions and offices.

Step 1 - Resolution of Public Comments

In this step:

a. The **RGB Task Leader** obtains copies of any comment letters on the proposed rule and provides copies to the other WG members. Copies of the comment letters can be obtained from the ADAMS folder on the specific rulemaking or the ruleforum webpage. In addition, The **RGB Task Leader** should check with SECY to make sure that all comment letters have been obtained. The **RGB Task Leader** provides copies of the comment letters to the WG members.

b. The **RGB Task Leader** will develop a detailed schedule for resolution of the public comments. The schedule will be dependent on the type and number of comments received. The schedule should include all milestones to complete the final rule package. The schedule should be consistent with the rulemaking plan and any EDO, NMSS, or IMNS tickets. The **RGB Task Leader** should discuss the schedule with the **WG members**.

c. The **RGB Task Leader** will meet with the **WG** to discuss the comments. The **RGB Task Leader** will explain the expectations in preparing the responses to comments and will provide the format and schedule to the WG. The **RGB Task**

Leader should summarize and bin the comments such that comments on the same or similar subjects will be grouped together. (For some rules, a contractor will summarize and bin the comments. The RGB Task Leader should review the contractor's work.) The RGB Task Leader should begin the summarization and binning process as soon as comments are received. The RGB Task Leader should develop a comment matrix (e.g. a road map) that identifies the response in which each comment is addressed and who is assigned the lead for each comment. The RGB Task Leader will provide the summarized/binned comments as well as copies of the matrix to the WG.

All substantive comments received on the proposed rule must be addressed in the Supplementary Information section of the final rule. Similar comments may be grouped with a common response, but each key issue raised by the groups of comments must be discussed and an indication given as to whether the comment was persuasive, and if so, what changes were made to the regulations as proposed. Each comment on the information collection must be addressed specifically. If the commenters were not persuasive, the response should provide a logical discussion of why the comment is not being implemented.

d. In order to monitor the response preparation, the RGB Task Leader should hold periodic meetings with the WG or with specific members. The RGB Task Leader should review the responses to make sure the comments have been appropriately addressed. The individual who prepares a particular response is responsible for ensuring technical accuracy. The RGB Task Leader and WG members should identify any controversial issues to management at an early stage.

e. The RGB Task Leader will consolidate all of the comments and responses and incorporate them into the FRN. The RGB Task Leader is responsible for identifying potential problems or issues to IMNS management. The WG members should keep their management informed.

Step 2 - Preparation of Final Rule Package

In this step:

a. The RGB Task Leader prepares a draft package for the final rule. All rule documents should be maintained on the 'O' drive. In preparing the draft rule package, the RGB Task Leader works with the WG members from other divisions or offices. WG members may take the lead in revising the specific parts of the rulemaking package for which they are responsible. The RGB Task Leader should also include the Risk Group for any rules that involve risk informing the regulations.

Where associated guidance (including licensing, inspection, and enforcement guidance) is to be prepared along with the rule, the RGB Task Leader assists the WG members, as necessary, in finishing the guidance so that final guidance will

be available at the time the rule is implemented. The NMSS Programmatic Division has the lead for guidance documents.

b. The **RGB Task Leader** assembles the rulemaking package for the final rule. The package contains the office concurrence memo, a Commission Paper and SECY Paper Distribution Form 6 (if signed out by the Commission) or a transmittal memo (if signed out by the EDO); the FRN; the supporting documents (e.g., an RA, EA or EIS, and backfit analysis, if they have been prepared as separate documents and are not embedded in the FRN); and as background material, the Congressional letters and a draft press release. The draft press release is prepared by OPA. The RGB Task Leader should coordinate with OPA so that the press release is part of the package that is issued for office concurrence. If OPA determines that a press release is not necessary, this should be stated in either the EDO memo or the Commission Paper. If the final rule is to be signed out by the EDO, the package also contains the authority statement for the EDO's signature and the Notice of Final Rule Signed by EDO. When a Commission Paper is prepared, particular attention should be paid to the recommendations section to ensure that all necessary requirements for publishing a rulemaking are met.

c. Concurrently, the **RGB Task Leader**, in coordination with the **RGB OMB PM**, finalizes any information collection requirements. If OMB has approved the information collection requirements of the proposed rule and:

1) If there are no changes (other than editorial) in the final rule, then the OMB clearance process is complete and the **RGB Task Leader** has no further action regarding preparation of OMB packages other than to include appropriate text in the statement of considerations for the rule.

2) If there are changes in the information collection requirements in the final rule, but the **RGB Task Leader** believes them to be insignificant, the RGB Task leader sends a completed Form 670 (containing an estimate of the information collection burden), and the draft final rule (marked pre-decisional), via E-mail to **OCIO**. ;

3) If there are changes to the information collection requirements in the final rule, which are considered significant, the **RGB Task Leader** should proceed to modify the OMB package prepared for the proposed rule and provide it to **OCIO** for review. OMB requires that we address each comment on the information collections and its resolution specifically in the clearance package (under "Consultations with the Public").

Step 3 - Branch Review of Final Rule Package

In this step:

a. The **RGB Task Leader** submits the draft final rule package to the **RGB Section Leader/Branch Chief** for review. The **WG members** provide a copy of the draft final rule package to their respective managements for review. **NMSS programmatic branch** reviews rule package to ensure that the rulemaking action and associated guidance is technically sound. **WG members** work to obtain comments from branch managers and notify branch managers of potential problems or policy issues that should be addressed in their comments. If the RGB Section Leader has significant comments, the package is returned to the RGB Task Leader for resolution. Otherwise, the RGB Section Leader provides the package to the RGB Branch Chief.

b. The **RGB Task Leader** addresses any comments from the RGB Section Leader/Branch Chief and any comments received from the programmatic branch.

c. Concurrently, the **RGB Branch Chief** sends the revised OMB package, if needed, to OCIO.

d. **OCIO** reviews content of OMB package.

e. The **RGB Task Leader** completes Small Business Regulatory Enforcement Fairness Act (SBREFA) form for the package. This form is available through informs as form GAO-0001-Submission of Federal Rules. RGB also collects input on a monthly basis, for each final action with an anticipated issue date within 90 days. The entries are provided to the **RGB Technical Assistant.**

f. The **RGB Task Leader** provides the Congressional letter, Commission Paper and/or memo to the EDO to the **NMSS Technical Editor** (or during office concurrence).

Step 4 - Division Review of Final Rule Package

In this step:

a. The **RGB Branch Chief** sends the draft final rule package to IMNS management and to other NMSS Programmatic Divisions. In some cases, RGB may provide the package to the **NMSS Correspondence Analyst** for issuance of an NMSS ticket to the NMSS Programmatic Divisions. The **RGB Task Leader** should discuss this with **RGB Management.**

IMNS management and **NMSS Programmatic Divisions** review the draft final rule package to ensure that the rulemaking action is consistent with division goals and missions. **WG members** in other divisions work to coordinate with their division management.

b. The **RGB Task Leader** prepares briefing sheets and briefs the **IMNS Director and NMSS Programmatic Divisions** on the final rule package.

c. The **RGB Task Leader** addresses comments from IMNS and NMSS Programmatic Divisions and prepares a revised draft of the final rule package. In addressing the comments, the **RGB Task Leader** works with **WG members** from other divisions or offices.

d. The **NMSS Programmatic Division** concurs in the final rule.

e. The **IMNS Division Director** signs the office concurrence memo and sends the draft final rule package to other NRC offices for concurrence. These offices are **OGC, OE, ADM, STP, OCIO, and OCFO.** The package will go to **NRR** if the rule impacts Part 20 or Parts 50 - 170.

f. The **IMNS Division Director** also provides an information copy of the draft final rule package to **ACMUI, ACRS, ACNW, CRGR, OIG,** and **OPA,** as appropriate, and to the **NMSS Office Director, NMSS Deputy Office Director,** and the **Regional Administrators.**

Step 5 - Office Review of Final Rule Package

In this step:

a. **Offices** review the package according to their programmatic responsibilities and the organizational responsibilities listed in MD 6.3, Sections 032 - 0311. The offices should provide any comments and the office concurrence within 20 calendar days.

b. The **RGB Task Leader** schedules a meeting with the cognizant offices to resolve any outstanding concerns for the day after the due date of the office concurrences. If all concurrences have been received, the meeting will be canceled.

c. The **RGB Task Leader** addresses comments from other NRC offices, as well as any comments received from the NMSS Office Director or Deputy Office Director, and prepares a final draft of the final rule package. In addressing the comments, the RGB Task Leader works with the **WG members** from other divisions or offices.

d. The RGB Task Leader submits the final draft of the final rule package to the RGB Section Leader and RGB Branch Chief for final concurrence.

e. The **RGB Branch Chief** forwards the final rule package to **IMNS** for final concurrence. If there were no significant changes, the package does not need to go back to the NMSS programmatic divisions for final concurrence.

Step 6 - Agreement State Review of the Draft Final Rule (if Appropriate, i.e., if the Rulemaking Would Impact Agreement States)

In this step:

a. The **RGB Task Leader** puts in the Plan of the week, under the NMSS TA section, that the draft final rule is being provided to the Agreement States for review and comment.

b. The **IMNS Division Director** provides the draft final rule, marked "pre-decisional" to STP via memo. The **RGB Task Leader** also provides an electronic copy of the draft final rule to **ADM**. **ADM** will post the draft final rule on the technical conference forum website for the use of the Agreement States. **STP** will notify the Agreement States of the draft final rule availability for review and comment.

c. The **RGB Task Leader** notifies the **Council Chair of the Conference of Radiation Control Program Directors (CRCPD) who has responsibility for suggested State regulations (SSRs)** of the draft final rule via the NRC's CRCPD SSR point of contact (IMNS Division Director).

d. **The Agreement States** have a 30-day comment period.

e. The **RGB Task Leader**, in concert with **WG members**, addresses comments from the Agreement States and CRCPD and prepares the final final rule package (if the Agreement States provide substantive comments and/or if the final rule has significant changes from the draft, **IMNS** will reissue the package to the appropriate **NMSS divisions and NRC offices** for concurrence in the manner of Steps 4 and 5, above).

   The statements of consideration for the final rule should include a discussion of the staff's disposition of Agreement State and CRCPD comments.

f. The **RGB Task Leader** submits the final draft of the final rule package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

g. The **RGB Branch Chief** forwards the final rule package to **IMNS** for final concurrence.

Step 7 - NMSS Concurrence in Final Rule Package

In this step:

a. The **RGB Task Leader** schedules a briefing of the **NMSS Office Director and/or Deputy Director**, provides a draft package prior to the briefing, and prepares briefing sheets. The RGB Task Leader conducts the briefing.

b. The final rule package is forwarded to the **NMSS Correspondence Analyst** for **NMSS Office Director** concurrence.

c. The **NMSS Office Director** concurs in the final rule package. If the rule is to be signed by the EDO, the **NMSS Office Director** signs the transmittal memo forwarding the package to the EDO.

d. If needed, the **RGB Task Leader**, prepares the final OMB package (containing the supporting statement, Federal Register notice for the clearance package, and Form 620) for submittal to **OCIO**.

e. No later than the date that the rule package is sent to the EDO, the **RGB Branch Chief** sends the final OMB package (containing the supporting statement, Federal Register notice for the clearance package, and Form 620) to **OCIO** after concurrence by **WG members** and the **NMSS programmatic branch**.

Step 8 - EDO/Commission Review of Final Rule Package

In this step:

a. The final rule package is sent to the **EDO**. The package should include, for Commission consideration where appropriate, proposed licensing and inspection guidance or a synopsis of the planned means of inspection and enforcement. If additional guidance is unnecessary, the package should include a statement to that effect.

b. Any comments from the EDO, either editorial or technical, that require return of the package for changes are to be discussed with **RGB management**.

c. After concurrence by the **EDO**, the package is provided to the **Commission**. If the final rule can be issued under the EDO's authority, it is signed by the **EDO** and a Daily Staff Note is sent to the Commission. After the final rule is signed by the EDO, it is returned to the RGB Task Leader.

Step 9 - Issuance of Final Rule

In this step:

a. The **Commission** votes on the rule package. The results of the vote, along with Commission directions regarding changes that should be made to the package, are sent to the **EDO** in a Staff Requirements Memorandum (SRM).

b. **RGB Task Leader** incorporates Commission directions in the SRM and prepares the package for publication.

c. Following incorporation of Commission direction, the following should occur:

If an OMB clearance is needed, the final rule cannot be issued until OMB approval is received. Hence the rule package must be held by the **RGB Task Leader** until the OMB clearance is received. Thus, the following should occur:

i) When the Commission's notation vote is obtained in the SRM, the **RGB Task Leader** sends the corrected version of the rule to OCIO;

ii) **OCIO** sends the OMB package, including the rule, to OMB and posts the rule and OMB package on the website, http://www.nrc.gov/NRC/PUBLIC/index.html;

iii) After OMB clearance is obtained, the **RGB Task Leader** notifies ADM that OMB approval has been received and that the final rule can now be published.

d. The **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the final rule package to ADM. The package is to be submitted to ADM at least 2 working days before the due date established in the SRM. The package to ADM should contain 3 copies of the FRN, a disk copy of the FRN, the Congressional letters, a disk copy of the Congressional letters, and the Press Release, and any supporting documents. **ADM** sends the final rule package to SECY for delivery to the OFR. Upon publication in the Federal Register, **ADM** places the final rule on the rulemaking website along with any supporting documents like the RA, EA or EIS, and any regulatory guidance.

e. If the rule package is being issued under EDO's authority, the **RGB Task Leader** prepares a memo for the RGB Branch Chief to send the final rule package to ADM, noting the date that the final rule can be forwarded to the OFR. The package should be submitted to ADM within 5 working days of the EDO's signature. The package should contain the original signed FRN, 11 copies of the FRN, and a disk copy of the FRN. The package should also contain the Congressional letters, a disk copy of the Congressional letters, the Press Release, and any supporting documents such as the RA and the EA or EIS. **ADM** will forward the final rule to the OFR for publication. Upon publication in the Federal Register, **ADM** will place the final rule documents on the rulemaking website. **ADM** will coordinate the release of the press release with OPA and the issuance of the Congressional letters with OCA.

f. The transmittal memo to ADM should indicate, as appropriate, any places in the FRN where a date must be inserted before publication. Also note that the disk copy of the FRN should not include the concurrence page.

g. The **RGB Task Leader** prepares an Item of Interest for inclusion in the NMSS Items of Interest once the final rule has been published in the Federal Register.

Checklist for Contents of Final Rule Package

The package contents is dependent on whether the final rule is to be issued by the EDO or the Commission.

Document	Commission	EDO
Commission Paper	X	
SRM (on proposed rule) from Commission	X	
Transmittal Memo from NMSS Office Director to EDO		X
Federal Register Notice	X	X
Regulatory Analysis (if a separate one was prepared)	X	X
Environmental Assessment (if a separate one was prepared) or EIS	X	X
Backfit Analysis (if a separate one was prepared)	X	X
Authority statement for EDO's signature		X
Notice of Final Rule Signed by EDO		X
SBREFA Form	X	X
Congressional Letter (as background)	X	X
Press Release (as background)	X	X

Checklist for Content of OMB Package

A separate package is prepared for those rules requiring OMB clearance. The package is provided to CIO and is necessary for both Commission and EDO issued rules.

Document	Commission	EDO
OMB Supporting Statement	X	X
OMB Federal Register Notice	X	X
Draft Final Rule FRN	X	X

Attachment 2

Generic Schedule for Final Rule*

Action	Timeframe
Proposed Rule Publication in FR	Day 0
Comment Period	75 days
Resolve Public Comments	2 - 8 weeks
Revise FRN, EA/EIS, OMB statement, etc.	1 - 4 weeks
Provide to RGB Section Leader and Section Leaders for review	1 week
Provide to RGB Branch Chief for concurrence	1 week
Resolve comments	1 week
Division briefings	
Division review and concurrence	1 week
Resolve comments	1 week
IMNS issue for Office concurrence	3 days
Office concurrence	20 days
Resolve office comments	1 - 3 weeks
RGB Branch Concurrence	1 week
IMNS Division review and final concurrence	1 week
Provide to STP and ADM for Agreement states	1 week
Agreement State comment period	30 days
Resolve Agreement State comments	2 weeks
RGB concurrence	1 week
IMNS Division review and concurrence	1 week
NMSS concurrence	1 week
EDO approval	7 days or date in ticket
Package to Commission	1 week
Make SRM changes	as specified in SRM

Forward final rule package to ADM	5 days or date in SRM
Publication in FR	3 weeks
Prepare an Item of Interest	Upon publication in FR
Prepare Regulatory History	60 days

*Note that these timeframes are intended as guidance, each rule will have its own schedule. For example, a rule may take more or less time to resolve public comments depending on the complexity and number of comments received. The schedule will also depend on any EDO, NMSS, or IMNS tickets.

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF DIRECT FINAL RULE PACKAGES

Direct final rules are regulatory documents that are used for noncontroversial, regulatory amendments containing no changes in information collections. A direct final rule becomes effective in a certain number of days, usually 75 days after publication in the Federal Register, unless the NRC receives significant adverse comments within a prescribed comment period, usually 30 days after publication. The NRC publishes a companion proposed rule with each direct final rule and announces in the direct final rule that any significant adverse comments received will be considered as comments on the companion proposed rule and that NRC will not initiate a separate comment period on the action. If significant adverse comments are received, the direct final rule does not take effect and the NRC publishes a notice of withdrawal of the direct final rule in the Federal Register. If no significant adverse comments are received, the NRC will publish a confirmation of effective date in the Federal Register. A direct final rule must meet the format requirements outlined for final rules. Each direct final rule and the companion proposed rule must be submitted for publication in the Federal Register as a package. The two documents are published concurrently in separate sections.

RGB has the overall responsibility for the preparation of direct final rule packages. The direct final rule package includes the Federal Register notices (FRN) for the direct final rule and the proposed rule, as well as the appropriate supporting documents (e.g., the regulatory analysis, an EA or EIS, a backfit analysis, the Congressional letters, and a press release). If the rulemaking is to go to the Commission, the package includes a Commission Paper transmitting the rulemaking from the EDO to the Commission. If the rulemaking is to be signed out by the EDO, the package should contain a transmittal memo from the NMSS Office Director to the EDO, the authority statements for the EDO's signature, a Daily Staff Note to the Commission, and an entry for the weekly report to the Commission. Other NMSS divisions and NRC offices have responsibilities for assisting with preparation of these documents and for their review. RGB has the responsibility for preparing regulatory guidance for those rulemakings for which IMNS has the programmatic lead. However, the NMSS programmatic division is responsible for development of regulatory guidance for those rules for which it has the programmatic lead. Attachment 1 contains a checklist for a direct final rule. Part 9 of the Regulations Handbook discusses the format and content for a direct final rule.

Attachment 2 contains the schedule template for direct final rules. The discussion below follows the schedule and details what actions need to be taken at each step of the process by the RGB Task Leader, by RGB, IMNS, and NMSS management, and by staff and management in other divisions and offices.

Step 1 - Preparation of Direct Final Rule Package

In this step:

a. **RGB management** assigns an RGB Task Leader. Consulting with the appropriate NMSS programmatic division and other offices, staff members from other NMSS divisions and offices are selected as members of a WG.

b. The **RGB Task Leader** contacts ADM for a rulemaking number and regulation identifier number and contacts the PMDA Program Analyst for a TAC number, if not yet established.

c. **RGB Management** prioritizes the rulemaking in accordance with the PBPM process, if not previously completed.

d. The **RGB Task Leader** prepares input for the RAP and the Regulatory Agenda and provides it to ADM (if this has not been done).

e. The **RGB Task Leader** prepares the milestone schedule to be consistent with any rulemaking plan and any EDO, NMSS, or IMNS tickets. The **RGB Task Leader** discusses the schedule with the **WG members** and provides a copy to the RGB Section Leader. The milestones should address preparation of all supporting documents and identify all necessary steps.

f. The **RGB Task Leader** prepares a draft package for the direct final rule. All rule documents should be maintained on the 'O' drive. In preparing the draft rule package, the **RGB Task Leader** works with **the WG members** from other divisions or offices in determining the responsibilities of each WG member in preparing the documents that comprise the proposed rule package. **WG members** may have the lead on preparing specific parts of the rule package based on their areas of programmatic responsibility and expertise (e.g., regulatory text, regulatory analyses, EAs, etc)

Where associated guidance (including licensing, inspection, and enforcement guidance) is to be prepared along with the rule, the **RGB Task Leader** assists the **WG members**, as necessary, in preparing the guidance so that final guidance will be available at the time the rule is implemented. The NMSS Programmatic Division has the lead for guidance documents.

g. The **RGB Task Leader** assembles the rulemaking package for the direct final rule. The package contains the office concurrence memo, a Commission Paper and SECY Paper Distribution Form 6 (if signed out by the Commission) or a transmittal memo (if signed out by the EDO); the FRN for the direct final rule; the FRN for the proposed rule; the supporting documents (e.g., an RA, EA or EIS, and backfit analysis, if they have been prepared as separate documents and are not embedded in the FRN); and as background material, the Congressional letters and a draft press release. The draft press release is prepared by OPA. The **RGB Task Leader** should coordinate with **OPA** so that the press release is part of the package that is issued for office concurrence. If OPA determines that a press release is not necessary, this should be stated in either the EDO memo or the Commission Paper. If the direct final rule is to be signed out by the EDO, the package also contains the authority statement for the EDO's signature, the Notice of Final Rule Signed by EDO, and the Weekly Report to the Commission. When a Commission Paper is prepared, particular attention should be paid to the recommendations section to ensure that all necessary requirements for publishing a rulemaking are met.

Step 3 - Branch Review of Direct Final Rule Package

In this step:

a. The **RGB Task Leader** submits the draft direct final rule package to the **RGB Section Leader/Branch Chief** for review. The **WG members** provide a copy of the draft direct final rule package to their respective managements for review. **NMSS Programmatic Branch** reviews rule package to ensure that the rulemaking action and associated guidance is technically sound. **WG members** work to obtain comments from branch managers and notify branch managers of potential problems or policy issues that should be addressed in their comments. If the RGB Section Leader has significant comments, the package is returned to the RGB Task Leader for resolution. Otherwise, the RGB Section Leader provides the package to the RGB Branch Chief.

b. The **RGB Task Leader** addresses any comments from the RGB Section Leader/Branch Chief and any comments received from the programmatic branch.

c. The **RGB Task Leader** completes the Small Business Regulatory Enforcement Fairness Act (SBREFA) form for the package. This form is available through informs as form GAO-0001-Submission of Federal Rules. RGB also collects input on a monthly basis, for each final action which the anticipated issue date is within 90 days. The entries are provided to the **RGB Technical Assistant**.

d. The **RGB Task Leader** provides the Congressional letters and the Commission Paper or EDO memo to the **NMSS Technical Editor** (or during office concurrence).

Step 3 - Division Review of Direct Final Rule Package

In this step:

a. The **RGB Branch Chief** sends the draft direct final rule package to IMNS management and to other NMSS Programmatic Divisions. In some cases, RGB may provide the package to the **NMSS Correspondence Analyst** for issuance of an NMSS ticket to the NMSS Programmatic Divisions. The **RGB Task Leader** should discuss this with **RGB Management**.

IMNS management and **NMSS Programmatic Divisions** review the draft direct final rule package to ensure that the rulemaking action is consistent with division goals and missions. **WG members** in other divisions work to coordinate with their division management.

b. The **RGB Task Leader** prepares briefing sheets and briefs the **IMNS Director and NMSS Programmatic Divisions** on the direct final rule package.

c. The **RGB Task Leader** addresses comments from IMNS and NMSS Programmatic Divisions and prepares a revised draft of the direct final rule package. In addressing the comments, the **RGB Task Leader** works with **WG members** from other divisions or offices.

d. The **NMSS Programmatic Division** concurs in the rule.

e. The **IMNS Division Director** signs the office concurrence memo and sends the draft direct final rule package to other NRC offices for concurrence. These offices are **OGC, OE, ADM, STP, OCIO, and OCFO**. The package will go to **NRR** if the rulemaking impacts Part 20 or Parts 50 - 170.

f. The **IMNS Division Director** also provides an information copy of the draft proposed rule package to **ACMUI, ACRS, ACNW, CRGR, OIG, and OPA**, as appropriate, and to the **NMSS Office Director, NMSS Deputy Office Director,** and the **Regional Administrators**.

Step 4 - Office Review of Direct Final Rule Package

In this step:

a. **Offices** review the package according to their programmatic responsibilities and the organizational responsibilities listed in MD 6.3, Sections 032 - 0311. The offices should provide any comments and the office concurrence within 20 days.

b. The **RGB Task Leader** schedules a meeting with the cognizant offices to resolve any outstanding concerns for the day after the due date of the office concurrences. If all concurrences have been received, the meeting will be canceled.

c. The **RGB Task Leader** addresses comments from other NRC offices, as well as any comments received from the NMSS Office Director or Deputy Office Director, and prepares a final draft of the direct final rule package. In addressing the comments, the **RGB Task Leader** works with the **WG members** from other divisions or offices.

d. The **RGB Task Leader** submits the final draft of the direct final rule package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

e. The **RGB Branch Chief** forwards the direct final rule package to **IMNS** for final concurrence.

Step 5 - NMSS Concurrence in Direct Final Rule Package

In this step:

a. The **RGB Task Leader** schedules briefing of the **NMSS Office Director and/or Deputy Director**, provides the draft package prior to the briefing, and prepares briefing sheets. The **RGB Task Leader** conducts the briefing.

b. The direct final rule package is forwarded to the **NMSS Correspondence Analyst** for **NMSS Office Director** concurrence.

c. The **NMSS Office Director** concurs in the direct final rule package. If the rule is to be signed by the EDO, the **NMSS Office Director** signs the transmittal memo forwarding the package to the EDO.

Step 6 - EDO/Commission Review of Direct Final Rule Package

In this step:

a. The rule package is sent to the **EDO**. The package should include, for Commission consideration where appropriate, proposed licensing and inspection guidance or a synopsis of the planned means of inspection and enforcement. If additional guidance is unnecessary, the package should include a statement to that effect.

Any comments from the EDO, either editorial or technical, that require return of the package for changes are to be discussed with **RGB management**.

b. After concurrence by the **EDO**, the package is provided to the **Commission.** If the rule can be issued under the EDO's authority, it is signed by the **EDO** and the weekly item is sent to the Commission. After the direct final rule is signed by the EDO, it is returned to the RGB Task Leader.

Step 7 - Issuance of Direct Final Rule Package

In this step:

a. The **Commission** votes on the rule package. The results of the vote, along with Commission directions regarding changes that should be made to the package, are sent to the EDO in a SRM.

b. The **RGB Task Leader** incorporates Commission directions in the SRM and prepares the package for publication.

c. The **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the direct final rule package to ADM. The package is to be submitted to ADM at least two working days before the due date established in the SRM. The package to ADM should contain 3 copies of each FRN, a disk copy of the FRN, the Congressional letters, a disk copy of the Congressional letters, and the Press Release, and any supporting documents. **ADM** sends the direct final rule

package to SECY for delivery to the OFR. Upon publication in the Federal Register, **ADM** places the direct final rule on the rulemaking website along with any supporting documents like the RA, EA or EIS, and any regulatory guidance.

d. If the rule package is being issued under EDO's authority, the **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the direct final rule package to ADM, noting the date that the direct final rule can be forwarded to the OFR. The package should be submitted to ADM within 5 days of the EDO's signature. The package should contain the original signed FRNs, 11 copies of each FRN, and a disk copy of the FRNs. A separate disk is necessary for the direct final and companion proposed rule. The package should also contain the Congressional letters, a disk copy of the Congressional letters, the Press Release, and any supporting documents such as the RA and the EA or EIS. **ADM** will forward the direct final rule to the OFR for publication. Upon publication in the Federal Register, **ADM** will place the direct final rule documents on the rulemaking website. **ADM** will coordinate the release of the press release with OPA and the issuance of the Congressional letters with OCA.

e. The transmittal memo to ADM should indicate, as appropriate, any places in the FRN where a date must be inserted before publication. Also note that the disk copy of the FRN should not include the concurrence page.

f. The **RGB Task Leader** prepares an Item of Interest for inclusion in the NMSS Items of Interest once the direct final rule has been published in the Federal Register.

Step 8 - Decision on Withdrawal of Direct Final Rule

In this step:

a. The **RGB Task Leader** obtains copies of any comment letters on the proposed rule and provides copies to the other WG members. Copies of the comment letters can be obtained from the ADAMS folder on the specific rulemaking or the ruleforum webpage. In addition, The **RGB Task Leader** should check with SECY to make sure that all comment letters have been obtained.

b. The **RGB Task Leader** meets with **WG** to discuss the comments. This meeting should be held within two to three weeks of the close of the comment period. The **WG** reviews the comments and makes a recommendation for consideration by IMNS, NMSS Programmatic division, and OGC management on whether any of the comments are considered significant adverse comments. The **RGB Task Leader** will prepare a summary sheet on the recommendation and schedule a meeting with management within 3 days of the WG meeting. The following criteria should be used in determining whether a comment is a significant adverse comment:

1. the comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is when:

   i. the comment causes the staff to reevaluate (or reconsider) its position or conduct additional analysis;
   ii the comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or
   ii the comment raises a relevant issue that was not previously addressed or considered by the staff.

2. the comment proposes a change or addition to the rule and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

c. **IMNS, NMSS Programmatic Division, ADM, and OGC** management meet to make the final determination on the significant adverse nature of the comments. If it is determined that there are significant adverse comments, **IMNS management** will instruct the **RGB Task Leader** to prepare a withdrawal notice for the direct final rule. If there are no significant adverse comments, the **RGB Task Leader** will prepare a confirmation notice. The rule will go into effect without further action.

d. The **RGB Task Leader** prepares the withdrawal notice or the confirmation notice for the direct final rule and provides it to the **RGB Section Leader** for concurrence. The withdrawal notice must be published in the Federal Register prior to the effective date of the rule. If withdrawn, the final rule is then prepared following Appendix C.

Attachment 1

Checklist for Contents of Direct Final Rule Package

The package contents is dependent on whether the direct final rule is to be issued by the EDO or the Commission.

Document	Commission	EDO
Commission Paper	X	
Transmittal Memo from NMSS Office Director to EDO		X
Federal Register Notice - Direct Final Rule	X	X
Federal Register Notice - Proposed Rule	X	X
Regulatory Analysis (if a separate one was prepared)	X	X
Environmental Assessment (if a separate one was prepared) or EIS	X	X
Backfit Analysis (if a separate one was prepared)	X	X
Authority statement for EDO's signature		X
Notice of Final Rule Signed by EDO		X
Weekly Report to the Commission		X
SBREFA Form	X	X
Congressional Letter (as background)	X	X
Press Release (as background)	X	X

Attachment 2

Generic Schedule for Direct Final Rules*

Action	Timeframe
Prepare Direct Final Rule Package	Time varies
Provide to RGB Section Leader for review	1 week
Provide to RGB Branch Chief for concurrence	1 week
Resolve comments	1 week
Division Briefings	
Division review and concurrence	1 week
Resolve comments	1 week
IMNS issue for Office concurrence	3 days
Office concurrence	20 days
Resolve office comments	1 - 2 weeks
RGB Branch concurrence	1 week
IMNS Division review and concurrence	1 week
NMSS concurrence	1 week
EDO approval	1 week
Package to Commission	1 week
Make SRM changes	as specified in SRM
Forward rule package to ADM	5 days or date in SRM
Publication in FR	3 weeks
Prepare an Item of Interest	Upon publication in FR
Comment Period	30 days
WG meeting on Public Comments to determine if substantive	within 2 weeks of close of comment period
WG meet with IMNS, Programmatic Division, OGC Management on whether final rule to be withdrawn	within 3 days of WG meeting
Prepare and Issue withdrawal FRN or Confirmation of effective date	2 days - Withdrawal FRN must be published prior to rule becoming effective.

Withdrawal FRN to EDO	10 days
Withdrawal FRN to ADM	1week
Publish Withdrawal FRN	1 week - Must be published before effective date
Confirmation Notice to RGB Branch Chief	1 week
Confirmation Notice to ADM for signature and publication	10 days
Publish Confirmation in FR	1 week

*Note that these timeframes are intended as guidance, each rule will have its own schedule. The timeframe will depend on the complexity of the rulemaking and on any EDO, NMSS, or IMNS tickets.

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF CERTIFICATE OF COMPLIANCE RULEMAKING PACKAGES

A. INTRODUCTION

CoCs for spent fuel storage casks are currently approved by the rulemaking process. A listing of approved casks is located in 10 CFR 72.214. Every time a new CoC or amended CoC is issued, the approval is through rulemaking. In a Staff Requirements Memorandum dated September 3, 1998, responding to SECY-98-188, the Commission approved the simplification of the CoC rulemaking process. The Commission agreed that future CoC rulemakings did not need a rulemaking plan. The Commission also gave approval to try the direct final rule approach after the solicitation of comments. The EDO signs CoC rulemakings. Currently the staff adds new casks to the list via the proposed rule approach. However, the direct final rule approach will be used for new CoCs as soon as they meet the criteria for a direct final rule approach. Amendments to existing CoCs are generally done through a direct final rule approach, however, each amendment is reviewed to make sure that it meets the criteria for a direct final rule and if it does not, a proposed rule approach is utilized. A direct final rule approach is generally used for amendments unless any one of the following conditions is met:

1. The change involves a new accident scenario.

2. The change significantly alters or implements a new method of evaluation or analysis.

3. The change causes the offsite dose consequences to be increased by 50% of the margin.

4. The change results in an increase in the frequency and likelihood of an accident previously evaluated by more than 50%.

5. The change significantly alters a design basis limit for a fission product barrier.

Certificate of Compliance (CoC) rulemakings (§ 72.214) are initiated by a user-need memo from the Spent Fuel Project Office (SFPO). SFPO issues a user-need memo indicating that a specific draft CoC will be issued by a specified date. SFPO requests that the rulemaking process be initiated and that a schedule for the rulemaking be developed. For CoC rulemakings, the process consists of preparation of the schedule and preparation and issuance of the proposed and final rules or the direct final rule. For amendments, the memo from SFPO will indicate whether a direct final rule approach can be used.

RGB has the overall responsibility for the preparation of CoC rulemaking packages. This Appendix contains information that is specific to CoC rulemakings. The basic process is the same as for other rulemakings (see Appendices B, C, and D), however the schedules are unique for CoC rulemakings and there are some differences in the processing steps. Attachment 1 contains a checklist for CoC rulemakings. Attachment 2 of this Appendix contains

the generic schedule for a CoC rulemaking to add a new cask system to the listing, and attachment 3 contains the schedule for a direct final rule.

The only other difference is in the office concurrence. For CoC amendments, CIO, OE, OCFO, and NRR do not need to concur on the package. They receive a cc copy. For new CoCs, NRR does not need to concur on the package but will be placed on the cc list. For final rules that address public comments, all offices should be placed on concurrence.

Attachment 1

Contents of CoC Rulemaking Package

The package contents is dependent on whether it is a proposed, final or direct final rule.

Document	Proposed	Final	Direct Final
Transmittal Memo from NMSS Office Director to EDO	X	X	X
Federal Register Notice - Proposed Rule	X		X
Federal Register Notice - Final Rule		X	X
Federal Register Notice - Direct Final Rule			X
Environmental Assessment	X	X	X
Authority statement for EDO's signature	X	X	X
Notice of Final Rule Signed by EDO		X	X
Weekly Report to the Commission	X		X
SBREFA Form		X	X
Congressional Letter (as background)	X	X	X
Press Release (as background, if required)	X	X	X

Attachment 2

Generic Schedule for New CoC Rulemakings*

Action	Timeframe
Receive SFPO Input	approximately 2 weeks before CoC ready
Prepare Proposed Rule Package	
Provide to RGB Section Leader for review	minus 10 days
Provide to SFPO WG Member for concurrence	minus 6 days
Provide to RGB Branch Chief for concurrence	minus 3 days
Receive CoC/SER	Day 0
RGB Branch Chief issue for office cocnurrence	Day 0
Office concurrence	1 week
Resolve office comments and RGB Branch Chief concurrence	1 week
NMSS concurrence	2 days
EDO approval	1 week
Forward proposed rule package to ADM	5 days
Publication in FR	2 weeks
Prepare an Item of Interest	Upon publication in FR
Comment Period	75 days
Resolve Public Comments	8 weeks
Provide to RGB Section Leader and SFPO Section Leaders for review	1 week to be provided in week 5 of resolution period
Provide to RGB Branch Chief for concurrence	1 week to be provided in week 8 of resolution period
Receive CoC/SER	Day 0
SFPO Division concurrence	1 week
IMNS issue for Office concurrence	1 week
Office concurrence	20 days

Resolve office comments	1 week
RGB Branch Concurrence	1 week
SFPO Division concurrence	3 days
IMNS Division concurrence	3 days
NMSS concurrence	1 week
EDO approval	1 week
Forward final rule package to ADM	5 days
Publication in FR	3 weeks
Prepare an Item of Interest	Upon publication in FR
Prepare Regulatory History	60 days

* This schedule should also be used for those amendments that do not meet the criteria for a direct final rule.

Attachment 3

Generic Schedule for Amendments to CoCs - Direct Final Rules

Action	Timeframe
Receive SFPO Input	approximately 2 weeks before CoC ready
Prepare Proposed Rule Package	
Provide to RGB Section Leader for review	minus 10 days
Provide to SFPO WG member for concurrence	minus 6 days
Provide to RGB Branch Chief for concurrence	minus 3 days
Receive CoC/SER	Day 0
RGB Branch Chief issue for Office concurrence	Day 0
Office concurrence	1 week
Resolve office comments and RGB Branch concurrence	1 week
NMSS concurrence	2 days
EDO approval	1week
Forward proposed rule package to ADM	5 days
Publication in FR	3 weeks
Prepare an Item of Interest	Upon publication in FR
Comment Period	30 days
WG meeting on Public Comments to determine if substantive	2 weeks
WG meet with IMNS, SFPO, OGC Management on whether final rule to be withdrawn	3 days
Prepare withdrawal FRN or confirmation of effective date	2 days
Withdrawal FRN to EDO	10 days
Withdrawal FRN to ADM	1week

Publish Withdrawal FRN	1 week - Must be published before the effective date
Confirmation Notice to ADM for signature and publication	10 days
Publish Confirmation in FR	1 week
Prepare Regulatory History	60 days after publication in FR

DESCRIPTION OF SPECIFIC STEPS IN PREPARATION AND REVIEW OF PETITIONS FOR RULEMAKING

A rulemaking action may be requested by submittal of a petition for rulemaking from an interested person (e.g., an individual, a private organization or company, a NRC licensee, a government agency).

Procedures for handling a petition for rulemaking are described in Part 15 of the Regulations Handbook. Part 15 draws its basis from 10 CFR 2.802 which codifies the actions that a member of the public would take, the contents of the petition, and the actions that the NRC would take to respond to the petition.

ADM has the overall responsibility in the agency for receiving petitions and tracking them. RGB has the overall responsibility in NMSS for resolving and completing action on petitions. A petition is considered to be resolved when the regulatory decision for the petition is made by deciding to grant the petition (all or in part) and proceed with a rulemaking action or by deciding to deny the petition. Other NMSS programmatic divisions and NRC offices also have responsibilities for preparation and review during the process. Attachment 1 contains a checklist for petition denial packages (granted petitions follow Appendix A for development of a rulemaking plan.)

Attachment 2 contains the generic schedule template for petitions. The paragraphs below provide a discussion as to what actions need to be taken at each step of the process by the RGB Task Leader, RGB, IMNS, and NMSS management, and staff and management in other divisions and offices.

Step 1 - Preliminary Processing

In this step:

a. ADM acknowledges receipt and reviews the petition in consultation with OGC to determine whether it meets the minimum content requirements for the NRC to find it acceptable for processing.

b. If the petition meets the minimum content requirements, ADM assigns a docket number and requests that NMSS do one of the following.

   1. Determine if the petition is suitable for "fast-track" processing. A "fast-track" petition is one where the NRC proceeds directly and promptly to initiate rulemaking. The petition is then published for comment for the first time in conjunction with the proposed rule.

   2. If the petition does not meet the criteria for fast-track processing, review and concur in a Federal Register notice to publish the petition for comment. This is the usual case.

c. Upon receipt of the ADM request, **RGB management** assigns a RGB Task Leader.

d. **RGB Management** contacts ADM for a rulemaking number and contacts the PMDA Program Analyst for a TAC number.

e. The **RGB Task Leader** makes a determination as to whether the petition is suitable for "fast-track" processing. See Section 11.15 of the Regulations Handbook for a discussion of when the "fast-track" approach is to be used. If the petition is not suitable for "fast-track" processing, the **RGB Task Leader** reviews and provides comment on the draft Federal Register notice prepared by ADM.

f. The **RGB Branch Chief** provides the recommendation on "fast-track" processing or concurs in the Federal Register notice. This is done by memo. If the recommendation is to "fast-track" the petition, the recommendation should be discussed with the **IMNS Division Director.**

g. **ADM** forwards the Federal Register notice to OFR for publication. There is a 75 day comment period.

Step 2 - "Fast-Track" Processing

In this step:

a. If the petition is approved for "fast-track" processing, **ADM** will notify the petitioner and provide the petitioner with the name of the staff contact (the RGB Task Leader).

b. **RGB** proceeds with development of a rulemaking plan. The normal rulemaking procedures apply to the rulemaking, including the use of a WG. See Appendix A.

c. In addition to normal rulemaking procedures, the following provisions apply for "fast-track" petitions:

   1. The rulemaking plan must be submitted to the Commission or to the EDO for approval within 90 days of informing ADM of the decision to adopt the "fast-track" approach.

   2. The rulemaking schedule should indicate expedited completion of the proposed and final rules.

   3. The **RGB Task Leader** should contact the petitioner at least every 6 months to advise the petitioner of the status of the petition. The status updates should be provided by letter, signed by the **RGB Branch Chief.**

4. The package containing the proposed and final rules should contain a letter to the petitioner.

5. Any discussion between the NRC staff and the petitioner regarding specific wording must occur in an open public forum.

Step 3 - Routine Processing of Petitions

In this step:

a. **RGB management**, consulting with the appropriate NMSS programmatic division and other offices, selects staff to form the WG for the petition. This is typically completed during the comment period for the petition.

b. The **RGB Task Leader** will provide copies of the petition and the comment letters to the WG members.

c. The **WG** will review the petition and the public comments and develop a recommended resolution on the petition (i.e., to grant or deny the petition).

In considering the merits of the petition, the **WG** should :

1. Review the petition, any supporting information presented by the petitioner, and the public comments received.

2. Develop an analysis of the petition that

   i. identifies each regulatory issue raised
   ii. describes the rationale for each request, including the supporting information
   iii. identifies the key points made by the commenters (can be in a summary form)
   iv. indicates how the petition supports the performance goals
   v. identifies the pros and cons of each issue and recommends a course of action

d. Once the **WG** has developed its recommended resolution, the **RGB Task Leader** will schedule a briefing for the **Petition Review Board** (PRB). The PRB consists of the NMSS Deputy Office Director, the IMNS Division Director, the NMSS Programmatic Division Director, the ADM/RDB Branch Chief, and the Assistant General Counsel for Rulemaking and Fuel Cycle. The NMSS Office Director may participate on the PRB on some petitions. The goal is to brief the PRB within 6 months after publishing the petition for comment.

e. The **RGB Task Leader**, with assistance from the **WG**, will prepare a briefing package for the PRB. The **RGB Task Leader** will conduct the briefing for the PRB. Other WG members may have the presentation lead on specific aspects of

the petition. The briefing should cover the petitioner's request and rationale, the comments received (summary), the pros and cons on each issue, and the WG recommendation on each issue. Briefing materials may be given to the PRB members in advance, if the issues are complicated.

f. The PRB will discuss the merits of the petition and vote to either grant or deny the petition or to grant or deny in part. The PRB may also refer the issue back to the WG to gather additional information. In this case the PRB would be reconvened after the WG has obtained the information. The PRB decision is considered to be the resolution of the petition. The resolution of the petition must occur within 1 year after publishing the petition for comment.

Step 4 - Granting of Petition

In this step:

a. If the PRB votes to grant the petition in whole or in part, RGB will proceed with development of a rulemaking plan. Normal rulemaking procedures apply to the rulemaking. See Appendix A.

b. In addition to the normal rulemaking procedures, the following provisions apply:

1. The rulemaking will be scheduled consistent with the NRC's PBPM process.

2. The RGB Task Leader should contact the petitioner at least every 6 months to advise the petitioner of the status of the petition. The status updates should generally be provided by letter, signed by the RGB Branch Chief. If a teleconference is held with petitioner, the RGB Task Leader should include ADM as a participant.

3. The RGB Task Leader should notify ADM of any significant actions or changes that occur during the processing of the petition.

4. The statement of considerations for the proposed rule should include a discussion of the petition and a response to any comments received on the petition.

5. The package containing the proposed and final rules should contain a letter to the petitioner. The letter would forward a copy of the proposed rule.

6. Any discussion between the NRC staff and the petitioner regarding specific wording must occur in an open public forum.

Step 5 - Deny the Petition

In this step:

a. If the **PRB** votes to deny the petition, the **RGB Task Leader**, with the assistance of the **WG**, will prepare a denial package. All petition documents should be maintained on the 'O' drive. The package should contain a transmittal letter to the EDO or a Commission Paper, the notice of denial to be published in the Federal Register, letter to the petitioner, Notice of Petition Denial Signed by EDO, and Congressional letters. It is NMSS policy to have the denial package to NMSS within 120 days of the Petition Review Board.

b. The **RGB Task Leader** provides the petition denial package to the **RGB Section Leader/Branch Chief** for review and concurrence. The **WG members** provide a copy of the draft package to their respective managements for review. If the RGB Section Leader has significant comments, the package is returned to the RGB Task Leader for resolution. Otherwise, the RGB Section Leader provides the package to the RGB Branch Chief.

c. The **RGB Task Leader** addresses any comments from the RGB Section Leader/Branch Chief and any comments received from the programmatic branch.

d. The **RGB Branch Chief** will forward the package to the NMSS programmatic Division Director for concurrence. The **NMSS programmatic Division** concurs in the package. In some cases, RGB may provide the package to the **NMSS Correspondence Analyst** for issuance of an NMSS ticket to the NMSS programmatic divisions. The **RGB Task Leader** should discuss this with **RGB Management**.

e. The **RGB Task Leader** should provide a copy of the Congressional letters, Letter to the Petitioner, and the Commission Paper or EDO memo to the **NMSS Technical Editor** (or during office concurrence).

f. The **IMNS Division Director** signs the office concurrence memo and sends the draft petition denial package to OGC and ADM for concurrence. Other offices will be included only if they were part of the WG.

g. The IMNS Division Director also provides an information copy of the package to **ACMUI, ACRS, CRGR, OIG**, and **OPA**, as appropriate, and to the **NMSS Office Director** and **NMSS Deputy Office Director**.

h. The **Offices** review the package according to their programmatic responsibilities. The **offices** should provide any comments and the office concurrence within 20 days.

i. The **RGB Task Leader** addresses the comments and prepares a revised version of the denial package.

j. The **RGB Task Leader** submits the petition denial package to the **RGB Section Leader** and **RGB Branch Chief** for final concurrence.

k. The **RGB Branch Chief** forwards the package to **IMNS** for final concurrence.

l. The package is forwarded to the **NMSS Correspondence Analyst** for NMSS Office Director concurrence.

m. The **NMSS Office Director** signs the transmittal memo forwarding the package to the EDO or concurs in the Commission Paper.

n. The rule package is sent to the **EDO**.

Any comments from the EDO, either editorial or technical, that require return of the package for changes are to be discussed with **RGB management**.

o. After concurrence by the **EDO**, the package is provided to the **Commission.** If the petition can be addressed under the EDO's authority, it is signed by the **EDO**. After the FRN and letter are signed by the EDO, they are returned to the RGB Task Leader.

p. The **RGB Task Leader** prepares a memo for the **RGB Branch Chief** to send the petition denial package to ADM, noting the date that the FRN can be forwarded to the OFR. The package should be submitted to ADM within 5 days of the EDO's signature. The package should contain the original signed FRN, 11 copies of the FRN, and a disk copy of the FRN. The package should also contain the Congressional letters, a disk copy of the Congressional letters, and the letter to the petitioner. **ADM** will forward the FRN to the OFR for publication. Upon publication in the Federal Register, ADM will place the petition denial documents on the rulemaking website. **ADM** will coordinate issuance of the Congressional letters with **OCA**.

Checklist for Contents of Petition Denial Package

The contents of a petition denial package are dependent on whether the denial can be signed under the EDO's authority or requires Commission approval.

Document	Commission	EDO
Commission Paper	X	
Transmittal Memo to the EDO		X
Letter to the Petitioner	X	X
Federal Register Notice	X	X
Notice of Petition Denial Signed by EDO		X
Congressional Letters	X	X

Attachment 2

Generic Schedule for Resolution/Closure of a Petition for Rulemaking*

Action	Timeframe
Notice of Receipt of Petition	
Public Comment Period	75 days
Formation of WG	During comment period
WG reviews petition and comments, develops recommendation	3 to 6 months
Hold Petition Review Board to resolve petition (grant petition go to Appendix A, deny petition continue)	
WG prepares denial package	4 weeks
Provide to RGB Section Leader for review	1 week
Provide to RGB Branch Chief for concurrence	1 week
Resolve comments	1 week
Division review and concurrence	1 week
Resolve comments	1 week
IMNS issue for Office concurrence	3 days
Office concurrence	20 days
Resolve office comments	1 week
RGB concurrence	1 week
IMNS Division review and concurrence	1 week
NMSS concurrence	1 week
EDO approval or signature	1 week
Package to Commission	1 week
Prepare an Item of Interest	Upon publication in FR

*Note that these timeframes are intended as guidance, each petition will have its own schedule. The timeframe will depend on the complexity of the petition and on any EDO, NMSS, or IMNS tickets. However, the agency goal is to have denied petitions resolved within 1 year of publication in the Federal Register. The INMS goal is to have all petitions resolved within 6

months of publication. If the petition is denied, the NMSS goal is have the denial package to NMSS within 120 days of the Petition Review Board.

Implementation of Proposed Revisions to Part 35 – Recognition of Board Certifications

Roger W. Broseus, CHP, Ph.D.
Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety

Commission Direction to Staff

SRM-02-0194 (Feb 12, 2003) & SRM-03-0145 (Oct 9, 2004)

- Provide for a regulatory determination that all boards meet relevant criteria
- Develop implementing procedures for adding to / removing from listing of "recognized boards"
- Staff is not to inspect boards
- Monitor trends in medical events. If due to inadequacy of training in radiation safety:
  - Assess adequacy of assessment of knowledge and skills by examinations administered by boards

2

Application for Recognition

- Boards request recognition via letter
- Information to be provided:
  - Type of use for which recognition is sought
  - Description of certification procedures / requirements
- Staff to review – compare to requirements in Subparts D-H

3

Application for Recognition (cont.)

- If questions on application:
  - Staff to notify board & request clarification; re-review
  - Consult with the ACMUI, as necessary
- If requirements not met:
  - Deny application
  - Notify board and Agreement States of basis
- If requirements are met:
  - Notify board of recognition via letter
  - Instruction to provide info to NRC if certification procedures change

4

Maintenance of Recognition

- Board to notify NRC of changes in procedures
- NRC staff to request confirmation of certification procedures every 5 years
- Review as for new application, i.e., compare to regulatory requirements
- Agreement States responsible for monitoring status of boards they recognize

5

Delisting

- Delist (withdrawal of recognition), possible reasons:
  - Changes to certification process
  - Medical trends due to inadequate training
  - Board becomes inactive or disbands
- Evaluate using procedures for review of applications
  - Contact board and ask for proposed changes to avoid delisting
  - Consult with the ACMUI

6

Listing of Recognized Certifications on the NRC's Web Site

- Name of board
- Type(s) of use for which certification is recognized
- Dates of recognition (from / to)
- Board's recertification requirement – number of years certification is valid

7

Path Forward

- Management approval of procedures
- Provide to ACMUI for review & comment
- Post to OSTP web site for Agreement State Review & comment
- Seeking input from ACMUI –
  - Are the draft procedures effective measures for oversight of board activities?
  - Undue burden on boards?

8

Procedures for Recognizing Certifications of Specialty Boards

BACKGROUND

The Commission directed the NRC staff, in SRM-02-0194, dated February 12, 2002, to prepare a proposed rule to modify the training and experience (T&E) requirements in 10 CFR Part 35 relating to the recognition of specialty board certifications by the NRC. The SRM directed the staff, as part of the rulemaking process, to discuss implementing procedures both for adding new speciality boards to the recognized listing and for removing boards from the recognized list. All boards that meet criteria for recognition are to be listed on the NRC's web site rather than in the rule itself. In SRM-03-0145, dated October 8, 2003, the Commission instructed the NRC staff to discuss its plans, in the specific situation when a medical event may have been due to inadequate radiation safety training, to assess whether the examinations adequately assess the such knowledge/skills. The procedures provided below implement the Commission's direction as specified in the SRMs.

PROCEDURES

The following procedures provide guidance to the NRC staff on how to evaluate applications from specialty boards to determine if their certification processes satisfy the requirements for recognition and posting of recognized board certifications on the NRC's web site. All boards, including those recognized under the current rule, will be required to apply for recognition so that a clear regulatory determination that all boards meet the relevant criteria in the revised regulations, as required by the Commission in SRM-02-0194. The NRC staff will request applications, via letter, from specialty boards now recognized under Subpart J of 10 CFR Part 35, for recognition of their certifications under applicable sections of Subparts B through H. The procedures also provide methods for monitoring the status of recognized board certifications and for delisting of boards, should the need arise.

Communications with Specialty Boards

Communications between the NRC staff and specialty boards should be in writing, via letter. Communications to the NRC from specialty boards for the purpose of supplying information in support of an application, change in certification procedures, or other change that would affect recognition of the board's certification under the regulations in 10 CFR Part 35, are to be signed by a person authorized to speak for the board, i.e., its chief executive officer or delegate; the letter from the board should acknowledge management's commitments to and responsibility for the completeness and accuracy of the information provided to the NRC.

Applications for Recognition of Specialty Board Certifications

1. Specialty boards requesting recognition should provide, via letter, a list of sections in Part 35 for which the board wishes to have its certification(s) recognized. The letter should include a clear description of their requirements for certification and a statement that candidates for certification must complete the requirements for training and experience required by the section(s) applicable to the type of certification, for which the board is seeking recognition, prior to receiving board certification and indicate that the letter of application should be dated and signed by the chief executive officer or delegate of the board. The board should also provide the location on the world wide web (URL), if the board posts its requirements for certification on the web. Include in letters to boards a request that boards notify the NRC, via letter, 6 months in advance, of plans for becoming inactive or disbanding as well as material changes to certification procedures that would affect their recognition status under the section of 10 CFR Part 35 that is applicable to their certification.

2. The NRC staff will review the procedures and requirements of specialty boards for conferring certifications to determine if they are in accord with the criteria established in the applicable sections of subparts B through H of 10 CFR Part 35 for NRC recognition of specialty board certifications. The requirements for recognition of a board's certification for Radiation Safety Officers (RSOs) appear in § 35.50(a), for Authorized Medical Physicists in § 35.51(a), for Authorized Nuclear Pharmacists (ANPs) in § 35.55(a), and for various classes of Authorized Users (AUs) in §§ 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a) and 35.690(a). The NRC's Advisory Committee for Medical Uses of Isotopes (ACMUI) will be consulted when the staff determines that such consultation is necessary.

3. When the NRC staff finds that a board meets an applicable set of requirements for NRC recognition, the staff will notify the board via letter of its finding and add the board's name to the list of recognized boards appearing on the NRC's web site for Part 35 matters. This information will be posted on the NRC's web site to indicate the dates for which the board's certification are recognized.

4. If the NRC staff is unable to make a determination about the adequacy of a board's certification process, or if a determination is made that the board's process does not meet the appropriate set of requirements in Part 35, the board will be notified of the NRC staff's finding and requested to provide additional information or clarifications, in writing. The NRC staff will review the additional information provided by the board and make a determination as noted in 2, above.

5. If the NRC determines that a board's certification processes do not meet the applicable criteria in Part 35, the NRC will notify the board, via letter, and Agreement States of the name of the board and the date of this determination.

6. Agreement States may recognize the certifications of boards that meet requirements of rules compatible with those in 10 CFR Part 35. These boards will be included in the

listing of recognized boards on the NRC's web site, with an annotation indicating which Agreement States recognized the boards.

Maintenance of Recognized Status

1. When the NRC recognizes a board's certification process(es) and notifies it that its name will be listed on the NRC's web site, the board will also be advised that the board is to notify the NRC, via letter, 6 months in advance, of plans for material changes to certification procedures that would affect its recognition status under the section of 10 CFR Part 35 that is applicable to its certification(s). (See item 1 under "Applications for Recognition of Specialty Board Certifications.")

2. The NRC staff will review the changes to certification process(es), using the procedures outlined above (under "Applications for Recognition of Specialty Board Certifications") and will seek the advice of the ACMUI if the staff determines that such consultation is necessary. The NRC staff will determine if the board's certification procedures continue to meet the criteria for recognition of board certifications, as established in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a), and notify the board regarding its finding.

3. The NRC staff will periodically, at intervals not to exceed 5 years, ask, via letter, each board whose certification process(es) has (have) been recognized by the Commission, to verify in writing that all changes in its certification procedures, that would affect the recognition of its certification(s), have been communicated to the NRC for review. If a board does not respond, the NRC staff will investigate why and delist the board.

4. The Agreement State which initially recognizes a board will be responsible for determining that board's continued eligibility for recognition.

Procedures for Delisting Specialty Boards

1. Delisting based on inadequate radiation safety training of candidates for certification.

   a. The NRC staff will monitor trends in medical events. If a trend in medical events for a particular speciality is attributable to inadequate radiation safety training, the staff will determine, in consultation with the ACMUI, if the trend is associated with a deficiency in the training of individuals traceable to inadequacies in a specialty board's certification process. If the trend is determined to be attributable to inadequate training related to the certification process, the NRC staff will assess whether the examinations provided by the certifying boards adequately assess the knowledge/skills reflected in the requirements for T&E related to recognition of specialty board certifications.

b. If the NRC staff determines that changes in training required of candidates for certification by a recognized specialty board are necessary in order for the board to maintain its recognized status, the board will be contacted and advised of this determination. The NRC staff will send a request to the board to provide a description of any changes it proposes to make to maintain its recognition by the NRC and to identify reasons for findings the board disagrees with. The NRC staff will use the procedures discussed under "Applications for Recognition of Specialty Board Certifications," item 1, as a guide in this process.

c. In the event that the board fails to respond or if, after reviewing the board's response, the NRC still believes that changes to certification requirements are necessary and the specialty board does not make changes to its requirements for certification that are considered adequate to address the NRC's concerns, then that specialty board's name will be removed from the NRC's list of recognized boards.

d. The Commission and the ACMUI will be informed of any decision by the NRC staff to remove a board's name from the list of recognized boards.

e. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.

f. If a board is delisted by the NRC or an Agreement State due to inadequacy of its certification process requirements, the NRC staff will determine the date when the inadequacy developed, beyond which the certification will no longer be recognized.

g. When a board is granted recognition by an Agreement State, that State shall be responsible for delisting that board.

2. Delisting based on change in the certification process.

a. If the NRC staff, in reviewing an instituted or proposed change in the certification process employed by a recognized board, determines, in consultation with the ACMUI, that the change may adversely affect the recognized status of the board, the board will be contacted and advised of this determination. The board will be requested to provide information to support continuation of NRC recognition of the board's certification.

b. In the event that the board fails to respond or if, after reviewing the board's response, the NRC staff still believes that the change in the board's certification process may adversely affect the recognized status of the board and the specialty board does not make adjustments to its certification process that are considered

adequate to address the NRC's concerns, then that specialty board's name will be removed from the NRC's list of recognized boards.

c. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.

d. The Commission and the ACMUI will be informed of an NRC staff determination that a board is to be removed from the list of recognized boards.

e. If a board is delisted by the NRC or an Agreement State due to inadequacy of its certification process requirements, the NRC staff will determine the date when the inadequacy developed, beyond which the certification will no longer be recognized.

f. When a board is granted recognition by an Agreement State, that State shall be responsible for delisting that board.

3. Delisting based on a recognized board becoming inactive or disbanding.

a. If the NRC staff becomes aware that a board has or intends to become inactive or disband, the staff will attempt to contact the board. The NRC staff will request that the board provide information confirming whether the board has, or intends to, become inactive or disband, and if so, why the change should not result in withdrawal of NRC recognition of the board's certification.

b. In the event that the board fails to respond or if, after reviewing the board's response, the NRC still believes, after consulting with the ACMUI, that the board has changed its status and that this change should result in withdrawal of the NRC's recognition of the board's certification, then that specialty board's name will be removed from the NRC's list of recognized board certifications. Information about the dates for which the board's certification was recognized will be posted on the NRC's web site.

c. The Commission and the ACMUI will be informed of any staff decision to remove a board's name from the list of recognized boards.

d. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.

e. If a board is delisted by the NRC or an Agreement State due to becoming inactive or disbanding, the NRC staff will determine the effective date of this change in status and the date when the certification is no longer to be recognized.

f. When a board is granted recognition by an Agreement State, that State shall be responsible for monitoring the status of the boards and taking action to de-list a board's certification if it becomes inactive or disbands.

Evaluation of Training and Experience — "Outdated" Certifications

If an individual holds certification from a board for which the NRC or an Agreement State withdraws recognition, the certification will be considered valid if it was granted before the board's certification process is determined to be inadequate for recognition of the board's certifications by the NRC. The NRC will annotate the listing of boards on its web site to indicate the effective dates of recognition of board certifications, including the date(s) of delisting and date(s) through which certifications were recognized. The listing will also indicate the length(s) of time for which the board certifications are valid. (Note: the recentness of training requirements contained in 10 CFR 35.59 must also be satisfied.)

Possible Licensee Implications Associated with the Training and Experience Recommendations in SECY 03-0145

Richard J. Vetter, Ph.D., CHP
November 12, 2003

Primary Issue: Requirement for a preceptor statement that certifies competency of the individual who is applying for authorized status (AU, AMP, ANP, RSO).

- Applied to qualification of boards
- Applied to alternate pathway

Primary Concern: Boards typically require letters of recommendation but do not require certification of competency to practice.

ACMUI Recommendation: Eliminate requirement for preceptor statement to condition boards. Alternatively, "decouple" preceptor requirement from criteria for recognition of boards as well as alternate pathway and place responsibility for obtaining a preceptor statement upon the individual seeking authorized status.

NRC Staff Response: Staff agreed (ACMUI teleconference of July 17, 2003) to provide recommendation to the Commission.

Commission Response: Approved alternate recommendation to "decouple" preceptor statement from criteria to recognize boards and to place requirement on the individual.

Possible Implications of proposed requirement for preceptor statement:

- Philosophical: various views
  - Preceptor statement is needed to assure that anyone who attends courses or passes boards has the functional knowledge to perform the job safely,
  - Neutral, i.e. not a problem,
  - Does not improve safety or guarantee that candidate has sufficient knowledge to perform job safely.
  - Board certification verifies that a person is qualified; a preceptor statement does not.
  - Authorized individuals may receive subtle or overt pressure to sign a preceptor statement for all graduates of a program, i.e. rubber stamp.
- Pragmatic
  - Licensees cannot allow a board certified individual, e.g. physician, to practice until preceptor statement is received, even if the individual has been approved by the hospital credentialling committee.
  - Preceptors who perceive additional liability may be reluctant to sign.
  - What to do if preceptor is not available, e.g. physician trained 3 years ago and preceptor has since died?
  - What to do if preceptor refuses to sign due to personality issues?
  - Perceived as nuisance due to additional paper work.
- Questions for Guidance Space
  - Preceptor may be many different people; thus examples must be given:
    - director of residency training program vs. AU;
    - supervising physician, physicist or RSO who provided on-the-job training and experience for multiple uses or a single type of use;
    - vendor who installed or demonstrated new type of use.

- Clarify that current authorized individuals remain authorized for up to 7 years if they change jobs or if they give up their authorized status and want it back later; thus, they do not need a preceptor statement. Examples:
  - medical RSO becomes RSO at a non-medical university for 6 years and wants to move back to a medical RSO job;
  - radiologist approved for 35.200 moved to a new practice where nuclear medicine is not practiced and after 5 years wants to initiate a nuclear medicine practice.
- Define requirements for individuals to become "reauthorized" if they left their practice more than 7 years ago; do they need a new preceptor statement? What additional training and experience do they need?
- Define options for individuals who cannot obtain a preceptor statement. Examples:
  - RSO at hospital dies; hospital wants to appoint Associate RSO as the RSO, but there is no preceptor statement.
  - Preceptor unavailable (e.g. death) cannot sign that a physician participated in treatment of 10 hyperthyroid patients.
  - Authorized individual is fired by hospital and refuses to sign any preceptor statements for current graduating trainees.
- Define requirements for current authorized individuals who want to add another type of use.
- Provide preceptor form that can be completed and signed by preceptor, i.e. institutionalize the preceptor statement for each type of authorized individual or provide a single generic form.

Examples:

- Ray D. Yates, CHP, has been RSO at Frog Holler Medical Center for 10 years. Thus, he qualifies as RSO under 35.57. He and his boss disagree over budgeting issues. Ray leaves disgruntled and his boss is glad he left. Ray consults for 8 years and then gets an RSO job at Benzene Cancer Center. His former employer refuses to sign a preceptor statement.

- Mary Maple, recent CHP, is the Associate RSO at State University Medical Center. The RSO died unexpectedly, and the President of SUMC wants to hire Mary as the RSO but there is no preceptor statement to qualify her.

- Rex Reis, Ph.D., DABR, DABMP, has been the medical physicist at Mel and Noma Radiation Oncology Clinic for 5 years where he has provided medical physics services for clinical linear accelerators and brachytherapy. Mel and Noma decide to acquire a Gamma Knife. What does Dr. Reis need to do to be the AMP for the gamma stereotactic radiosurgery unit?

- Annie Anderson, M.D. completed her residency in Radiology, which included a 3-month rotation in Nuclear Medicine, and she passed the ABR exam in Diagnostic Radiology. Five years later, she joins a practice that includes Nuclear Medicine. Her residency preceptor has retired, and they can't track him down, so she can't provide a preceptor statement.

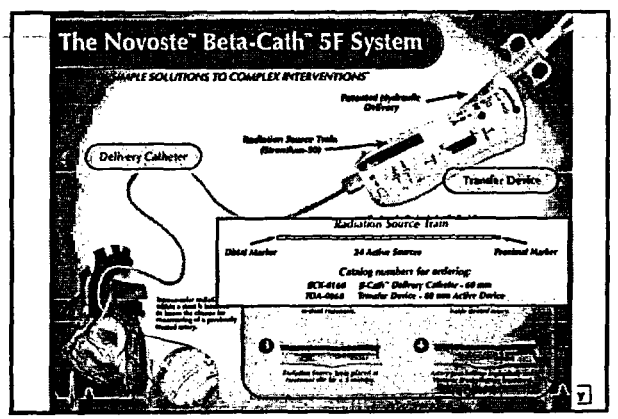
Analysis of NMED reports for Novoste Intravascular Treatment Systems

Jeffrey F. Williamson, Ph.D.

VCU Radiation Oncology Physics

System Description

- Novoste Beta-Cath and Beta-Rail Systems
  - Hand held afterloading device hydraulically propels train 12-16 Sr-90 pellets from device to tip of treatment catheter
- Beta-Cath system: introduced 1998
  - 5 F (1.6 mm OD) triple lumen catheter
  - Still marketed
- Beta-Rail system: introduced late 2002?
  - 3.5 F (1.1 mm OD) double lumen catheter
  - Engineering improvements address many types of NMED incidents



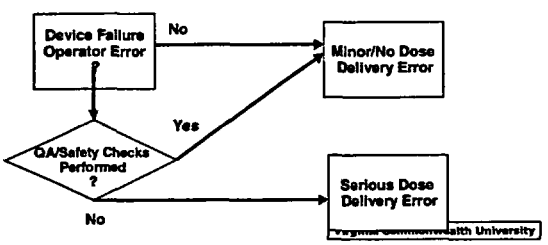
Novoste System Limitations

- Positive pressure must be exerted via syringe for sources to remain fixed in either treatment position or in retracted position
  - Failure: sources will move under influence of gravity
    - 8F sources and markers can separate
- In contrast to cable-driven source
  - No automated measurement of source position
    - Operator MUST verify source location fluoroscopically and have reasonable eye-hand coordination
  - OD source ≈ ID catheter ⇒ Mobility sensitive to catheter deformation

Virginia Commonwealth University

Williamson's event analysis model

- Primary Cause: Device failure or initial operator error that leads to dose error
- Secondary Cause: Omission of QA check that would have caught primary error



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Major Types of Primary Causes

- Failure of sources to reach treatment position
  - Loss of positive pressure
    - User errors: fumbling with second syringe etc
    - Leaking seals: design problem
    - O-ring fragments, screws, etc., in hydraulic system
  - Catheter kinking/crimping
    - Touhy-Bourst valve too tight
    - Catheter (especially 3.5 F) damaged during shipping, unpacking, or insertion
    - Underlying causes: T-B valve inadequacy + excessively fragile catheters + rough handling

Virginia Commonwealth University

Example: O-ring damage

Virginia Commonwealth University

Major Types of Primary Causes

- Source retraction failure
  - Positive pressure loss
  - Kinking
- Incorrect treatment calculation
  - Vendor calibration error
  - Stop watch incorrectly set
- Loss of source train integrity (seeds drift apart)
  - Positive pressure loss
  - Kinking

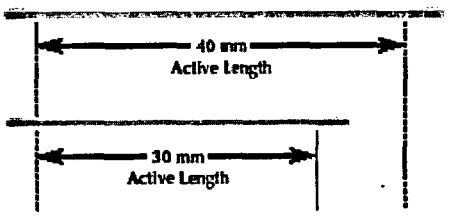
Virginia Commonwealth University

Major types of 'Errors' and their Primary/Secondary Causes

- Large dose to wrong site
  - Kinking (P) & no fluoro localization (S)
  - *On retraction {Kinking (P) OR Pressure loss (P)} &* untimely emergency response
  - Pressure loss/source drift/separation (P) & no fluoro localization (S)
- Over or underdose to treatment site
  - *Initial calc/cal error (P) + Inadequate check (S)*
  - Untimely retraction due to {Kinking (P) OR Pressure loss (P)} & untimely emergency response

Virginia Commonwealth University

Fluoroscopic Localization



Major types of 'Errors' and their Primary/Secondary Causes

- Loss of source control upon retraction
  - (Indicator light OK & source drift) (P) + failure to visualize sources before shutting gate & disconnecting catheter (S)
  - Sources jam in gate (P) & disconnecting catheter (S)

Ideal QA Program

- Verify calibration/labeling of all sources
- Double check each treatment time calculation and timer setting
- Equipment checks
  - Prior to insertion, test run with treatment catheter and source RAL (Test for leaking, damaged catheter, and malfunctioning RAL)
  - After catheter insertion: perform test run with dummy RAL (Test for fluoro localizability and catheter damage during insertion)

Ideal QA Program

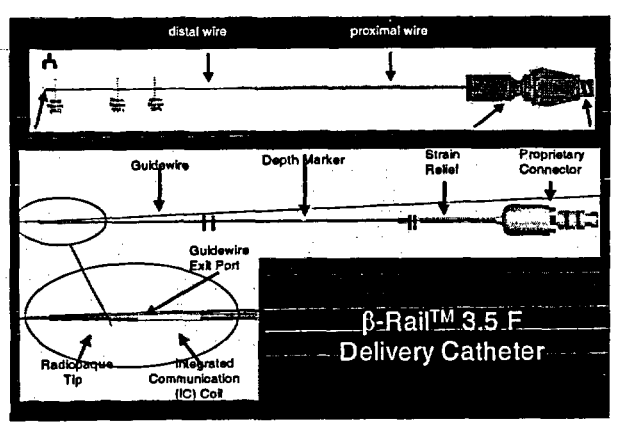
- During treatment
  - Initial fluoroscopic localization is ESSENTIAL!
  - Verify source positioning every 30 sec.
  - Ensure positive pressure maintained + extra syringe connected
  - Use T-B protector sleeve if possible
- During/After retraction
  - Maintain positive pressure until gate closed
  - Visually count sources before closing gate
  - Don't disconnect catheter if sources don't return
  - Survey with thin window instrument

Virginia Commonwealth University

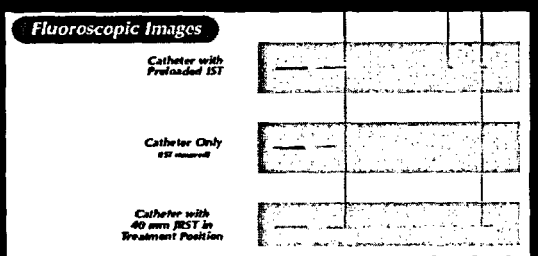
Recent "Beta-Rail" Improvements

- 3.5 f catheter inserted into patient with "dummy source train" in place
  - Perhaps reduces kinks
  - Permits radiographic confirmation before Sr-90 ejected
- Sr-90 pellets encapsulated in steel spring
  - Can't separate or fool source retraction detector
- Plumbing improved: fewer leaks
- Remaining primary causes
  - Catheter deformation by T-B valve
  - Dummy source train prevents on-site testing of catheter
  - Catheter kinking??

Virginia Commonwealth University



3.5F Beta-Cath System
Fluoroscopy Images



Conclusions

- Beta-Cath has ≈10-fold higher reportable event rate (10^{-3}) than other byproduct modalities reflecting higher rate of primary failures
- Most primary failures can be detected by meticulous technique, adequate QA and training
  - Users must adapt their implementation and QA programs to potential error pathways
  - Successful management of primary failures will result in small, clinically insignificant dose errors
- Design improvements to the 3.5 F system may reduce primary failure rate significantly

Virginia Commonwealth University

DR. NAG'S REVIEW OF NOVOSTE EVENTS

To: NRC and ACMUI:

Let me start the ball rolling so this can be a starting point for discussion. The following are my personal views. I have used several intravascular brachytherapy systems, but not the Novoste since I did not feel I could rely on its design.

The Novoste system is very convenient as it is small, hand-held and uses a beta source, obviating the need for shielding. The system relies on hydraulic pressure from saline to move a number of Strontium sources. Unlike the other intravascular systems where the source is (or sources are) physically attached to a wire, in the Novoste system there is no physical attachment. Herein lies the weakness of the system. If there is even a mild resistance, narrowing or obstruction of the catheter, the saline is able to flow but not the sources. In a tortuous vessel like those in the coronary system, the catheter will not be straight and the curvatures in the catheter will introduce resistance to flow. This can (and does) result in the following:

1. The sources may not reach the end of the catheter (site of intended radiation) hence irradiating a segment of the vessel proximal to the intended site.

2. After reaching the site of irradiation, the sources may not be able to return back to the Novoste system. This can result in increased radiation of the treatment site or irradiation of vessel site proximal to the target.

3. The sources may break up, rather than travelling together end-to-end hence irradiation sites proximal to the target and not irradiating the target.

The commonality and the root cause of most of the events is the design of the Novoste system whereby there is no direct attachment between the sources themselves and between the sources and the force moving the sources.

The ACMUI will have to discusss whether incidence of medical events (misadminstrations) with the Novoste is acceptable or whether Novoste will have to change its design so that the sources are physically held together and physically attached to a wire (or similar device) that will be able to exert a force to move the sources reliably in either direction within the catheter.

Thanks for allowing me to express my thoughts.

DR. DIAMOND'S NOVOSTE REVIEW

ACMUI Colleagues:
As a preface to my remarks I note that 1) I have reviewed the Novoste event data, and 2) that I have had extensive personal experience with least 2 iterations of the Novoste device, as well as with the two other commercially available intravascular brachytherapy systems.

I myself have experienced no events with the Novoste system.

I believe the root cause for these reported events derives from a design which relies on hydraulic pressure to propel a series of small, unconnected solid sources anterograde and retrograde through the catheter system. As such, perterbations which produce transient loss of positive hydraulic pressure (including loss of hydraulic fluid, catheter kinking, or catheter obstruction) may cause the seeds to not reach their desired distal dwell position, migrate from their desired dwell positions during treatment, or impair them from returning to the source delivery unit at the conclusion of treatment.

A secondary root cause for these events would include the failure of operators to quickly identify inappropriate seed positioning. This failure could be the result of operator inexperience (both AU and interventional cardiologist), suboptimal fluoroscopic/cine imaging capabilities, and a distal/proximal "marker seed" design which can at times be difficult to distinguish from the interposed therapeutic sources.

My thoughts, therefore, generally parallel those of Dr. Nag's from his memo of October 8, 2003.

The ACMUI will need to deliberate whether the current rate of new Novoste events (keeping in mind that many--but not all--of these events pose no threat to patient safety) mandates a design change, or whether this goal can be met through better education regarding the secondary root causes.

David Diamond, MD
Member, ACMUI

Agenda Topic: SeedSelectron and 35.1000

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

November 2003
ACMUI Meeting

Donna-Beth Howe, Ph.D.

1

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Nucletron seedSelectron® System,

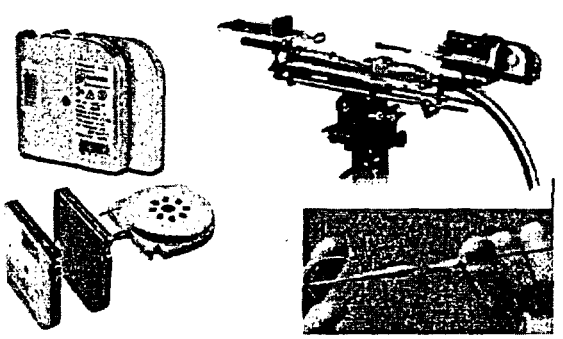
Isotron brachtherapy sources, and

Nucletron FIRST™ System

2

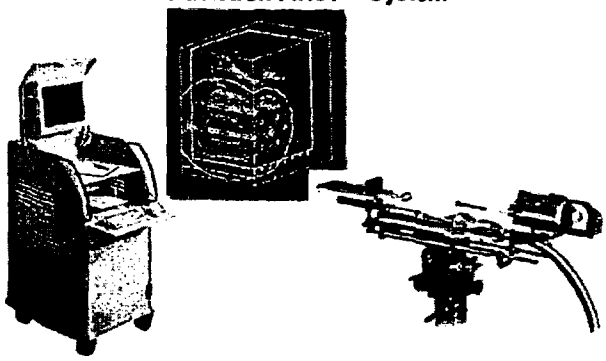
Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Nucletron seedSelectron®



Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Nucletron FIRST™ System



Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

The authorized user,

(1) 10 CFR 35.490 or 35.940 with work experience in remote-afterloading brachytherapy, or

(2) 10 CFR 35.690 or 35.960 with work experience in manual brachytherapy

5

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

The permanent implant low dose-rate remote afterloader medical physicists

(1) AMP with work experience in manual brachytherapy, or
(2) Board certified with work experience in manual brachytherapy and full calibration measurements and periodic spot-checks for low dose remote afterloader units, or
(3) Alternate pathway with work experience in manual brachytherapy and full calibration measurements and periodic spot-checks for low dose remote afterloader units.

6

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Radiation Safety Program Elements

(1) Permanent implant brachytherapy source use and low dose remote afterloader use in Part 35, Subpart A, "General Information," Subpart B, "General Administrative Requirements," and Subpart C, "General Technical Requirements"

(2) Except: define "completion of the procedure" in the written directive; and request authorization for revisions to conform to changes in the NRC website licensing guidance.

7

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Radiation Safety Precautions and Instructions

(1) Permanent implant brachytherapy requirements;
(2) Low dose remote after loader unit requirements;
(3) Securing the treatment room - conforming - 35.610(a)(1);
(4) Physical Presence - conforming - 35.615(f));
(5) Full calibration measurements requirements - conforming - 35.633)
(6) Periodic spot-checks for remote afterloader units - conforming -35.643

8

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Permanent implant brachytherapy requirements

35.404(a) and (c) and 35.2404

35.406 (a) and (c) and 35.2406(a) and (c)

35.410 and 35.3045

35.415

35.432

35.457 (for manually transferring treatment delivery parameters from the treatment planning system)

35.3045

8a

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Low dose remote after loader unit requirements

36.600,

35.605, and 35.2605,

35.610,

35.615(a) and (e);

35.657 (when using the FIRST System or other system electronically transferring treatment delivery parameters to the treatment delivery system from the treatment planning system),

35.3045

8b

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

(1) Securing the treatment room - will secure the treatment room when the Nucletron SeedSelectron® brachytherapy seed are present. (conforming change for 35.610(a)(1))

(2) Physical Presence - an permanent implant low dose remote afterloader medical physicists and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit will be physically present during the implantation. (conforming change for 35.615(f))

8c

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

Will be performed on each unit--

(a) Before the first medical use of the unit;

(b) Before medical use following reinstallation of the unit in a new location outside the facility; and following any repair of the unit that includes major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding 1 year

8d

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

(b) Will include determination of:
(1) Calibration measurements of brachytherapy sources described in 10 CFR 35.432
(2) Source positioning accuracy to within ±1 millimeter;
(3) Length of the source transfer tubes;
(4) Length of the applicators; and
(5) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
(c) The full calibration measurements required will be made in accordance with published protocols accepted by nationally recognized bodies.
(d) In addition to the full calibration, an autoradiograph of the source(s) will be performed to verify inventory and source(s) arrangement.

8e

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

(e) Measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (d) of this section may be used.
(f) Mathematical correction will be made of the outputs for physical decay at intervals consistent with 1 percent physical decay.
(g) Full calibration measurements and physical decay corrections will be performed by the authorized low dose-rate remote afterloader medical physicist, unless provided by the manufacturer in accordance with paragraph (e).
(h) A record of each calibration will be retained in accordance with §§ 35.2632.

8f

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Periodic spot-checks for remote afterloader units

(a) Spot-checks will be performed of each remote low dose-rate afterloader facility and on each unit before each patient treatment

(b) The measurements necessary for the periodic spot checks will be performed in accordance with written procedures established by the authorized permanent implant low dose-rate remote afterloader medical physicist. This individual does not need to actually perform the spot check measurements.

(c) the authorized permanent implant low dose-rate remote afterloader medical physicist will review the results of each spot-check within 15 days and notify the licensee as soon as possible in writing of the results of each spot-check.

8g

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Periodic spot-checks for remote afterloader units

(d) the spot-checks will, at a minimum, assure proper operation of--
(1) Source exposure indicator lights on the remote afterloader unit, and on the control console;
(2) Emergency response equipment;
(3) Radiation monitors used to indicate the source position;
(4) Clock (date and time) in the unit computer or the treatment planning computer;
(5) decayed source(s) activity in the unit's computer or treatment planning computer after each source installation.

(e) If the results of the spot checks indicate the malfunction of any system, the system will be secured and not used except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A record of each check and a copy of the procedures used for the spot check will be retained in accordance with §§ 35.2643. 8h

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Procedures for Administrations Requiring Written Directives:

To confirm the treatment site for each administration is in accordance with the treatment site in each written directive, consider developing procedures for the following (conforming expansion of § 35.41(a)(2)):

1. To assure the specifications for the ultrasound imaging system, ultrasound probe, and ultrasound operational software are compatible with the Nucletron SeedSelectron® system.
2. To assure that the ultrasound probe is properly positioned to provide an appropriate view of the treatment area, and
3. To assure that the ultrasound imaging system is properly functioning to provide appropriate imaging of the treatment area and the implanted seeds. 9

Agenda Topic: Update: Listing Sources by Model/Serial Number on Licenses

Potential 10 CFR Part 35 Rulemaking

November 2003
ACMUI Meeting

Donna-Beth Howe, Ph.D.

1

Potential 10 CFR Part 35 Rulemaking

10 CFR 30.32 requires an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source either (1) identify the source or device by manufacturer and model number as registered with the Commission under §§32.210 of this chapter or with an Agreement State; or (2) contain the information identified in §§32.210(c).

Recommend revising §35.13, "License Amendments," and 35.14, "Notifications,"

Permit licensee flexibility when obtaining sealed sources from a new manufacturer or new model of sealed sources from a manufacturer listed on the license for an existing medical use.

NRC provided required information.

2

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.49 (b) permits a licensee to use sealed sources or devices non-commercially transferred from a Part 35 licensee.

Recommend revision to 10 CFR 35.49(b) ... "sealed sources or devices non-commercially transferred from a Part 35 or equivalent Agreement State medical use licensee.

3

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.65(b) permits the redistribution of sealed sources, not exceeding 1.11 Gbq (30mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original package and shielding and accompanied by the manufacturer's approved instructions.

Revise the requirement to clarify this license is authorized to redistribute under a § 32.74 or equivalent Agreement State license authorization.

4

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.65(b) permits the redistribution of sealed sources, not exceeding 1.11 Gbq (30mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter, providing the redistributed sealed sources are in the original package and shielding and accompanied by the manufacturer's approved instructions.

Recommend revision to 10 CFR 35.65(b)

...authorized to redistribute the sealed sources manufactured and distributed by a person licensed under §§ 32.74 of this chapter or equivalent agreement state regulations, ...

5

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.655(a) requires a licensee to have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

Recommend decoupling the 5 year requirement from the gamma-knife full inspection and servicing and require the full inspection and servicing at source exchange.

6

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.40(b)(6) requires written directives for all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) Before implantation: treatment site, the radionuclide, and dose; and (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Recommend 10 CFR 35.40(b)(6) be revised to decouple permanent implants from temporary implants and that "before completion of the procedure" be defined for permanent implants.

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.40(c) permits a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

Revise 10 CFR 35.40(c) to reduce ambiguity of whether the physician can revised a procedure that would not be delivered in fractions to include a fraction when an error is discovered during a permanent implant.

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.3045 (a)(2)requires a liensee report a medical event for A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any an administration of a wrong radioactive drug containing byproduct material.

Recommend the requirements for reporting a medical event include wrong radioisotope for a brachytherapy procedures.

Since June 16, 2003, Guthrie Healthcare System has reported a total of 21 medical events that occurred at their facility between January 2001 and January 2002 during the implant of iodine-125 seeds for treatment of prostate cancer. On September 15, 2003, the licensee submitted a report which included a review of the dosimetry from these treatments. Because the dose is prescribed to the entire prostate gland, rather than to a point, and the dose to any point within the prostate volume is determined by the distribution of the iodine-125 seeds, the licensee evaluated the treatments by determining the percentage of the prostate volume that received at least 100% of the prescribed dose (V100) and used the 20% value referenced in the definition of a misadministration in 10 CFR 35.2 (currently described in 10 CFR 35.3045) to establish the threshold for a medical event at a V100 of 80%. The licensee's decision was based on their interpretation of NRC regulations. As noted in Column 3 of the table below, the V100 values for the 21 medical events reported ranged from 0 to 73.3%.

We question the licensee's use of "80% V100" as a criterion for identifying a medical event. As described below, nationally recognized experts in brachytherapy have established less restrictive, and possibly more realistic, criteria for judging the adequacy of a treatment. We are concerned that the licensee, by reporting these 21 events and potentially more events where the results might be closer to that which was intended, will cause many other licensees to report a large number of medical events which would not be necessary unless the "80% V100" criterion for identifying medical events is correct guidance on how to evaluate these treatments. We ask for guidance on how to evaluate these treatments.

AAPM Task Group 64, in their review of permanent prostate seed implant brachytherapy, states, "For dosimetric evaluation performed at the optimum imaging time [approximately 4 weeks post-implant for I-125], it is recommended to use D90 in comparison to the prescribed dose, as an indicator of implant quality in dose coverage." D90 is the dose received by at least 90% of the prostate volume. We have documented the D90 values for each patient in Column 4 of the table. The D90 values range from 11.52% to 70.7% of the prescribed dose. If we considered 80% of the prescribed dose to be an acceptable D90, all of the events reported by Guthrie thus far would still be reported.

The federally-funded Radiation Therapy Oncology Group (RTOG), which runs clinical trials and establishes criteria for entry into the trials, established, for iodine-125 prostate implants, that greater than or equal to 80% of the prostate volume receive at least 90% of the prescribed dose. This is the same as saying V90 is greater than or equal to 80%. Using this criteria, a few of the medical events reported by Guthrie get close to falling out but the number of medical events is not reduced. Note: The RTOG recognizes, as acceptable variation, when 50% or more of the prostate volume receives at least 90% of the prescribed dose. This is the same as saying V90 is greater than or equal to 50%. If this were the criteria for a medical event, 13 of the 21 medical events reported by Guthrie would no longer be considered medical events.

Also of note, Pro-Qura, a program of the Seattle Prostate Institute that provides independent evaluations of the quality of prostate implants, including feedback for technique improvement, recognizes the inherent difficulty in performing seed implants and established a standard that 80% of a radiation oncologist's treatments have V100s exceeding 75 to 80%, depending on the timing of post implant CT images.

Event #	Patient #	V100 (% of prostate volume receiving at least 100% of the prescribed dose)	D90 (dose received by at least 90% of the prostate volume expressed as a % of the prescribed dose)	V90 (% of prostate volume receiving at least 90% of the prescribed dose)
1	093952	0	11.52%	0
2	270315	23.6%	24.9%	27%
3	756460	30.7%	32%	35.4%
4	278805	18.8%	21.4%	22.4%
5	332613	45.4%	39%	49.3%
6	041678	36.9%	34.8%	44.3%
7	584964	29%	22.4%	31.8%
8	665986	59.5%	54.8%	72%
9	037003	52.5%	38.4%	57%
10	190760	39.3%	47.1%	45.4%
11	245500	62.2%	42.9%	65.4%
12	438183	69.9%	68.2%	79.1%
13	068409	49.2%	47.9%	55.7%
14	468957	67.8%	60%	73.7%
15	551595	58.6%	43.9%	63.7%
16	717059	72.9%	70.7%	78.4%
17	319381	67.7%	64%	73%
18	882208	54%	43.7%	59.1%
19	976182	73.3%	63.7%	77.7%
20	127970	72.5%	63.6%	78.2%
21	050004	66.7%	61.8%	72.8%

Emerging Technologies

November 2003
ACMUI Meeting

Donna-Beth Howe, Ph.D.

Emerging Technologies

Radiation Safety Program Changes for
10 CFR 35.1000 medical uses

Problem:

The NRC website licensing guidance for specific 10 CFR 35.1000 medical uses may be revised as additional experience is gained but 10 CFR 35.26 cannot be used to revise the radiation safety program when the elements are authorized by license conditions.

Emerging Technologies

Radiation Safety Program Changes for
10 CFR 35.1000 medical uses

Solution:

Preauthorize licensees to make changes to their 10 CFR 35.1000 medical use radiation safety program with the flexibilities provided in 10 CFR 35.26 if the changes are to bring the program into conformance with revised website licensing guidance and certain other conditions are met.

Emerging Technologies

Radiation Safety Program Changes for
10 CFR 35.1000 medical uses

Request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

(1) the revision is in compliance with the regulations;
(2) the revision is based upon NRC's current guidance for the ---------- 35.1000 use posted on the NRC website;
(3) the revision has been reviewed and approved by the licensee's RSO and licensee's management;
(4) the affected individuals are instructed on the revised program before the change is implemented;
(5) the licensee will retain a record of each change for 5 years; and
(6) the record will include a copy of the appropriate web site guidance, the old procedure, the new procedure, the effective date of the change, the signature of the licensee management that reviewed and approved the change.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

November 2003
ACMUI Meeting

Donna-Beth Howe, Ph.D.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

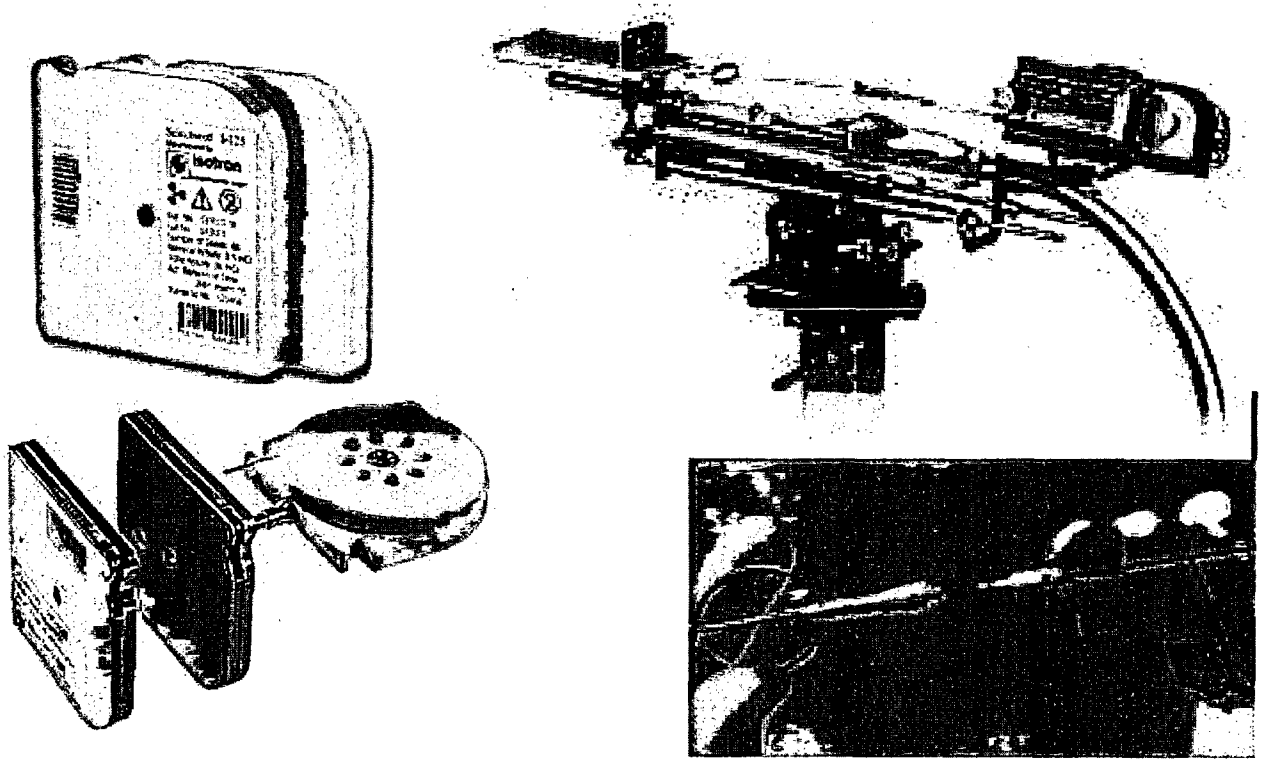
Nucletron seedSelectron® System,

Isotron brachytherapy sources, and

Nucletron FIRST™ System

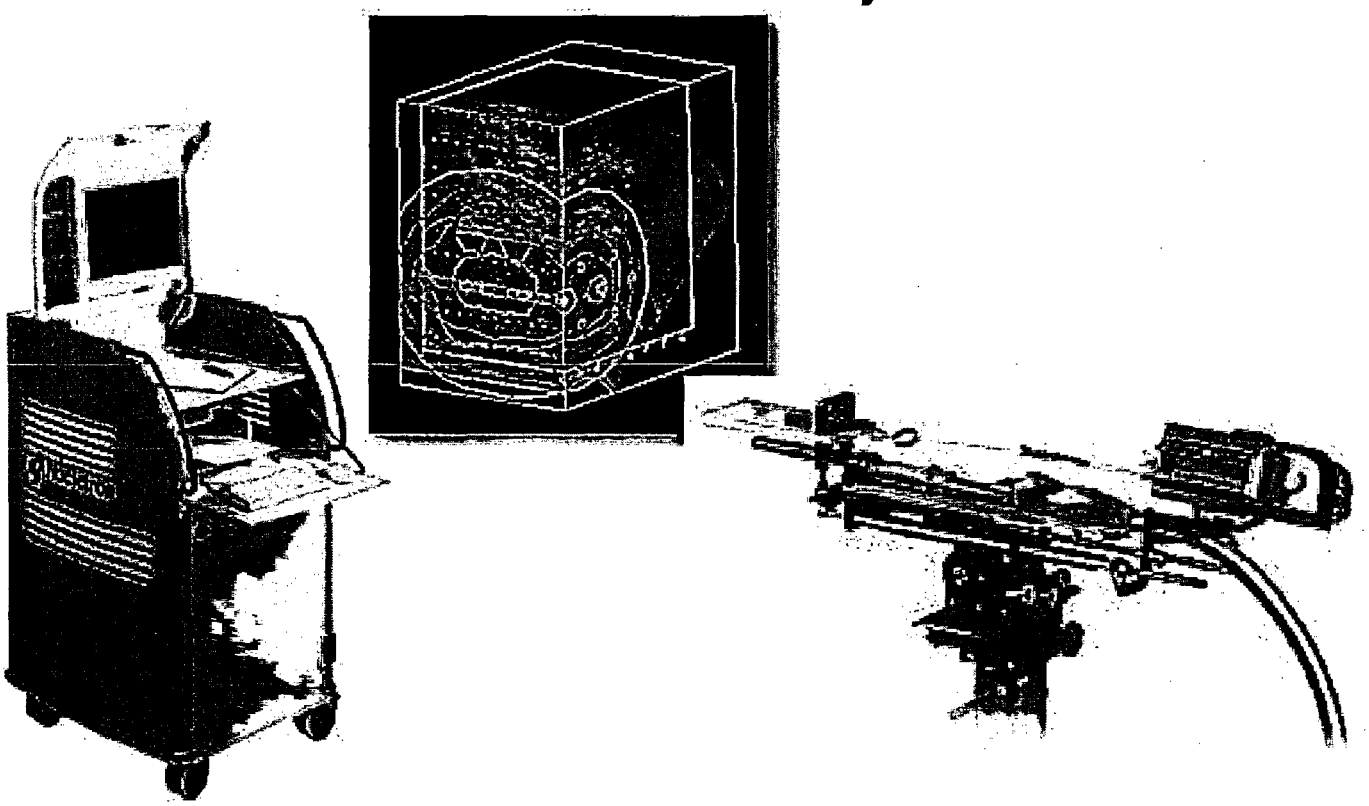
Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Nucletron seedSelectron®



Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Nucletron FIRST™ System



Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

The authorized user,

(1) 10 CFR 35.490 or 35.940 with work experience in remote-afterloading brachytherapy, or

(2) 10 CFR 35.690 or 35.960 with work experience in manual brachytherapy

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

The permanent implant low dose-rate remote afterloader medical physicists

(1) AMP with work experience in manual brachytherapy, or
(2) Board certified with work experience in manual brachytherapy and full calibration measurements and periodic spot-checks for low dose remote afterloader units, or
(3) Alternate pathway with work experience in manual brachytherapy and full calibration measurements and periodic spot-checks for low dose remote afterloader units.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Radiation Safety Program Elements

(1) Permanent implant brachytherapy source use and low dose remote afterloader use in Part 35, Subpart A, "General Information," Subpart B, "General Administrative Requirements," and Subpart C, "General Technical Requirements"

(2) Except: define "completion of the procedure" in the written directive; and request authorization for revisions to conform to changes in the NRC website licensing guidance.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Radiation Safety Precautions and Instructions

(1) Permanent implant brachytherapy requirements;
(2) Low dose remote after loader unit requirements;
(3) Securing the treatment room - conforming - 35.610(a)(1);
(4) Physical Presence - conforming - 35.615(f));
(5) Full calibration measurements requirements - conforming - 35.633)
(6) Periodic spot-checks for remote afterloader units - conforming -35.643

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Permanent implant brachytherapy requirements

35.404(a) and (c) and 35.2404

35.406 (a) and (c) and 35.2406(a) and (c)

35.410 and 35.3045

35.415

35.432

35.457 (for manually transferring treatment delivery parameters from the treatment planning system)

35.3045

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Low dose remote after loader unit requirements

36.600,

35.605, and 35.2605,

35.610,

35.615(a) and (e);

35.657 (when using the FIRST System or other system electronically transferring treatment delivery parameters to the treatment delivery system from the treatment planning system),

35.3045

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

(1) Securing the treatment room - will secure the treatment room when the Nucletron SeedSelectron® brachytherapy seed are present. (conforming change for 35.610(a)(1))

(2) Physical Presence - an permanent implant low dose remote afterloader medical physicists and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit will be physically present during the implantation. (conforming change for 35.615(f))

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

Will be performed on each unit--

(a) Before the first medical use of the unit;

(b) Before medical use following reinstallation of the unit in a new location outside the facility; and following any repair of the unit that includes major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding 1 year

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

(b) Will include determination of:

(1) Calibration measurements of brachytherapy sources described in 10 CFR 35.432

(2) Source positioning accuracy to within ±1 millimeter;

(3) Length of the source transfer tubes;

(4) Length of the applicators; and

(5) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) The full calibration measurements required will be made in accordance with published protocols accepted by nationally recognized bodies.

(d) In addition to the full calibration, an autoradiograph of the source(s) will be performed to verify inventory and source(s) arrangement.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Full Calibration Measurements

(e) Measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (d) of this section may be used.

(f) Mathematical correction will be made of the outputs for physical decay at intervals consistent with 1 percent physical decay.

(g) Full calibration measurements and physical decay corrections will be performed by the authorized low dose-rate remote afterloader medical physicist, unless provided by the manufacturer in accordance with paragraph (e).

(h) A record of each calibration will be retained in accordance with §§ 35.2632.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Periodic spot-checks for remote afterloader units

(a) Spot-checks will be performed of each remote low dose-rate afterloader facility and on each unit before each patient treatment

(b) The measurements necessary for the periodic spot checks will be performed in accordance with written procedures established by the authorized permanent implant low dose-rate remote afterloader medical physicist. This individual does not need to actually perform the spot check measurements.

(c) the authorized permanent implant low dose-rate remote afterloader medical physicist will review the results of each spot-check within 15 days and notify the licensee as soon as possible in writing of the results of each spot-check.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Periodic spot-checks for remote afterloader units

(d) the spot-checks will, at a minimum, assure proper operation of--
(1) Source exposure indicator lights on the remote afterloader unit, and on the control console;
(2) Emergency response equipment;
(3) Radiation monitors used to indicate the source position;
(4) Clock (date and time) in the unit computer or the treatment planning computer;
(5) decayed source(s) activity in the unit's computer or treatment planning computer after each source installation.

(e) If the results of the spot checks indicate the malfunction of any system, the system will be secured and not used except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A record of each check and a copy of the procedures used for the spot check will be retained in accordance with §§ 35.2643. 8h

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Procedures for Administrations Requiring Written Directives:

To confirm the treatment site for each administration is in accordance with the treatment site in each written directive, consider developing procedures for the following (conforming expansion of § 35.41(a)(2)):

1. To assure the specifications for the ultrasound imaging system, ultrasound probe, and ultrasound operational software are compatible with the Nucletron SeedSelectron® system.
2. To assure that the ultrasound probe is properly positioned to provide an appropriate view of the treatment area, and
3. To assure that the ultrasound imaging system is properly functioning to provide appropriate imaging of the treatment area and the implanted seeds.

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Low dose remote after loader unit requirements

(1) Securing the treatment room -(conforming change for 35.610(a)(1))

(2) Physical Presence - (conforming change for 35.615(f))

(3) Full calibration measurements

(4) Periodic spot-checks for remote afterloader units

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

The permanent implant low dose-rate remote afterloader medical physicists

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Procedures for Administrations Requiring Written Directives:

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Radiation Safety Precautions and Instructions

Permanent Implant Low Dose Remote Afterloader Brachytherapy Sources and Devices

Procedures for Administrations Requiring Written Directives(conforming expansion of § 35.41(a)(2))

Consider the following so that you can confirm that each administration is in accordance with the written directive:

1. Procedures to assure the specifications for the ultrasound imaging system, ultrasound probe, and ultrasound operational software are compatible with the Nucletron SeedSelectron® system.

2. Procedures to assure the ultrasound probe is properly positioned to provide an appropriate view of the treatment area(conforming expansion of § 35.41(a)(2))

3. Procedures to assure the ultrasound imaging system is properly functioning to provide appropriate imaging of the treatment area and the implanted seeds. (conforming expansion of § 35.41(a)(2))

RADIOIODINE ACTIVITY THRESHOLD FOR TREATMENT OF HYPERTHYROIDISM

Angela R. Williamson
NRC

BACKGROUND

- Previous 10 CFR 35 – no I-131 activity listed on licenses for treatment of hyperthyroidism
- Revised (as of Oct 2002) 10 CFR 35 – Authorized User must meet either:
  - 10 CFR 35.392 (≤ 33mCi) or
  - 10 CFR 35.394 (> 33mCi)

ISSUE

- Licenses now renewed against 10 CFR 35.392 or 35.394
- Licensees claiming experience using >33mCi under "old" 10 CFR 35
- Licensees also requesting broad authority with respect to activity amount
- Experience using > 33mCi not documented on existing licenses

QUESTIONS

- Should activity be restricted or is this practice of medicine issue?
- If activity should be restricted, what is the upper limit?

Access to the Nuclear Materials Events Database by ACMUI Members

Thomas Essig, Chief, MSIB
IMNS / NMSS

Issue: In order for ACMUI to effectively support the NRC staff's needs in the evaluation of medical events, Committee members need to be provided with appropriate data.

Options:

1. **Provide periodic (e.g., quarterly) downloads of medical events data from NMED on a CD to each ACMUI member. User would need to sort data via Access.**

   Advantage:
   - Data will have been reviewed by the staff. Only reportable medical events would be included (focused data set – extraneous information excluded)

   Disadvantages:
   - Data may not be totally current – function of latest batch update (e.g., quarterly)
   - Search engine not available, user must use Access database to process events data

2. **Provide real-time access to NMED database for each ACMUI member.**

   Advantages:
   - More flexible, unfettered access to all data by ACMUI members
   - Use of NMED search engine to sort information

   Disadvantages:
   - Data may be somewhat daunting – medical events data represent a relatively small subset of the overall events data
   - Data includes those events which have not yet been reviewed by the staff and which may later prove to be non-reportable (fail to meet event criteria)

Proposed approach: Option 2

Considerations/Constraints:

- Access can be provided to ACMUI members starting next week
- Access will be limited to the member's term of office on the Committee
- NMED is to be accessed and used only in the performance of official ACMUI duties
- NRC staff available to provide orientation to NMED, respond to questions

Discussion of Draft Information Notice Re: Issuance of Identification Cards to Patients Released after Treatment with Radiopharmaceuticals

NO HANDOUT PROVIDED
NOVEMBER 12-13, 2003 ACMUI MEETING

NRC DOSE MODELING

and

EXTREMITY (Hand) MONITORING

- PURPOSE :
  - To address concerns that NRC's dose assessments tend to be excessively conservative.
  - To discuss difficulties in monitoring dose to the hands

- Dose Modeling Discussion:
  - Three cases involving dose assessment will be described and used to illustrate NRC's general approach to dose calculations.

General Approach to Modeling

- Use data rather than make assumptions.
- Reconstruct events based on first-hand accounts if possible.
- Make realistic assumptions when necessary.

General Approach to Modeling

- If uncertain, slightly overestimate the dose rather than underestimate it.
- Use a graded approach to accuracy; i.e. the complexity of modeling should be proportional to the expected dose.

Case I – Basic facts

- MIT 1995
- Ingestion of P-32 by a research student.
- Exposure was occupational.
- An incident investigation team inspected the site to gather information.
- Dose was calculated by the NRC, the licensee, and an independent consultant.
- Different computer codes were used in the independent calculations, as well as tables of retention functions.

Case I – NRC's calculations

- NRC used urine analysis and whole body counting data to estimate intake of P-32.
- The Code For Internal Dosimetry (CINDY) was used in the calculations.
- Manual calculations were also done as a QA check. These were done using the intake retention functions in NUREG-4884.

Case I - Results

- The three independent intake estimates were
  - NRC 600 µCi
  - Licensee 564 µCi
  - Consultant 580 µCi
  - The ALI for P-32 ingestion is 600 µCi.
  - NRC accepted the licensee's estimate.

Case I - Conclusion

- NRC will accept the licensee's assessments, even if they show doses lower than NRC's results, if these assessment are of adequate quality.

Case II – Basic facts (a)

- May 2002
- 1 Ci Cs-137 source at an oil well rig in Montana.
- 31 non-radiation workers (members of the public) were exposed for periods up to 12 hours.

Case II - Basic Facts (b)

- The licensee's assessments showed doses in the range of 0.03 – 6.2 rem.
- A blood test (cytogenetics) on one of the workers showed a whole body dose of 200 rads.

Case II – NRC's Calculations (a)

- Initial calculations using a bare source and gamma constants quickly indicated that the reported doses are unrealistically high.
- More refined calculations using Microshield and some source shielding supported the initial conclusions.

Case II – NRC's Calculations (b)

- A special NRC inspection interviewed the workers and the licensee, obtained detailed drawing of the source, and detailed reconstruction of the event (time and motion study).
- The dose rate from the source was also measured using TLDs to verify source activity.

Case II – NRC's Calculations (c)

- Blood testing was repeated for 10 workers at two independent laboratories, one in the UK.
- NRC modeled the detailed source structure and the worker using the MCNP Monte Carlo transport code and the MIRD phantom to calculate doses to the workers.

Case II - Results

- NRC's detailed calculations showed doses less than about 0.3 rem for all workers.
- The second set of blood tests showed zero dose for all workers.
- NRC rejected the licensee's assessments and initial blood test, and used its own results in determining final dose estimates and appropriate enforcement actions.

Case II - Conclusion

- NRC will reject the licensee's assessments if they are of insufficient quality, even if the licensee assesses doses that are much higher than those obtained by the NRC.
- In this case, the result of the initial blood test was clearly in error, and the licensee's dose estimates were based on excessively conservative assumptions.

Case III – Basic Facts

- St Joseph Mercy Hospital.
- External exposure from hospitalized patient administered 300 mCi I-131.
- Exposed member of the public was the patient's daughter.
- Exposure occurred during the period July 1-7, 2002.

Case III – Dose Calculations (a)

- It was not necessary to calculate the dose rates because daily surveys at the location of exposure (bedside) were available. The monitoring instrument used for the surveys was appropriate for the radiation field being measured.
- Initial calculations verified that the dose rate measurements were of the correct magnitude.

Case III – Dose calculations (b)

- Total dose to the daughter was assessed by both the licensee and the NRC.
- Estimates of total dose were based on the daily survey results and estimates of stay times.
- Stay time estimates were based on interviews with the daughter and the hospital staff.

Case III – Results (a)

- Significant differences between the NRC and licensee estimates of stay times have resulted in a significant difference in the dose rate estimate for the daughter.
- There is no disagreement regarding the dose rates.

Case III – Results (b)

- Stay time estimates will be incorporated in a comparative evaluation to be presented at a future ACMUI meeting.

Extremity Monitoring

- Issue:
  - Dosimeters used to monitor hand dose are not normally at the location of highest exposure, as required by 10 CFR Part 20.
  - What correction factor, if any, is needed to adjust the dosimeter reading to show compliance ?

Background

- NRC inspectors found that ring badge readings were being used directly to show compliance, even though there were indications that this may underestimate the required dose.
- Enforcement action was considered.

Background

- A meeting was held between NRC and industry representatives to discuss these issues. Consensus was that work needs to be done to better understand the dosimetry.
- NRC issued interim guidance for its regional inspectors following this meeting.

Interim Guidance

- The guidance stated, among other things, that if a ring badge reading was over 25 rem, inspectors needed to take a closer look at the licensee's practices in this area.
- Inspectors used this guidance, but also viewed it as a trigger for considering enforcement action.

Interim Guidance

- The interim guidance was withdrawn, and current guidance is to assume that the appropriate correction factor for ring dosimeters is 1.
- Understanding of the dosimetry was insufficient to justify a clear position.

Complicating Factors

- Procedures used in handling radioactive materials, particularly radio-pharmaceuticals, are highly varied, making selection of a generally applicable correction factor very difficult.
- The skin dose limit in Part 20 was recently changed. This change has a significant impact on the values of any correction factors, generally leading to a reduction of these factors.

Current Status

- Industry has undertaken to study this question and to make some measurements.
- NRC has initiated a contract with Oak Ridge National Laboratory to calculate the correction factors for a variety of geometries and radio-nuclides.

Outcome

- Industry and NRC efforts should enable a judgment to be made on the appropriate values of the correction factors or of methods to determine doses with the appropriate degree of accuracy.

Conclusion

- These efforts should enable a reliable answer to be given to the questions:
  - Does a correction factor of 1 give a sufficiently accurate estimate of the dose to the worker's hand during the monitoring period?
  - If the answer to the above is no, then how should correction factors be determined, and how should they be applied?

July 2, 2003

The Honorable Edward McGaffigan, Commissioner
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Commissioner McGaffigan:

On behalf of the California Chapter of the American College of Nuclear Physicians, I respectfully request that you appoint an expert Dosimetry Panel whose task it will be to review NRC's internal and external dosimetry calculations affecting medical (including pharmacy) and academic licensees. This panel would also make recommendations to the Commission concerning appropriate methodology for preparing such calculations.

Differences of opinion on the accuracy of NRC calculations will only be resolved through a rigorous scientific review process, and we believe that an expert panel is a good way to achieve this.

It is essential, however, that the right people be on this panel, or else the effort will be useless. For example, we do not need a "balanced" committee with representation from Greenpeace.

We would envision that most members would be highly qualified scientists and professionals with experience in dosimetry. I should be on this panel, and I believe that Jeffry Siegel, Ph.D., must not only be on it, but should be the Chair. Other suggestions would be Richard Sparks, Ph.D., Michael Stabin, Ph.D., Pat Zanzonico, Ph.D., Andrew Taylor, M.D., Henry Royal, M.D., Myron Pollycove, M.D. (recently retired from NRC), Ronald Zelac, Ph.D., and Diane Case, Ph.D. (the last two individuals are from NMSS).

Please give this suggestion your most serious consideration, as it appears to be a good way of resolving contentious issues.

Sincerely,

Carol S. Marcus, Ph.D., M.D.
President, ACNP-CA

Cc: Chairman Diaz, Commissioner Merrifield

D:\My Documents\NRC-McGaffigan-dosimetry panel 06-19-03.doc

ACNP

American College of Nuclear Physicians
California Chapter
P.O. Box 31
Los Altos, Ca 94023
Dorothy Duffy Price, Executive Director
Telephone/Fax: 650/949-1341
Email: CalACNP@worldnet.att.net
Internet: www.acnp-cal.org

UCLA MEDICAL CENTER
Radiation Oncology

CAROL S. MARCUS, Ph.D., M.D.
Professor
1877 Comstock Avenue
Los Angeles, California 90025-5014
(310) 277-4541
(310) 552-0028 FAX
csmarcus@ucla.edu

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

July 8, 2003

Commissioner Edward McGaffigan, Jr.
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Dear Commissioner McGaffigan:

On behalf of the Society of Nuclear Medicine and the American College of Nuclear Physicians (SNM/ACNP), international scientific and professional organizations with 16,000 members dedicated to promoting and enhancing the science, technology and practical application of nuclear medicine to clinical practice, we are writing to express our concerns about some of the dose reconstructions that have been performed by the NRC in the past. Most recently, our concerns have been raised by an NRC calculation related to the dose received by a family member of a patient who was treated with I-131. The patient died and the hospital was subsequently cited for not taking additional measures to lower the dose to the grieving family member. This incident raises many issues regarding the appropriateness of the NRC's actions. One of the issues is the accuracy of the dose reconstruction.

The culture of the NRC seems to be to perform "conservative" dose reconstructions that are based on a series of worst-case assumptions. The resultant calculation is often much higher than a more realistic estimate of the dose. Unfortunately, the details of the NRC's dose reconstruction are not revealed in enough detail so that the NRC's methodology can be peer reviewed.

SNM and ACNP urge that the NRC review its dose reconstruction methodology. SNM and ACNP believe that the details of the dose reconstruction should be publicly available in enough detail so that the methodology can be peer reviewed. The goal of the dose reconstruction should be to estimate an accurate dose, not the worst-case dose.

Finally, an independent committee composed of SNM/ACNP and other dosimetry experts should review the NRC calculations using realistic calculation methodologies as described in the new SNM/ACNP therapy guidance document. The SNM/ACNP *Guide for Diagnostic and Therapeutic Nuclear Medicine*, now "in press", addresses this issue in some depth.

We look forward to working with you and the other Commissioners to review this matter. The NRC and the regulated community will be better served if a more realistic and credible dose calculation method can be put in place. If you have any questions, please feel free to contact us

at our national office or through Bill Uffelman at 703-708-9773 or by email at wuffelman@snm.org.

Thank you for your attention to this important matter.

Sincerely,

Henry D. Royal, M.D.
President
Society of Nuclear Medicine

Siimin Dadparvar, M.D.
President
American College of Nuclear Physicians

September 23, 2003

Carol S. Marcus, Ph.D., M.D.
President, ACNP-CA
1877 Comstock Avenue
Los Angeles, California 90025-5014

Dear Dr. Marcus:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to your letter of July 2, 2003, to Commissioner McGaffigan. In that letter, you requested that the NRC appoint an expert dosimetry panel to review NRC's internal and external dosimetry calculations affecting medical, pharmacy, and academic licensees.

Although we appreciate your suggestion to establish an independent dosimetry panel to review our calculations, we believe the staff receives sufficient support from its existing medical and scientific consultants; contractors; and our current advisory panel, the Advisory Committee on the Medical Uses of Isotopes (ACMUI), in performing and reviewing its dose reconstructions. However, because of recent interest in this issue, the Commission will place this issue on the agenda for the next public meeting with the ACMUI so there can be further public discussion on this topic.

The staff will continue to augment its dose reconstruction capabilities with specific individuals, dosimetry groups, and laboratories when their unique expertise is needed. The staff also will continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible.

I have enclosed a copy of a letter the Commission recently sent to the Society of Nuclear Medicine and the American College of Nuclear Physicians on a similar topic. The NRC staff is available to meet with you to discuss its dose calculation approaches in detail. If you have further questions on the matter, please contact Charles L. Miller, of the NRC staff at (301) 415-7197.

Sincerely,

/RA/

Nils J. Diaz

Enclosure: As stated

September 9, 2003

Henry D. Royal, M.D., President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

Dear Dr. Royal:

I am responding to your letter of July 8, 2003, to Commissioner McGaffigan in which you expressed concerns about dose reconstructions that the U.S. Nuclear Regulatory Commission (NRC) performed. Your letter discussed a specific dose reconstruction performed by NRC staff, and you requested that the details of this and other dose reconstructions be made publicly available so that they can be peer reviewed to ensure that they are not overly conservative.

It is my understanding that during your meetings with Commissioners McGaffigan and Merrifield on July 29, 2003, a specific dose reconstruction case was discussed. This case involved the therapeutic administration of about 300 mCi of I-131 to a terminally ill patient and the subsequent exposure of the patient's daughter while sitting next to the hospital bed. In this particular case, the hospital had performed daily dose rate measurements at the bedside. The NRC estimated the stay times next to the bed based on interviews with the daughter and the hospital staff. The dose to the daughter was then calculated using these stay times and the measured exposure rate for each day. Since the NRC staff was able to use measured dose rates and did not have to perform a complex dose reconstruction analysis, the Commission does not feel that the staff's results were overly conservative. Based on information presented by the staff on several other cases, we do not have any other indications that the staff's analyses are overly conservative. The NRC staff is available to meet with you to discuss its dose calculation approaches in detail. In addition, the Commission will place this issue on the agenda for the next public meeting with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) so there can be further public discussion on this topic.

As for making all dose reconstruction information publicly available, the NRC inspection reports that contain the details of these analyses are publicly available in NRC's AgencyWide Documents Access and Management System (ADAMS). These reports should include sufficient information concerning the dose evaluations for the public to see the particular methodologies NRC used in specific dose reconstructions. The inspection report for the case mentioned above can be located at accession number ML023440102. If you have trouble accessing this or other documents, please notify the staff, and they will assist you in obtaining copies of publicly available documents.

In your letter, you also suggest that the NRC consult an independent committee composed of experts from the Society of Nuclear Medicine and American College of Nuclear Physicians (SNM/ACNP) and other dosimetry experts to conduct peer reviews of NRC's calculations. While we appreciate your offer to have an independent SNM/ACNP Committee review our calculations, we believe the staff gets sufficient support from its existing medical and scientific consultants, contractors, and the ACMUI in performing and reviewing its dose reconstructions. The staff will continue to augment its dose reconstruction capabilities with specific individuals, dosimetry groups, and laboratories when their unique expertise is needed.

The staff will also continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible.

If you wish to meet with the staff or have any questions, please contact Charles L. Miller, of NRC's Office of Nuclear Materials Safety and Safeguards. Mr. Miller can be reached by telephone at (301) 415-7197

Sincerely,

/RA/

Nils J. Diaz

cc: Dr. Dadparvar
Mr. Uffelman

Identical letter sent to:

Henry D. Royal, M.D., President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

Simin Dadparvar, M.D., President
American College of Nuclear Physicians
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

October 9, 2003

Mr. Ralph P. Lieto, MS
Radiation Safety Office
St. Joseph Mercy Hospital
Radiation Safety officer
5301 E. Huron River Drive
P.O. Box 995
Ann Arbor, MI 48106-0995

Dear Ralph:

I am responding to your letter of July 14, 2003, addressed to me and received via e-mail, concerning interpretation of 10 CFR 35.61, "Calibration of Survey Instruments." Your letter relates specifically to §35.61(b), on conditions for use of survey instruments, as discussed at the May 21, 2003 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). I understand that your communication with me on this issue is through your role as a member of the ACMUI.

Acting for NRC staff, I have reviewed pertinent printed and transmitted information relating to this issue. The documents reviewed included: USNRC Regulatory Guide 10.8; NUREG-1556, Volume 9 (including the Appendix BB comment and response on Appendix K); ANSI-N323A-1997; Part 35 Q&A #1002004; May 21, 2003 comments on the issue from Penny Lanzisera (USNRC, Region 1); May 22, 2003 proposed comments on the issue received from G. White (AAPM) via e-mail; May 27, 2003 comments received from D. Keys (AAPM) via e-mail, on G. White's proposed comments; and your May 29, 2003 e-mail reply to D. Keys.

Through this review, and consideration of the information provided in your letter, I conclude that your assessment of the issue, as stated in your letter of July 14, 2003, is the correct interpretation of the requirement of §35.61(b), namely that 1) this section applies to the outcome of the calibration process, not to the use of survey instruments after acceptable calibration, and 2) the use of energy correction charts/graphs after acceptable calibration is permissible. As you know, this interpretation was supported by those members of the ACMUI that expressed opinions on the issue during the discussion at the May 21, 2003 meeting of the ACMUI.

This interpretation is also supported by NRC management and the NRC Office of the General Counsel. It will be conveyed to other Headquarters staff, to the staff of the Regions, to members of the regulated community, and, of course, to the ACMUI.

Thank you very much for your efforts to resolve this issue. If you wish to discuss it further, I can be reached at (301) 415-7635.

Sincerely,

Ronald E. Zelac, Ph.D., CMP, CHP
Senior Health Physicist
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear material Safety
and Safeguards

AGENDA TOPIC: RECOMMENDATIONS FROM SPRING 2003 ACMUI MEETING

Remarks: the following table contains the recommendations from the May 2003 ACMUI public meeting along with the NRC staff's response. This table also includes any action items that require staff follow-up, as well as tasks for which ACMUI is assisting NRC staff.

DISPOSITION OF ACMUI RECOMMENDATIONS , TASKS, and STAFF ACTION ITEMS							
Date	ACMUI Recommendation (R) ACMUI Task (T) Staff Action Item (A)				Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up
	R	T	A	Name and/or Description of Recommendation, Task, or Action Item			
May 2003	X			**GENERIC LISTING OF SOURCES AND MODEL NUMBERS ON LICENSES** That NRC initiate a rulemaking process to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), to allow more generic listing of interstitial seeds and sources on NRC licenses.	N	A rulemaking initiative to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), may ultimately reduce radioactive source accountability. Title 10 CFR Part 30.32 (g)(1), which requires the listing of all sources or devices by manufacturer and model number, was implemented to ensure that licensees maintain full accountability of the sources/devices under their care. Staff believes that identification of all sources/devices by manufacturer and model number is a reasonable measure to ensure that accountability is maintained. Such accountability aids licensees in keeping an accurate inventory of sources, which helps prevent loss of radioactive material, thereby protecting public health and safety. Furthermore, staff does not believe it to be prudent to reduce accountability of radioactive material in an environment of heightened public awareness and sensitivity, brought on by the terrorist events of September 11, 2001. For these reasons, staff is unable to support the stated rulemaking initiative.	After discussion at the May 20, 2003 ACMUI meeting, staff has committed to revisiting this issue, which was previously discussed at the October 28, 2002, ACMUI public meeting. Staff agreed to try to develop an alternative to rulemaking that would allow licensees to list seeds generically. Staff plans to re-address this issue at the next regularly scheduled semi-annual ACMUI meeting, to be held in November 2003.

Date	ACMUI Recommendation (R) ACMUI Task (T) Staff Action Item (A)				Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up
	R	T	A	Name and/or Description of Recommendation, Task, or Action Item			
May 2003	X			**CONTINUOUS TRACKING OF ITEMS OF INTEREST GENERATED DURING ACMUI PUBLIC MEETINGS** That approximately two weeks after distribution of the staff response to the ACMUI's recommendations, a conference involving ACMUI and staff is held to review and prioritize items of discord.	Y	Staff agrees in principle with this recommendation. Instead of holding a meeting two weeks after the staff's response to ACMUI recommendations, staff plans to schedule at least one public teleconference meeting approximately mid-point between semi-annual meetings. The meeting will be used to discuss and track any item of interest as well as items of discord	
May 2003			X	Staff needs to explore ways to improve the application process so that licensees are more likely to submit quality applications.	N/A	Staff to prepare an article for publication in the NMSS licensee newsletter. Article will inform licensees of the requirement to use NRC Form 313A when applying for status such as AMP, or when requesting exemption to the regulations. Staff to prepare a Regulatory Issues Summary (RIS) as another means of informing licensees.	Staff must amend NRC Form 313A before publication of article or RIS.
May 2003			X	Staff needs to explore ways as to how ACMUI can be more involved in decisions regarding exemption requests.	N/A	Staff received Commission approval to amend the ACMUI charter so that ACMUI may be used as consultants for issues like amendment requests and exemption requests. See SRM-SECY-03-0149.	
June 2003		X		R. Lieto and J. Williamson review of Ellen Grein and Joseph Krzysik's request for AMP status.	N/A	Ellen Grein: ACMUI recommended authorization for all modalities in application. Staff agreed. Joseph Krzysik: ACMUI recommended limited AMP recognition. Staff agreed.	Staff granted recognition to Dr. Grein and Mr. Krzysik at the level of recognition recommended by ACMUI.
Sep 2003		X		ACMUI review and comment on draft Information Notice re: patients setting off radiation alarms in public places	N/A	ACMUI generally agreed that issuance of such cards could be useful, but voiced several concerns. These include possible law enforcement difficulty in determining the veracity of the card; challenges to licensees' ability to verify persons who call to inquire about a patient; patient privacy concerns; and the cost of producing the cards.	Staff will re-discuss this item with the ACMUI at the Nov 12-13, 2003 ACMUI meeting

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
May 20-21, 2003

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on May 20-21, 2003.

ACMUI members present at the meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Jeffrey A. Brinker, MD	Interventional cardiologist (designee)
David A. Diamond, MD	Radiation oncologist
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist
Leon Malmud, MD	Healthcare administrator
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB) participated in the meeting. Specific participating staff members are listed below:

Robert Ayres	NMSS/IMNS/MSIB
Roger Broseus	NMSS/IMNS/RGB
Charles Cox	NMSS/IMNS/MSIB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Donna-Beth Howe	NMSS/IMNS/MSIB
Michael Markley	NMSS/IMNS/MSIB
Charles L. Miller	NMSS/IMNS
Linda Psyk	NMSS/IMNS/MSIB
Roberto Torres	NMSS/IMNS/MSIB
Anthony Tse	NMSS/IMNS/RGB
Angela Williamson	NMSS/IMNS/MSIB
Ronald Zelac	NMSS/IMNS/MSIB

Invited guests present at the meeting:

Ryan T. Coles, Government Accounting Office
William R. Hendee, American College of Radiology
Jeffry Siegel, Society of Nuclear Medicine
Prabhakar Tripuraneni, American Society of Therapeutic Radiology and Oncology

The meeting came to order at 1:04 p.m.

OPENING REMARKS

Thomas H. Essig, Designated Federal Officer, introduced each ACMUI member and welcomed all present to the meeting.

SOCIETY OF NUCLEAR MEDICINE LICENSING GUIDE

Thomas Essig, NRC, gave a brief presentation on this agenda topic.

Mr. Essig began by explaining that this agenda topic's title is a bit of a misnomer. He explained that the guide is not a licensing guide per se, but is actually a guide for the medical use of byproduct material in a diagnostic setting.

Next, Mr. Essig outlined the genesis of this guide. He noted that the Society of Nuclear Medicine (SNM) developed this guide to assist the diagnostic regulated community in implementing the new 10 CFR Part 35 (Part 35). SNM reviewed and commented on NRC's licensing guide, NUREG 1556, Volume 9 (Consolidated Guidance About Materials Licenses: Program-Specific Guidance Aboujt Medical Use Licenses). Nonetheless, SNM volunteered to create its own version of Volume 9, because they believed that the NUREG was difficult to use due to its extensive detail.

Mr. Essig explained that as SNM developed its guidance, it gave the guidance to NRC to review, and eventually, NRC entered into a licensing agreement with SNM so that this guidance could be published on NRC's website as a service to licensees. This diagnostic guidance is not a substitute for NRC's regulations, but is one acceptable method of assisting licensees in implementing the regulations; therefore; it can be considered an adjunct to NUREG 1556, Volume 9. Mr. Essig further explained that the Agency stated its position on SNM's diagnostic guidance in a Regulatory Issues Summary, dated November 27, 2002.

Regarding licensees who choose to use SNM's diagnostic guidance, the ACMUI asked Mr. Essig to clarify whether it will have the same level of recognition as NRC's guidance if licensees use the SNM guidance and then need to defend their actions because they followed the guidance's recommendations. Mr. Essig explained that since NRC recognizes the guidance as one acceptable method of implementing Part 35, it carries an equivalent level of recognition as the NRC guidance document.

This presentation begins on page 6 of the meeting transcript.

UPDATE: REVIEW OF DOMESTIC REGULATION OF NUCLEAR MATERIAL

Mr. Ryan T. Coles of the U.S. Government Accounting Office (GAO), initially made a presentation on this topic at the October 28, 2002 meeting. He returned to give the ACMUI an update.

Mr. Coles began by explaining that the GAO was in the process of completing its investigation into the accountability of radiation sources (an effort that was undertaken at the request of Senator Daniel Akaka, Chairman of the Subcommittee on International Security, Proliferation,

and Federal Services; Senate Committee on Governmental Affairs). As such, he had no findings that he could share with the ACMUI. However, was able to update the ACMUI on three items: 1) a status update on GAO's three separate efforts in which they are reviewing materials regulation and security; 2) a description of GAO's objectives, scope, and methodology used to review the domestic regulation of nuclear material; and 3) a synopsis of a report GAO has already released, regarding the U.S. Department of Energy's (DOE) source recovery program.

Regarding GAO's review of domestic regulation and security, Mr. Coles explained that the final report will be issued most likely in late July/early August. He explained that as this effort began, GAO structured it so that the findings will be an educational tool to teach Congress how radioactive materials are regulated in the United States. Questions GAO attempted to answer are: What is the scope of radioactive material use in the United States, specifically, how many licensees exist? How many radioactive sources are in use? What are the typical uses of these sources? What kinds of radiation-related incidents are occurring (such as lost/abandoned sources, misadministrations, and malfunctioning devices) and what are licensees' reporting requirements? Mr. Coles further explained that GAO is attempting to get a grasp on the effectiveness of Federal and State controls over this material, as well as what efforts have been initiated to safeguard this material since the terrorist attacks of September 11, 2001.

To answer these questions, Mr. Coles explained that GAO issued a survey to 32 Agreement States, all of the non-Agreement States, all four NRC regions, and to Puerto Rico. Furthermore, GAO visited and interviewed several State and local officials, as well as some licensees. During its visits, GAO reviewed a cross section of radioactive material programs (e.g., academic, research, and industrial programs). Moreover, GAO had extensive discussion with several Federal agencies besides the NRC (the U.S. Department of Transportation, the U.S. Environmental Protection Agency, the U.S. Federal Emergency Management Agency, the DOE, and the U.S. Department of Justice).

Mr. Coles concluded his presentation by giving a synopsis of GAO's findings on DOE's source recovery program. He explained that DOE appeared to not give the mission to collect Greater Than Class C sources sufficient attention. He explained that DOE's environmental management office does not believe that this mission is an appropriate one for DOE to conduct, and that in the nearly 20 years in which it has been tasked with this mission, no progress toward ultimate disposal of this material has been made.

After thanking Mr. Coles for his update, ACMUI advised him on the outcome of one of the briefings NRC staff gave them earlier during the closed session portion of the meeting. This briefing involved staff's efforts regarding the implementation of NRC's Interim Compensatory Measures (ICM) to safeguard sources. The ACMUI expressed their belief that the Agency's ICMs reflected a logical and well-thought out approach to safeguarding sources, and they hoped that any recommendations included in the GAO's report on the domestic regulation of radioactive material will also be as well-thought out. The ACMUI believed that GAO's report may provide the basis for new legislation. If so, the ACMUI emphasized the need to include accurate and common sense information and recommendations in the report, otherwise, legislators could use it to develop laws that will adversely impact the practice of medicine.

This presentation begins on page 11 of the meeting transcript.

TRAINING, EDUCATION, BOARD CERTIFICATION AND THE NEW PART 35

William Hendee, Ph.D, American College of Radiology (ACR) led the discussion on this topic. Dr. Hendee began by relaying the experience he had with three NRC staff members in a meeting earlier in the day. He explained that he met with Roger Broseus, Patricia Holahan, and Sandra Wastler, (NRC/NMSS) in which he laid out ACR's concerns. Dr. Hendee found the discussion "excellent, open, and frank", and he thanked Dr. Broseus, Dr. Holahan, and Ms. Wastler for their willingness to work with him to address ACR's concerns.

Next, Dr. Hendee expounded on three issues of concern to ACR regarding the proposed training and experience (T&E) to be applied as an acceptable method of recognition to gain authorized user status in Part 35.

The first issue involves the default pathways to gain NRC recognition for the various categories of users [Authorized User (AU); Authorized Medical Physicist (AMP); Authorized Nuclear Pharmacist (ANP); or Radiation Safety Officer (RSO)]. According to Dr. Hendee, the pathway in the proposed T&E language that allows for recognition via didactic instruction and supervised practical training is vague, with respect to how it applies to boards. He explained that this pathway does not specify whether a board must require its candidates to obtain a specific number of hours of this instruction/supervision. Dr. Hendee believes that, consequently, the language in the proposed rulemaking makes it difficult to ascertain whether NRC views board certification as assurance that candidates have met the specific hours of didactic instruction and training that NRC considers essential. To address this issue, Dr. Hendee stated that ACR recommends that the NRC recognize the certification process of well-established boards (such as the American Board of Radiology (ABR)) as sufficient to certify users. Dr. Hendee believes NRC should allow these boards to define the education, training, and experience that is most appropriate to delivering quality care within the medical specialty for which they offer certification.

Dr. Hendee's second concern related to the appropriate person to attest to satisfactory completion of training. The proposed T&E rule language requires that this person be an experienced preceptor AU (or AMP, ANP, etc.). However, Dr. Hendee believed that the more appropriate person to provide this attestation is the program director. He stated that the AU would be an acceptable preceptor in non-accredited training programs, but in cases where the program is accredited, the program director would be the best person to attest to satisfactory completion of training. According to Dr. Hendee, this is true because the program director is the person responsible for the training in accredited programs.

Dr. Hendee's third concern involved certification examinations as a measure of competency. Regarding this concern, Dr. Hendee recommended that any reference to successful passing of board examinations as a measure of competence be removed. His rationale was that the passing of board examinations illustrates the mastery of a body of knowledge, but it does not evaluate competence in a clinical setting.

Dr. Hendee concluded his discussion by announcing a position statement and a comment. The position statement was that the ACR supported the listing of certain NRC-recognized boards o

the NRC website. The comment was that ACR strongly objects to the omission of the ABR as one of those NRC-recognized boards. Dr. Hendee believes that the ABR should be included because, as he stated, there are many present RSOs with oversight responsibilities in diagnostic nuclear medicine programs who are certified by the ABR. Furthermore, according to Dr. Hendee, diagnostic uses of source material constitute the greatest use of this material (in the medical arena), so the omission of the ABR as a recognized board will create a shortage of RSOs to oversee the safety program of most licensees. Moreover, certification by the ABR meets or exceeds that of the other three certification boards the ACMUI recommends. Those boards are the American Board of Health Physics in Comprehensive Health Physics; the American Board of Medical Physics in Medical Health Physics, and the American Board of Science in Nuclear Medicine and Radiation Protection.

The ACMUI had extensive discourse with Dr. Hendee regarding his concerns. With respect to Dr. Hendee's concern about board certification and the T&E rule language, the ACMUI explained that the T&E language was not intended to make boards require a specific number of hours of didactic training as part of the certification process. ACMUI underscored that the only pathway intended to prescribe hours of training was the alternate training pathway to certification, not the default board certification pathway.

Regarding Dr. Hendee's opinion on the appropriate person to attest satisfactory completion of training, ACMUI assured Dr. Hendee that they recommended that the program director be the party that attests to this training. Nonetheless, the Commission believed that the party best suited to this task was a preceptor AU who is listed on an NRC or Agreement State license.

Regarding the third concern, certification examinations as a measure of competency, ACMUI explained that a tremendous number of program directors felt uncomfortable attesting to competence, and that these individuals stated that the certification boards were the party responsible for attesting to competence. In response, Dr. Hendee then suggested that the ACMUI define "competence." If "competence" is the mastery of a body of knowledge, then Dr. Hendee agrees that the boards should attest to competence. However, if competence can be demonstrated only through one's performance in clinical practice, then program directors should attest to competence. Following that suggestion, there was some discussion as to which way the word "competence" should be defined in this context. Dr. Patricia Holahan, NRC, clarified that the Commission has allowed for the word "competence" to be defined as sufficient attestation to demonstrate that the candidate has knowledge to fulfill the duties of the position for which certification is sought. ACMUI asked Dr. Hendee if that was an acceptable way to define competence, and Dr. Hendee agreed it was.

Regarding Dr. Hendee's comment on the omission of ABR as a recognized board for RSO status, the ACMUI believed that the essence of the problem is in the language in the T&E, which asserts that a user can serve as the RSO only in programs where the use of source material is similar to the use for which the RSO has certification. Mr. Hendee responded that a way to address this would be to allow a person certified as an AMP to function as the RSO over research and diagnostic applications, if that person has had some basic education in the safe handling of unsealed sources. The ACMUI agreed to that proposition.

This presentation begins on Page 23 of the meeting transcript.

DISCUSSION: NRC LICENSING TIME LINES, PROPOSAL FOR MONTHLY/BI-MONTHLY TELECONFERENCES

Thomas Essig, NRC, briefed the ACMUI on this agenda topic. This was a discussion to create a course of action that staff can use to keep ACMUI meaningfully involved and updated, in a timely manner, on issues where they can contribute.

Action suggested was staff use of periodic, public teleconference calls with the ACMUI. However, as Mr. Essig explained, there are several points to consider regarding teleconferences. One consideration is the increased time consumption for both NRC staff and the ACMUI. NRC staff would have to expend a significant amount of time preparing for these calls by coordinating staff and ACMUI schedules. The schedule of teleconference meetings would require listing in the Federal Register several months in advance to allow for public participation. Furthermore, because of advanced meeting announcements, there would be no flexibility to revise meeting dates to accommodate changes in participants' schedules. A possible consequence of that restriction would be that the committee's business would be impaired during some meetings, because of an insufficient number of participants needed to reach a quorum.

Yet another concern, as explained by Mr. Essig, would be the increased cost to the Agency. The Agency would experience increased costs for meeting-related activities, to include meeting preparation, participation, and follow-up actions, where required. Mr. Essig explained that these costs have not been factored into the Fiscal Year 2004 budget, although it is possible that savings from a reduced effort elsewhere could finance increased effort in this area.

Nontheless, ACMUI and staff agreed that teleconferences are necessary, so that important issues are not inadvertently forgotten. During the closed session meeting, ACMUI and staff agreed that a reasonable approach would be to schedule at least one teleconference in the period between the semi-annual meetings. Toward that end, the ACMUI made a recommendation during the closed session meeting.

Recommendation:

Approximately 2 weeks after distribution of the staff response to ACMUI recommendations, a conference involving the ACMUI and staff be held to review and prioritize items of discord.

This discussion begins on Page 58 of the meeting transcript. The recommendation is on Page 66 of the May 20, 2003, closed session transcript of the meeting. (Accessible to NRC employees only, in ADAMS under ML031700405).

T&E RULEMAKING, STATUS, AND DISCUSSION

Roger Broseus, NRC, made a presentation on this topic. Dr. Broseus explained that the Commission approved, in Staff Requirements Memorandum 02-0194, the ACMUI's T&E recommendations. Those recommendations included a suggestion that the NRC list boards it recognizes in 10 CFR Part 35. That suggestion notwithstanding, the Commission approved

the ACMUI's T&E recommendations with a caveat suggested by staff. This caveat was that the approved boards be listed on the NRC website rather than directly in the rule.

Regarding evidence of authorized users' competence, Dr. Broseus affirmed that the proposed rule should require that candidate AUs satisfactorily demonstrate to preceptors a mastery of a body of knowledge, rather than have the preceptor attest to the candidate's clinical "competence."

Dr. Broseus then outlined small, detailed changes that staff made to the ACMUI's recommendations. The changes were numerous, and they involved formatting revisions to increase clarity, ensure that items are cross-referenced properly, and remove redundancy in the language. Next, Dr. Broseus informed the ACMUI there was one area where staff still needs advice, and that is whether the Royal College of Physicians and Surgeons of Canada (RCPSC) should be added to the list of approved boards that will eventually be posted to the NRC website. (Later, ACMUI clarified that RCPSC is actually an accreditation program, not a board).

Dr. Broseus continued to outline other modifications that staff made to the ACMUI's T&E recommendations. However, these changes involved extensive re-wording and re-formatting, such that ACMUI had difficulty comprehending them. Therefore, ACMUI suggested that staff perform redline/strikeout edits to the T&E in its original form, so that the modifications can be clearly seen. Staff responded that simple redline/strikeout changes would be difficult to insert, because of the reformatting of the language. To address this issue, staff suggested that they meet with ACMUI to go over the document thoroughly to get a grasp on all the changes. The ACMUI agreed that the best way to do so would be via conference calls some time soon. Staff informed the ACMUI that the goal was to get the proposed rule up to the Commission by the end of July (2003).

Follow-up: On June 20, 2003, staff concurred on the draft memorandum, "REVIEW AND CONCURRENCE: PROPOSED RULE ON RECOGNITION OF SPECIALTY BOARDS." Staff forwarded the draft memorandum to the ACMUI for review. Staff discussed the ACMUI's comments on the draft memorandum during the July 17, 2003, teleconference, which was closed to the public. This meeting was announced in the Federal Register (68 FR 41665).

This discussion begins on Page 64 of the meeting transcript.

SEALED SOURCE MODEL NUMBERS AS LICENSE CONDITIONS

Donna-Beth Howe, NRC, provided a briefing on this subject. Dr. Howe began by reminding the ACMUI that, at their October 28, 2002, meeting, they made a recommendation to staff to initiate rulemaking that would modify 10 CFR Part 30.32(g)(1) to allow more generic listing of interstitial seeds and sources on NRC licenses. (The ACMUI made this recommendation because licensees are required to list, by manufacturer and model number, all of their individual sources, or in the case of multiple sources in a single device, they must list each device. The ACMUI said this requirement is overly burdensome because device names and/or model numbers change frequently, resulting in ceaseless license amendments). Dr. Howe noted that staff evaluated this recommendation but decided to not adopt it because of the likelihood that such a change may ultimately result in reduced source accountability (For more discussion of this topic, see "Update: Recommendations from Fall 2002 Meeting" in these minutes). Dr. Howe

emphasized that both staff and the Commission are very concerned, particularly in this post-September 11 environment, about licensees maintaining adequate control and security over radioactive sources.

Dr. Howe then reminded ACMUI of alternative methods they may employ to reduce the burden of needing to update their licenses every time there is a change in the device name or model number. One alternative is to identify the sources or devices by manufacturer and model number as they are registered with the Commission in the Sealed Source and Device Registry (SSDR). The other is for licensees to provide the information that is contained in 10 CFR 32.210, Registration of Product Information.

The ACMUI believed that the options are still overly burdensome, and suggested that better alternatives could be developed. They stated that the number of seed models has increased dramatically, so a requirement to list every radioactive seed by manufacturer and model number, rather than generically, seriously restricts licensees' ability to negotiate for the most economically priced seeds. The ACMUI further stated that device model numbers change, but the seeds within them do not change substantially, so in terms of radiation safety, it does not matter whether the licensee is using Model A, B, or C. Therefore, a generic statement to describe the seed, such as "encapsulated radioactive iodine" rather than "Theragenics, Model XYZ" would suffice. ACMUI reiterated that public health and safety would not be compromised.

In response, an NRC staff member, Ronald Zelac, Ph.D., pointed out another consideration. He explained that another reason for listing sources on licenses by manufacturer and model number was to protect the public health by giving the Agency an opportunity to ensure that the source to be used was registered in the SSDR. The ACMUI replied that the revised Part 35 requires licensees to use only those sources that are in the SSDR; therefore, NRC verification that licensees are using only these sources is unnecessary. The ACMUI believes that NRC should assume that licensees will use only the SSDR-registered sources, then should apply the Agency's performance-based regulation philosophy to address those licensees who do not follow this requirement.

As the discussion ensued, the ACMUI and the staff reached an impasse regarding the need to list sources by model number and manufacturer, to protect the public health and safety. Therefore, the ACMUI made the following recommendation:

Recommendation:

Whereas the ACMUI sees no conceivable patient or public health hazard from listing interstitial brachytherapy sources generically on license applications, NRC should develop a strategy for eliminating this requirement for this narrow class of sources.

This discussion begins on Page 92 of the meeting transcript.

NATIONAL MATERIALS PROGRAM PILOT PROJECT ON OPERATING EXPERIENCE EVALUATION

Michael Markley, NRC, gave a presentation on this subject. Mr. Markley began by introducing members of the pilot project working group. They were Debbie Gilley, Florida; Cynthia Taylor, Region 2, NRC; and Marsha Howard, Ohio. Ms. Gilley participated via telephone, and Ms.

Taylor was present in the audience. Ms. Howard was not present.

Mr. Markley then explained that the working group had already developed its charter and was approaching the ACMUI to get their input early in the process of the working group's efforts. Next, Mr. Markley outlined the working group's efforts. He explained that the group hoped to use licensees' common operating experience information to conduct trending. This effort is not an evaluation of Agreement State performance, but rather an attempt to use their operating experience to make better resource allocation and regulatory decisions. Mr. Markley explained that the group, ultimately, is seeking to develop a data evaluation process that would produce similar outcomes, regardless whether the Agreement States or the NRC was using the process.

Later in his presentation, Mr. Markley emphasized the need for effective communications as part of this effort. He noted that both the NRC and the Agreement States perform many positive deeds, but do not necessarily share results of outcomes with each other. He emphasized the necessity that the NRC and the Agreement States create efficiencies and reduce burden by sharing information.

ACMUI was supportive of the Working Group's philosophy. Furthermore, ACMUI suggested, and Mr. Markley agreed, that it would be useful for NRC to share any insights gained from this exercise with the regulated community as well.

This presentation begins on Page 115 of the meeting transcript.

CONTENT AND STATUS OF DIRECT FINAL RULE

Anthony Tse, NRC, gave a presentation on the Direct Final Rule (DFR) to clarify and amend 10 CFR Part 35.

Dr. Tse began by informing the ACMUI that this rule was published (in the Federal Register) in April 2003 for public comment. However, the NRC has received no comments to date, and if no significant adverse comments are received by May 21, 2003, then the rule will automatically become effective July 7, 2003. Note: No adverse comments were received, so the rule became effective July 7, 2003.

Dr. Tse then explained the necessity of the DFR: Shortly after the revised Part 35 was published, staff became aware of an unintended restriction within the rule, as well as inconsistencies in the rule application. Furthermore, certain areas needed clarification and correction. Dr. Tse then outlined the affected areas. The major areas he outlined were:

- The retraction of a restriction that requires that training of ophthalmic uses of Strontium- 90 be done only at major medical institutions. Staff believed this training can appropriately be performed by an authorized user in a private medical clinic or ophthalmic office as well.

- Correction to the title "National Institute of Science and Technology." The organization is correctly entitled "National Institute of Standards and Technology."

- The addition to the record-keeping section of the rule that refers to calibrations of brachytherapy sources (§35.2432). This section was amended to add that calibration can

be done by the licensee or by the manufacturer or by calibration laboratories. This was added so that the language is consistent with the language in the section that outlines calibration requirements (§35.432).

The ACMUI understood the changes and made no substantive comments or suggestions.

This presentation begins on Page 130 of the meeting transcript.

HEALTH AND HUMAN SERVICES DATABASE OF REGULATORY ACTIONS: STATUS AND DISCUSSION

Linda Psyk, NRC, gave a presentation on this topic.

Ms. Psyk provided an overview: 1) the purpose of the database; 2) what the NRC reports to the database and how it reports to the database; 3) the NRC's internal guidance document (Management Directive 8.6) that outlines the procedure the Agency uses to identify what needs to be reported and how; and, 4) a discussion of the Agreement States' reporting responsibilities.

Ms. Psyk then explained that the Health Insurance Portability Database is a database that contains information on certain adverse actions applied against health care practitioners, providers, and suppliers. This confidential database was created as a result of the Health Insurance Portability and Accountability Act of 1996, a law designed to address health care fraud in the United States. Ms. Psyk emphasized that the general public cannot access the database.

Next, Ms. Psyk stated that entities and persons who are reported to the database are notified. The reported entities/persons are given access to the database, so that they can view the information it contains about them. In addition to reported persons who can review their own information, certain other interested parties also have access to the database. These parties include State and Federal agencies; health plan providers (i.e., insurance or programs that provide health benefits); and other health practitioners, providers, and suppliers.

Ms. Psyk outlined the three criteria any reportable action must meet:

1. The negative action or finding must be final.
2. The negative action/finding must be publicly available.
3. The negative action/finding must directly affect health care.

Ms. Psyk then provided examples of actions the NRC reported to the database. One example included a hospital that received a Notice of Violation, with a civil penalty, for failure to obtain the AU's signature on a written directive before administration of a therapy dose of Iodine - 131. Ms. Psyk explained that NRC reported this licensee to the database because the licensee's actions could have directly affected health care.

The ACMUI expressed concern with this action. They believed this illustrates a scenario in which a licensee's failure to perform a technicality could result in punitive action. The ACMUI stated that, in an instance similar to this, a patient may ingest the therapeutic dose three

seconds before the physician signed the written directive. Furthermore, the ACMUI was not convinced of the database's confidentiality. Instead, ACMUI believed this information would find its way into the public domain, and possibly increase physician liability and result in litigation.

Ms. Psyk, along with Sally Merchant from NRC's Office of Enforcement, restated this example to demonstrate the grievous nature of this particular licensee's action. They emphasized that the Agency does not intend to use technicalities in rule applications, in order to locate licensees to report to the database.

Ms. Psyk then briefly explained that Agreement States must report all their affected licensees to the database as well. To remind them of the requirement, NRC plans to forward an Agreement States letter once Management Directive 8.6 is finalized.

Ms. Psyk concluded her presentation by explaining that NRC must submit any reportable actions starting from 1996, since that was the year the requirement to report came into effect.

This presentation begins on Page 135 of the meeting transcript.

DISCUSSION: WRITTEN DIRECTIVES FOR BRACHYTHERAPY NOT ASSOCIATED WITH PERMANENT IMPLANTS

Ronald E. Zelac, NRC, gave a presentation on this subject.

Dr. Zelac explained that this presentation is being provided in response to an apparent ACMUI concern that the written directive requirements concerning low and medium dose rate brachytherapy are inappropriate. The specific concern is that the written directives are only applicable to high dose rate brachytherapy and permanent radioactive source implants, but are not applicable to low, medium, and pulsed rate doses of brachytherapy, nor to temporary radioactive source implants.

Dr. Zelac then briefly outlined the written directives requirements in the rule for low, medium, and pulsed rate doses of brachytherapy as described in 10 CFR 35.40(b)(6). The requirements state that an AU must date and sign a written directive that includes the treatment site, radionuclide, and dose before implantation. After implantation, but before completion of the procedure, the AU must state the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose).

Next, Dr. Zelac explained the changes in the new Part 35 as compared to the previous rule. The first change is that the number of total sources used must be entered after implantation rather than before implantation. The second change is that the listing of individual source strengths is no longer required. The third and final change is that the treatment site and the dose need to be entered into the written directive before implantation, besides being verified afterward. Dr. Zelac informed the ACMUI that these changes were implemented to make brachytherapy requirements consistent with other sealed source therapy requirements. Furthermore, these changes were based upon previous ACMUI comments.

ACMUI stated that the requirement to have a written directive that specifies the treatment site,

radionuclide, and dose before the implantation of the radioactive seed is appropriate for implanting permanent seeds, but inappropriate for the implantation of temporary seeds. The reason this requirement is inappropriate for temporary seed implantation is because, with temporary implants, one must put in a number of seeds, then calculate the volume of tissue being treated. Since volume and dose are interrelated, the amount of calculated volume will determine whether the dose needs to be increased or decreased (i.e., more seeds need to be added or seeds need to be removed).

In response, Dr. Zelac noted that the AU has flexibility to modify the written directive based on findings associated with the treatment. ACMUI concurred.

In conclusion, the ACMUI agreed that the rule, as written, is adequate and flexible enough to address both temporary and permanent radioactive seed implantation.

This presentation begins on Page 152 of the meeting transcript.

DOWNLOADING PART 35 FROM THE NRC WEBPAGE

In this extremely brief presentation, Tom Essig, NRC, distributed a set of instructions entitled "Saving Part 35 to Disk from NRC's Website." These instructions show how to download 10 CFR Part 35, in its entirety, from the NRC website. Previously, Part 35 was downloadable by section only. The ACMUI believed that the "section only" accessibility was burdensome to print, and requested that Part 35 be made available as one unit on its website. In response, NRC staff put a full text version of Part 35 on the 10 CFR Part 35 webpage, so that the public now has the choice to view/print sections of Part 35 or view/print Part 35 in its entirety. The ACMUI was pleased with this result.

This presentation begins on Page 163 of the meeting transcript.

SOCIETY OF NUCLEAR MEDICINE'S SUGGESTED GUIDANCE FOR THERAPY APPLICATIONS

Dr. Jeffry Siegel, SNM, presented this topic to the committee.

Dr. Siegel began by explaining that SNM developed some diagnostic nuclear medicine guidance. (For more information on the purpose and history of this guidance, see the agenda topic entitled "Society of Nuclear Medicine Licensing Guide" as summarized earlier in these minutes.) Now, SNM has developed some therapy guidance.

Dr. Siegel stated that he met with Chairman Meserve, NRC, in December 2001, and it was "agreed upon" that new guidance to address therapeutic uses of nuclear medicine was needed. Therefore, SNM and the American College of Nuclear Physicians drafted some therapy nuclear medicine guidance. Dr. Siegel explained that, although NRC has guidance in the form of NUREG 1556, SNM believes its draft guidance is easier for the regulated community to follow. Dr. Siegel then requested that the ACMUI review the guidance and comment on it, and explained that SNM's hope was that ACMUI would ultimately endorse the the SNM's therapy guidance to the NRC.

On July 30, 2003, SNM met with Commissioner McGaffigan to discuss this issue. SNM informed him that that they will get letters support on the therapy guidance from these other organizations, such as the American Collage of Radiology, and the American Society of Therapuetic Radiology and Oncology. Commissioner McGaffigan then indicated his support of NRC staff review of SNM's therapy guidance.

This presentation begins on Page 163 of the meeting transcript.

The above-entitled matter went off the record at 4:55 p.m., and the committee reconvened at 5:08 p.m. to discuss miscellaneous matters related to the Commission briefing, to be held May 28, 2003. The ACMUI adjourned for the day at 6:45 p.m.

May 21, 2003 Meeting

The meeting convened at 8:08 a.m.

REVIEW OF "COMPLICATED" LICENSING ISSUES SINCE 10/24/02

Donna-Beth Howe, NRC, briefed the ACMUI on this topic.

During this agenda topic, Dr. Howe outlined the Agency's handling of non-routine licensing issues. The issues involved calibration of Strontium-90 eye applicators; intravascular brachytherapy (IVB) using the Novoste system; recentness of training; and radiation doses to family members.

Regarding a Strontium-90 eye applicator case, Dr. Howe explained that the licensee requested that a physicist who performs service for him be allowed to perform decay corrections for the eye applicators. The problem was that the regulation requires that the person who performs these decay corrections be an AMP, and this person was not an AMP. Dr. Howe then reminded ACMUI that this was a case that was brought to them for recommendation, and, based on their recommendation, the individual was granted authority to perform the decay corrections, although the person was not granted AMP recognition.

In the IVB case, Dr. Howe explained that the licensee requested they be allowed to use their AMP as a consultant, who would communicate with them via telephone or fax, since he moved several hours away. After review of this licensee's license, staff decided to not grant an exemption. Staff learned that the licensee had many complicated issues associated with its use of IVB, and because staff considered consulting on this type of action to be an activity in which the AMP must be intimately involved in the treatment planning and subsequent verification, remote consulting was not acceptable.

In the recentness of training case, Dr. Howe stated that an individual wanted to be recognized as an AU, and that he was board-certified, but failed to meet the regulatory requirement that the the AU's training and experience be within the past 7 years. Staff denied this request based on failure to meet the recentness of training stipulation, despite this physician's board certification (which was 26 years ago). Dr. Howe further stated that, in matters where the individual obtains continuing training and experience, NRC, not the licensee, has the authority to determine if this training and experience is adequate.

In the final case, Dr. Howe spoke about a request to allow a family member to receive a dose of up to 2 rem while caring for a young child undergoing treatment using byproduct material. She stated that the staff agreed, but that the Commission stated emphatically that these types of requests must be considered individually. However, if staff gets repeated requests of this nature, rulemaking may be considered, to increase the allowable dose that members of the public may receive during special cases such as this one.

The ACMUI made numerous comments on the specifics of each case. Generally, they agreed with staff's handling of the issues.

This presentation begins on page 4 of the transcript.

PHYSICAL PRESENCE REQUIREMENTS DURING STEREOTACTIC RADIOSURGERY TREATMENTS

Robert Ayres, NRC, gave a presentation on this subject. In this presentation, Dr. Ayres underscored the physical presence requirements that licensees must meet while delivering gamma stereotactic radiosurgery (GSR) treatments. The purpose of his presentation was to provide illustrative examples of the type of exemption requests the Agency will either honor or deny.

Dr. Ayres explained that 10 CFR 35.615(f)(3) requires that the AU and the AMP be physically present throughout all patient treatments involving GSR. He stated that since this rule became effective on October 24, 2002, the NRC has received three requests for exemptions to the physical presence requirement in §35.615(f)(3), and one was granted while the other two were denied.

Dr. Ayres then explained the two criteria the Agency uses to either grant or deny an exemption request. First, the licensee must provide a justification for the exemption. Second, the licensee must outline an equivalent level of protection that will be used to ensure health and safety are not compromised.

Next, Dr. Ayres outlined the exemption request that was granted. In this request, the licensee proposed that an adequately trained neurosurgeon be substituted to fill the physical presence requirement of the AU after the AU (and AMP) initiated the treatment. The licensee explained that the AMP would be present throughout the entire treatment, and the AU would be in close enough proximity to the treatment such that (s)he could respond quickly to an emergency. The licensee further explained that this exemption was needed so that the AU could be used maximally in the Radiation Oncology Department, while not diminishing patients' access to GSR treatments.

The staff granted this request because the licensee provided an equivalent level of health and safety assurance by substituting the neurosurgeon for the AU on average for not more than 50 percent of the treatment time; having the AU immediately available in the event of an emergency; and requiring the AMP to be present throughout the procedure.

In one of the requests that was denied, the licensee proposed several exemptions:

- That the AU, accompanied by a neurosurgeon trained in the use of GSRs, be present at the treatment as an alternative to the requirement that the AU and the AMP be physically present throughout GSR treatment;

- That during some treatments, the neurosurgeon be physically present instead of the AU, while the AU is present at the control console.

- That they have the flexibility to interchange the presence of these individuals so that some combination of either the AU, neurosurgeon, or AMP be physically present at the treatment site while the other(s) are present in the central treatment planning room.

The staff denied this request based on the Agency position that an AU and AMP must be physically present throughout all GSR treatments. Furthermore, the licensee's alternative physical presence scenarios do not ensure that two individuals with the necessary knowledge and experience will be available to respond effectively to emergencies. Finally, the licensee provided no substantive need for this exemption.

There was extensive discussion with the staff, in which the ACMUI commented on specifics of the requests. Basically, they questioned the staff's decision to deny the requests that were denied (particularly the one outlined above). Dr. Ayres explained that in the cases where exemptions were denied, the licensee, in some respects, did not provide enough detailed information to determine the safety of the proposed alternative and that - combined with the reasons already stated - factored into the decision to deny the exemption requests. One ACMUI member agreed with Dr. Ayres on that point. Furthermore, Dr. Prabhakar Tripuraneni, ASTRO, addressed the committee and agreed strongly with Dr. Ayres that it is critically important that the AU and the AMP be present during GSR treatments. He explained that setting the coordinates to treat the diseased area involves a lot of numbers, and mistakes that are not readily apparent can be easily made. Therefore, it is critical that adequately trained professionals are present during treatment to ensure treatment is accurate, or to respond to emergencies.

Dr. Tripuraneni commended the staff in its decision to deny the exemptions, particularly in the case outlined above. However, Dr. Tripuraneni did not agree with the staff's decision to grant the exemption it granted, because he believed it was done too much for the convenience of the radiation oncologist. Nonetheless, Dr. Tripuraneni conceded that there may be extenuating circumstances for granting the exemption.

As this extensive discussion continued, the ACMUI stated that they would greatly appreciate being consulted on matters such as exemption requests. ACMUI expressed a belief that even in cases where the rule seems clear it is still subject to interpretation. Furthermore, ACMUI noted that NRC staff may be able to approve more exemption requests if staff would more actively engage the licensee to get additional information that would aid the staff in making a more informed decision.

In response, Charles Miller, Director, IMNS, stated that the ACMUI's stance on the need for staff to discuss licensee-related matters with them more often is worth considering. He quantified that stance, however, by adding that NRC has deadlines to respond to these applications, and frequent consultation with ACMUI could adversely affect those deadlines. He

further explained that NRC has limited resources (time, money, etc.) to engage licensees who submit inadequate applications for exemptions. Nevertheless, in the interest of public service, he would get advice from staff on how staff could help improve the application process so that licensees are more likely to submit better applications. Likewise, he would get staff input as to how ACMUI can be more involved in these decisions. ACMUI was receptive to these proposals.

ACTION ITEMS:

Charles Miller, Director IMNS, will:

- **Get staff input on how to improve the application process so that licensees are more likely to submit quality applications.**
- **Get staff input as to how ACMUI can be more involved in these decisions.**

This presentation begins on page 33 of the transcript.

DISCUSSION: THE LISTING OF CERTAIN PRACTITIONERS IN 10 CFR 35.1000

Background note: This discussion involves a brachytherapy device known as TheraSpheres® microspheres. Theraspheres are microscopic glass beads that deliver radiation therapy to inoperable liver cancer. Theraspheres administration is a type of therapy treatment for cancer that is handled by radiation oncology specialists. However, nuclear medicine specialists have a role in evaluating candidates for the procedure, as well as assessing the procedure's success. TheraSpheres are manufactured by MDS Nordion.

Leon S. Malmud, MD, ACMUI, led the discussion on this subject.

In this discussion, Dr. Malmud outlined how the Theraspheres approval process has unintentionally curtailed nuclear medicine physicians' ability to administer them.

Dr. Malmud explained that when the manufacturer introduced Theraspheres, it did so representing it as a therapy device. Accordingly, when NRC reviewed the use of Theraspheres, Dr. Malmud explained that NRC apparently viewed them as therapy devices; and consequently, hospitals view the use of Theraspheres as a radiotherapy technique, rather than a nuclear medicine technique.

Dr. Malmud's stance is centered around the method of introducing Theraspheres to the patient. Theraspheres administration is a type of therapy — generally the purview of radiation oncologists. However, Theraspheres are injected into patients (i.e., administered as radiopharmaceuticals) — generally the purview of nuclear medicine physicians. According to Dr. Malmud, the currently accepted view that Theraspheres are strictly therapy devices has resulted in denying professionals with the greatest amount of radiopharmaceutical injection experience an appropriate level of involvement in Theraspheres administration. These professionals are nuclear medicine physicians.

To prevent recurrence of this type of situation, Dr. Malmud suggested that NRC review not only the type of administration involved in radiation treatments, but also the method of delivery.

Next, Dr. Malmud explained what he believed are the practical problems associated with this issue. Theraspheres are not readily accessible to nuclear medicine physicians listed on broad scope licenses, according to Dr. Malmud; therefore, broad scope licensees require amendments to get access to Theraspheres. Also, licensees with specific licenses must apply for Theraspheres use. These requirements create delays in the delivery of this new therapy to patients. Another committee member, Dr. Vetter, clarified that a broad scope licensee would not require an amendment since they have the authority to determine who may administer material; however, a limited scope licensee would require an amendment.

The ACMUI as a whole acknowledged that, due to the numerous components of Theraspheres delivery and numerous types of professionals involved in its delivery, turf wars amongst physicians have appeared. A way to alleviate this issue would be to determine the following: Who has specific purview over certain aspects of treatment delivery? What aspect of treatment requires the services of a particular type of physician? What aspect of treatment can be delivered by any physician who simply receives additional training to deliver it?

The nuclear medicine physician of the committee, Dr. Douglas Eggli, believed that for strategic marketing reasons and not medical reasons, Theraspheres were marketed as therapy devices. Furthermore, because there are many more limited scope licensees than broad scope licensees, Theraspheres cannot be rapidly approved at most institutions that have well-qualified nuclear medicine physicians that could administer it. Dr. Eggli suggested that this be corrected in the rule rather than by exemption, since this is a widespread issue.

Because Theraspheres are registered in the SSDR, ACMUI asked staff to verify that Theraspheres meet the definition of sealed sources. Donna-Beth Howe, NRC, replied that as glass-encapsulated sources entered into the patient as permanent implants, they do. Furthermore, staff determined that radiation oncologists are the most appropriate physicians to deliver them after staff reviewed the required training and experience necessary for delivery of therapy sources. Additionally, Dr. Howe explained that staff recognizes that newer products may cross boundaries in terms of classification, so staff has flexibility, in guidance space, to allow a product such as Theraspheres to be classified in multiple categories. (For detailed discussion on NRC's rationale for classifying Theraspheres as therapy devices, see agenda topic "10 CFR 35.1000 Licensing Guide" in these minutes).

The ACMUI, in general, agreed that Theraspheres should not be strictly categorized as either a radiation therapy or nuclear medicine application, but that institutions should have the flexibility to view it either way. ACMUI agreed that further discussion and a possible recommendation later in the day during the 10 CFR 35.1000 subcommittee meeting was warranted.

This presentation begins on page 102 of the transcript.

INTERPRETATION OF 10 CFR 35.61(b)

Ronald E. Zelac, NRC, led the discussion on this topic. Dr. Zelac explained what 10 CFR 36.61(b) requires. This section, Calibration of survey instruments", requires that the exposure rate, as read on the instrument when it is measuring a radiation field, may not differ by more than plus or minus 20 percent from the exposure rate that was calculated during calibration of the instrument. If they differ by more than 20 percent, then the instrument is not calibrated to

detect radiation fields accurately, and may not be used.

Dr. Zelac noted that all Federal agencies are required to use national performance standards when they are available and they apply to a particular activity the agency is regulating. The national standard for instrument calibration is the American National Standards Institute N323A, better known as ANSI Standard N323A. ANSI N323A explicitly states that instruments that are used to measure radiation fields must give measurements that do not differ by more than 20 percent from the calculated exposure.

Next, Dr. Zelac explained that in practice, instrument probe calibrations are usually performed with a high energy source although the energies that will be measured are not necessarily high energies. He further explained that many energy-dependent instrument probes that are calibrated with high energy sources are able to respond within the plus or minus 20 percent allowance when they are used to measure lower energies. However, specialized probes, such as probes designed specifically to detect low energies, will give inaccurate readings if calibrated with a high energy source, because they are designed to detect low energies. Dr. Zelac stated that licensees who own such specialized instrument probes should calibrate them with lower energy sources. The special calibration requirement for these types of instrument probes is neither onerous nor cost-prohibitive, according to Dr. Zelac.

One ACMUI member disagreed that the need to calibrate certain instrument probes in a certain manner, as Dr. Zelac outlined, is not a problem. He contended that those licensees who must measure fields of various energies yet possess only the type of instrument probe that is suited to measuring high energies, must purchase additional probes to measure lower energies. Therefore, licensees in this situation should be given the more cost-effective alternative to use the manufacturer's energy response curve to mathematically calculate what the actual exposure is at the lower energies they measure.

Dr. Zelac responded that licensees cannot do this, because 10 CFR Part 35 does not allow licensees to use the manufacturer's energy response curve to extrapolate measurements of energies the instrument is not specifically designed to detect (nor does Part 35 allow them to use any other type of correction chart for this purpose). Dr. Zelac restated his earlier position -- that if one has an instrument probe suited to measuring a broad range of energies, then calibration with a high energy source will leave the probe sufficiently sensitive to detect lower energies as well.

Some ACMUI members, as well as members of the general public, informed staff that they still believe that licensees should be allowed to use correction charts of some sort to measure energies that an instrument's probe is not specifically designed to measure. They underscored their position by the fact that Part 35 allowed the use of correction charts before it was revised.

ACTION ITEM: Dr. Zelac informed ACMUI that staff will re-discuss this issue and provide the ACMUI feedback at the next public meeting.

This presentation begins on page 132 of the transcript.

REVIEW OF MEDICAL AREA OPERATING EXPERIENCE AND ENFORCEMENT ACTIONS: ONE YEAR AND SINCE 10/24/02

Roberto Torres, NRC, gave the ACMUI a presentation on this topic. The purpose of Mr. Torres's presentation was to provide ACMUI with a snapshot of the type and severity of events that have occurred since the new 10 CFR Part 35 has been promulgated. The ACMUI requested this briefing in an effort to ascertain how effective the revised regulations are at protecting public health and safety.

Mr. Torres began by explaining that, since the rule has been promulgated for such a short period of time, it is too early to determine with any precision whether the updated rule has improved safety across the population of medical licensees. Nonetheless, he outlined select events data on misadministrations and medical events, that was collected in 2000 and 2001 (before the new rule was promulgated) and compared that to the misadministration/medical event data that were collected through April 2003.

As Mr. Torres continued, he supplied details on the various causes of the events, and associated NRC responses. The events data generally showed a trending toward human error as the cause, either by omission or commission of activities. The data also showed a trending toward fewer events as the years progressed. The data showing trending toward fewer events, is not statistically significant, however.

Jeffry Siegel, SNM, commented on the low numbers of events involving diagnostic nuclear medicine. Dr. Siegel implied that diagnostic procedures may not need regulatory oversight, since events within that area are low. In response, Angela Williamson, NRC, acknowledged that the record of safety for diagnostic nuclear medicine procedures is good, but noted that the Agency must keep track of these events (as well as others) because it is required to report these numbers to Congress.

Toward the end of the presentation, the ACMUI suggested that when the NRC presents these types of numbers to them, to put the data in perspective by presenting it as a ratio to the estimated numbers of procedures given, and further quantify the data by factoring in relative risk as well as the absolute number of adverse events or severity violations.

Charles Miller, NRC, informed the ACMUI that before the Agency can justify expending the necessary resources to present data in this manner, the ACMUI would need to explain its value in assisting them in their advisory role to staff. Dr. Miller further explained that expenditure of staff effort for this purpose must assist the ACMUI in providing NRC with information that can be used to help frame the future regulatory structure. As discussion ensued, ACMUI stated that they believed that they could use this information to help staff frame future regulatory structure, and that the professional medical societies they are affiliated with tend to collect data of this nature. ACMUI suggested that staff approach them individually to get these data.

This presentation begins on page 153 of the transcript.

UPDATE: RECOMMENDATIONS FROM FALL 2002 MEETING

Angela R. Williamson, NRC, gave this update. During this presentation, Ms. Williamson

outlined the staff's response to several recommendations the ACMUI made at the October 28, 2002 meeting.

A recommendation that generated a lot of discussion involved the listing, by serial and model number, of interstitial radioactive seeds in licenses. (See the summary of the agenda topic "Sealed Source Model Numbers as License Conditions" for related discussion of this topic.) The ACMUI believed that this requirement was overly burdensome since manufacturers often change model and serial numbers, resulting in the need to amend licenses to reflect the changes. ACMUI recommended that staff initiate a rulemaking to allow licensees to list their seeds generically, so that amendments are not necessary when manufacturers change model/serial numbers.

Ms. Williamson explained that, although staff fully understood the rationale to change the rule to allow for generic listing of radioactive seeds, staff did not believe it was wise from either a safety or regulatory standpoint to do so. Ms. Williamson explained that staff believed that a relaxation of the requirement to list seeds by model/serial number will ultimately reduce accountability; and thereby, undermine the Agency's ability to protect public health and safety. She furthermore explained that such a move in a politically sensitive environment where the threat of terrorism is ever-present is not prudent public policy.

One ACMUI member replied that generic listing of radioactive seeds would not lead to reduced source accountability, and that political sensitivity and public perception are not good enough reasons to resist changing the rule. He argued that in a performance-based, less prescriptive environment, the rule should be relaxed, and that the argument surrounding public perception of hazards can be applied to resist any attempt to change any rule. However, the ACMUI Chairman, stated that NRC staff seem to be aware of the arguments supporting the generic listing of radioactive seeds on licenses. He indicated that he agreed that the public perception of reduced accountability is a valid factor to consider.

Another ACMUI member underscored the need to not reduce source accountability; nevertheless, the burden of listing seeds and sources by model/serial number should be reduced. He reminded everyone that NRC staff and the ACMUI agreed, in previous discussion, that it is necessary that staff go back and revisit this issue to come up with an alternative to rulemaking that would reduce the licensee burden of listing interstitial seeds by model/serial number on licenses.

The other recommendations briefly discussed were:

- That the Chairman, ACMUI, contact the NRC Chairman to inquire about the status of the ACMUI Subcommittee recommendations to amend the revised 10 CFR Part 35's T&E;
- That ACMUI formation of a standing subcommittee to review 10 CFR 35.1000 licensing guidance;
- That NRC staff initiate replacement members for the approaching nuclear cardiologist, patient advocate, and state government representative vacancies.

Ms. Williamson briefly expounded on the other recommendations, explaining that staff implemented those that required staff action. ACMUI understood and offered no further suggestions regarding staff's action, nor any substantive comments.

This presentation begins on page 197 of the transcript.

10 CFR PART 35 QUESTION AND ANSWER PROCESS

Ronald E. Zelac, NRC, briefed the ACMUI on this topic.

Dr. Zelac informed the ACMUI that the NRC staff is developing answers to frequently asked questions regarding the revised Part 35. These questions and answers (Q&As) are being posted to the Agency's website.

Next, Dr. Zelac explained that the questions come from various avenues: from staff during internal training; from the public during public workshops on the revised Part 35; from telephone calls, e-mails, and letters to staff from stakeholders; and finally, questions are generated from implementation issues that staff becomes aware of as the rule is being applied.

Dr. Zelac then gave a general outline showing how staff processes questions. He explained that the Part 35 Implementation Working Group, consisting of Headquarters and regional staff, meets regularly to discuss questions and propose solutions. Once the group decides it has answered a batch of questions satisfactorily, they are put in a paper and circulated throughout the Agency for comment. The Q&As are then adjusted as necessary and forwarded to the Office of the General Counsel (OGC). After OGC input, IMNS reviews them once more before posting them to the NRC website.

The ACMUI praised this effort and wanted to know how they can assist staff in making this resource widely known. Dr. Zelac informed them that NUREG 1556 Vol. 9 mentions that Q&As are available on the website. Additionally, anyone who visits the website can easily locate the Q&As. Dr. Zelac then stated that he is open to suggestions for ways to make the Q&As more widely known. The ACMUI suggested that the staff contact professional societies.

This presentation begins on page 191 of the transcript.

10 CFR 35.1000 LICENSING GUIDANCE

Donna-Beth Howe and Robert Ayres, NRC, made presentations on this topic.

Dr. Howe ultimately explained where the guidance stands on issues presently identified under §35.1000 of 10 CFR; but first, she explained the relationship between NRC and the U.S. Food and Drug Administration (FDA). Dr. Howe stated that the NRC and the FDA work closely, sharing information. NRC staff participates on some of FDA's advisory committees, and this interaction is a primary means of informing the NRC of new technologies.

Dr. Howe next explained the process NRC uses to categorize new technologies in Part 35. First, the technology is reviewed for its standard characteristics, its unique characteristics, and unique safety problems. Next, staff reviews definitions within the rule to see if the new technology fits nicely into a pre-existing definition. Following that, staff reviews an internal document that shows how it regulates different materials, and will look to see how well the new technology fits into that process. If the product does not fit nicely into how NRC regulates similar products, Dr. Howe explained, then staff usually must develop guidance. Dr. Howe

then explained the rationale used to classify microspheres.

NRC regards microspheres as devices. The ACMUI mentioned during an earlier presentation ("The Listing of Certain Practitioners in 35.1000") that manufacturers were driven by marketing interests to market microspheres as devices, although they are more appropriately categorized as radiopharmaceuticals. However, as Dr. Howe explained, the Agency believes microspheres are most appropriately categorized as devices, because they do not meet the FDA's definition of a radiopharmaceutical. Unlike pharmaceuticals, microspheres do not interact pharmacologically, physiologically, or biochemically within the body. Dr. Howe also stated that although microspheres are injected, they are not injected using syringes or intravenous drips, which is yet another argument to not classify them as radiopharmaceuticals.

Next, Dr. Howe explained the unique safety issues involving Theraspheres microspheres. Two conditions must be met in order to deliver microspheres satisfactorily. First, the microspheres must be adequately suspended in the source vial. Second, the delivery device must function properly. The safety issues, as Dr. Howe explained, are that the product is not always in adequate suspension, and the delivery system does not always perform properly. Yet another safety problem is shunting. Shunting occurs when the microspheres are delivered to the target organ (the liver); yet, too many of them end up migrating into the major vasculature of the body and carried to an unintended organ, usually the lung. Any of these problems can result in improper dosages and/or spillage.

Dr. Howe then explained the Agency's actions to address, specifically, the problem of shunting. Because some shunting appears to be inevitable with Theraspheres microspheres, NRC had to develop criteria to preclude the possibility that every procedure winds up being a medical event. Therefore, NRC decided that, as long as the dose shunted to unintended organs does not meet a certain threshold, it is the physician's medical decision to define the level of acceptable shunting for every patient.

Next, Dr. Howe briefly explained the safety issues with the SirSpheres® brand of microspheres. Sirspheres have a different delivery system than do Theraspheres. Also, because Sirspheres have a much smaller specific gravity than do Theraspheres, they stay suspended better. However, backflow of Sirspheres is common, which means that they end up migrating to unintended places. It appears that only so many of the spheres can be delivered to the target organ (liver), so that backflow is inevitable. To address this issue, Dr. Howe explained that the NRC's Sirspheres guidance recommends that the AU record in the written directive the patient-specific dosages that state the acceptable dose of spheres that can be delivered to unintended sites.

Dr. Howe also spoke about issues with a particular liquid brachytherapy treatment. Like the Theraspheres and Sirspheres microspheres, this item, named Iotrex, is a device and not a radiopharmaceutical. This device is a balloon in which liquid radioiodine is placed. The balloon is then placed in a catheter that is inserted into the patient's body. One of the problems with this device is that the radioiodine can become disassociated with the molecule it is attached to, and seep through the catheter membrane to be absorbed by unintended parts of the body. Another problem is that if the licensee mistakenly leaves too much radiopaque dye in the balloon, the dye will absorb too much of the radioiodine so that the patient doesn't receive the proper dose.

Dr. Howe noted that a certain amount of seepage into undesired areas is inevitable. Using the strict definition of leaking sources, a leaking source would occur every time this procedure is administered. To prevent this occurrence, NRC has drafted guidance that explains that for this device, a failure of the catheter to contain the source is considered leakage, not the inevitable seepage of some small volume of radioiodine. Further, to address the issue with radiopaque dye remaining in the balloon and causing underdoses, NRC's licensing guidance encourages licensees to follow the manufacturer's instructions, and Dr. Howe briefly explained what this entails.

Regarding the microspheres discussion, a small number of ACMUI members believed that customizing a written directive for each patient may impinge on the practice of medicine. However, most other ACMUI members' responses to that proposal were positive. With respect to either therapy, they believed that the freedom to craft a written directive that is patient-specific in terms of dose delivered is a useful, flexible tool that will eliminate "excessive" medical event cases. Regarding the liquid brachytherapy discussion, after the staff provided a few more clarifying comments, the ACMUI's consensus was that staff's actions were appropriate.

Dr. Ayres centered his presentation around IVB issues. He began by explaining that NRC requires that IVB procedures are conducted under the supervision of the AU, who must consult with the AMP and the interventional cardiologist during the treatment planning phase. Dr. Ayres further explained that in clinical practice, IVB procedures are far broader in scope than the procedure that FDA approved (which is the use of IVB to treat a condition called in-stent restenosis). However, licensees may conduct these broader uses of IVB, due to the NRC's requirement that the AU and AMP be present during IVB procedures. The presence of these professionals allows licensees to safely conduct IVB procedures for other than the FDA-approved use.

Next, Dr. Ayres provided information regarding medical events associated with IVB use. He noted that over the years, he has collected about 100 medical events involving IVB. This number is far above what NRC has seen with almost any other modality. Furthermore, NRC is aware of other issues - that cause medical events and are associated with IVB - that are reportable to the FDA. These issues contribute to failure of the device to work as intended. Dr. Ayres explained that these combined factors contributed to the need for certain NRC requirements, such as the requirement that the AMP perform an independent measurement of source output during IVB, and the requirement that licensees have written emergency procedures.

Dr. Ayres then briefly outlined the guidance that NRC has posted to its website for licensees to use to assist them in obtaining licensing for the Novoste Beta-Cath; Cordis Checkmate, and Guidant Galileo IVB systems.

ACMUI and Dr. Ayres discussed in detail the specifics of each IVB system with respect to licensing, regulatory requirements, and problems unique to each system. The discussion concluded with no recommendations or general consensus forwarded to the staff. ACMUI offered no substantive comments regarding Dr. Howe's presentation.

These presentations begin on page 205 of the transcript.

10 CFR 35.1000 SUBCOMMITTEE WORKING MEETING

Ruth McBurney, the ACMUI's state government representative, and Chair of the 10 CFR 35.1000 Subcommittee, led the discussion on this topic. This was a working meeting where members of the public had an opportunity to provide the ACMUI with information they believed the subcommittee should consider as it develops recommendations for 10 CFR 35.1000 licensing guidance.

The first item discussed was microspheres. Ms. McBurney stated the unique nature of microspheres: that their physical properties and behavior in the body has led them to be officially considered sealed sources (and therefore therapy devices that would come under the auspices of radiation oncology), but their drug-like properties makes it possible for them to be licensed as radiopharmaceuticals (which would bring them under the auspices of nuclear medicine). This dual view of microspheres' applicability has created physician training issues.

Several ACMUI members, as well as NRC staff, believed that a team should administer microspheres, because of the complexity of the procedure and types of problems that could arise. Dr. Hevezi, representing ASTRO, also agreed that the team approach is appropriate; however, what group of professionals should comprise the team? One ACMUI member believed the AU should always be a team member and should determine who the others are for each case. Dr. Donna-Beth Howe, NRC, suggested that the way to determine the team members would be for the ACMUI to identify the task being performed. Once it is clear what the different types of tasks are, NRC will be able to identify the appropriate professional who should be available to oversee that task. The ACMUI agreed.

Later on, the discussion focused on physician training issues. The general question was: If a physician team member does not quite meet the level of training in 10 CFR 35.390 that is needed to administer certain Theraspheres or Sirspheres therapies, what further training is needed? Dr. Robert Ayres, NRC, suggested that the ACMUI assist the NRC staff in writing Information Notices that will notify licensees about training-related issues. Regarding which professionals should administer the Sirspheres therapy treatments, the general committee and NRC consensus was that this is best accomplished by professional medical societies. Lynne Fairobent, representing ACR; and William Uffelman, representing SNM; suggested that ACR, SNM and ASTRO meet to draft some recommended training. Ms. McBurney asked them to get a consensus on recommended training and correspond with her by e-mail on the result.

Regarding Gliasite IVB, the subcommittee indicated they believed it should be moved from §35.1000 to §35.400 , the uses of manual brachytherapy section. However, Dr. Howe explained that it doesn't fit entirely within §35.400. The discussion continued at length. Although neither the ACMUI nor members of the public communicated that they believe there must be changes to the licensing guidance regarding the written directive, there was no discernable agreement on what other changes may be needed.

The meeting adjourned at 5:01 p.m.

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. **Committee's Official Designation:**

   Advisory Committee on the Medical Uses of Isotopes

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 (IMNS), 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 Committee may provide consulting services as requested by the Director, IMNS

3. **Time period (duration of this Committee):**

   From March 20, 2002, to March 20, 2004

4. **Official to whom this Committee reports:**

   Charles L. Miller, 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. $160,000.00 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 Full Time Equivalent

8. **Estimated number of meetings per year:**

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

9. **The Committee's termination date.**

March 20, 2004

10. **Filing date:**

September 25, 2003

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

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

CONTENTS

PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, tand that the resulting reports represent, to the extend possible, the best of which the Committee is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulatins as appropriate.

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the Committee will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with Committee business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the Committee (referred to below as "the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the committee will review the findings of the Office of the General Counsel regarding

possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the committee, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.

2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Commission. The Commission has the final authority for selection. The term of an appointment to the committee is three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).

3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the committee, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations.

5. ADOPTION AND AMENDMENTS

5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.

5.2 Any member of the committee or NRC may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular committee meeting.

5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.

5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.

5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 15th day of September 2003.

For the Nuclear Regulatory Commission.

John A. Nakoski,

Chief, Section 1, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation

[FR Doc. 03–24093 Filed 9–18–03; 12:01 pm]

BILLING CODE 7590–01–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 will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on November 12–13, 2003. The meeting will take place at the address provided below.

DATES: All sessions of the meeting will be open to the public with the exception of the first session, which will be closed to conduct administrative business related to internal personnel rules and/or practices of ACMUI members, and to provide safeguards training to ACMUI members. A sample of agenda items include: (1) The NRC method of dose reconstruction; (2) Update: Listing Sources by Model/Serial Number on Licenses; (3) Update: National Materials Program Pilot Project on Operating Experience Evaluation; and, (4) Update: Emerging Technologies.

ADDRESS FOR PUBLIC MEETING: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Conference Room T2B3, 11545 Rockville Pike, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION CONTACT: Angela R. Williamson, telephone (301) 415–5030; e-mail *arw@nrc.gov* of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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 Angela Williamson, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, 11545 Rockville Pike, Rockville, MD 20852–2738. Submittals must be postmarked by October 17, 2003, and must pertain to the topics on the agenda for the meeting.

2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection on NRC's Web site (*www.nrc.gov*) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852–2738, telephone (800) 397–4209, on or about December 1, 2003. Minutes of the meeting will be available on or about January 15, 2004.

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 16, 2003.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 03–24089 Filed 9–18–03; 12:01 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Rules 17h–1T and 17h–2T, SEC File No. 270–359, OMB Control No. 3235–0410

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget requests for extension of the previously approved collections of information discussed below. The Code of Federal Regulation citations to this collection of information are the following rules: 17 CFR 240.17h–1T and 17 CFR 240.17h–2T.

Rule 17h–1T requires a broker-dealer to maintain and preserve records and other information concerning certain entities that are associated with the broker-dealer. This requirement extends to the financial and securities activities of the holding company, affiliates and subsidiaries of the broker-dealer that are reasonably likely to have a material impact on the financial or operational condition of the broker-dealer. Rule 17h–2T requires a broker-dealer to file with the Commission quarterly reports and a cumulative year-end report concerning the information required to be maintained and preserved under Rule 17h–1T.

The collection of information required by Rules 17h–1T and 17h–2T is necessary to enable the Commission to monitor the activities of a broker-dealer affiliate whose business activities is reasonably likely to have a material impact on the financial and operational condition of the broker-dealer. Without this information, the Commission would be unable to assess the potentially damaging impact of the affiliate's activities on the broker-dealer.

There are currently 166 respondents that must comply with Rules 17h–1T and 17h–2T. Each of these 166 respondents require approximately 10 hours per year, or 2.5 hours per quarter, to maintain the records required under Rule 17h–1T, for an aggregate annual burden of 1,660 hours (166 respondents × 10 hours). In addition, each of these 166 respondents must make five annual responses under Rule 17h–2T. These five responses require approximately 14 hours per respondent per year, or 3.5 hours per quarter, for an aggregate annual burden of 2,324 hours (166 respondents X 14 hours). In addition, there are approximately seven new respondents per year that must draft an organizational chart required under Rule 17h–1T and establish a system for complying with the Rules. The staff estimates that drafting the required organizational chart requires one hour and establishing a system for complying with the Rules requires three hours, thus requiring an aggregate of 28 hours (7 new respondents × 4 hours). Thus, the total compliance burden per year is approximately 4,012 burden hours (1,660 + 2,324 + 28).

Rule 17h–1T specifies that the records required to be maintained under the Rule must be preserved for a period of not less than three years. There is no specific retention period or record keeping requirement for Rule 17h–2T. The collection of information is mandatory and the information required to be provided to the Commission pursuant to these Rules are deemed confidential, notwithstanding any other provision of law under section 17(h)(5) of the Securities Exchange Act of 1934 (15 U.S.C. 78q(h)(5)) and section 552(b)(3)(B) of the Freedom of Information Act (5 U.S.C. 552(b)(3)(B)).