(5) 7/24/97 S. Treby's comments

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

(5)

10 CFR Part 35

RIN-3150-AF74

Medical Use of Byproduct Material:

Issues and Request for Public Comment

AGENCY: Nuclear Regulatory Commission

ACTION: Request for comment.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) has developed a program for revising the regulations governing the medical use of byproduct material. The decision to revise this regulation resulted from the NRC Strategic Assessment and Rebaselining Initiative (SA), a process involving identification of the direction-setting issues and associated options for the future of NRC activities. This notice describes the NRC's program for revising the medical use regulation; notifies the public of the availability of documents associated with this action, on the INTERNET; and solicits informal public comment on rulemaking and associated document text during the development stages. The Commission plans to formally propose specific rulemaking text for public comment during the summer of 1998.

and through the NRC Public Document Room, ✓

are solicited during development of the proposed rule but, to be most helpful, should be

DATES: Comments ~~will be most helpful if~~ received by March 1, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission only is able to ensure consideration of comments received on or before this date.

ADDRESSES: Send written comments and suggestions to Secretary, Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudication Staff. Hand-Deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

Written comments may also be submitted electronically on the Internet via NRC's interactive rulemaking web site, through the NRC home page (http://www.nrc.gov). This site provides the ability to upload comments as files (any format), if your web browser supports this function. For information about the interactive rulemaking site, contact Mary Thomas at (301) 415-6230; e-mail MLT@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6825; Diane Flack, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5681; or Susanne Woods, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7267.

SUPPLEMENTARY INFORMATION:

Background

The NRC has examined the issues surrounding its medical use program in great detail during the last four years. This process started with NRC's 1993 internal senior management review report; continued with the 1996 independent external review report by the National Academy of Sciences, Institute of Medicine; and culminated in NRC's SA process. In particular, medical oversight was addressed in the SA Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996).

In its "Staff Requirements Memorandum (SRM) - COMSECY-96-057, Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission directed the NRC staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement. Further, the SRM stated:

> With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. Further, during development of the rule and associated guidance, as well as during review of the Medical Policy Statement, the NRC staff was directed to consider the following issues:

1. Focusing Part 35 on those procedures that pose the highest risk.

2. Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures.

3. The best way to capture not only relevant safety-significant events, but also precursor events.

4. The need to change from the term "misadministration" to "medical event" or other comparable terminology.

5. Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner.

6. Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety.

7. The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC needs.

Program for Revision of Part 35

The June 30, 1997, SRM informed the NRC staff of the Commission's approval, with comments, of the NRC staff's proposed program in SECY-97-131, Supplemental Information on SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material,' and Associated Federal Register Notice," dated June 20, 1997. With this approval, the NRC staff initiated development of draft language using an entirely modality-based approach. The modality approach places all requirements for a given type of treatment into a single section of the regulation, including: who or what organization is licensed; what type of license is issued; the necessary technical requirements, such as surveys and calibration; the training and experience requirements; the event recording and reporting requirements; and the quality improvement and management objectives. The NRC staff anticipates that the following modalities would be addressed:

(1) Low-dose unsealed materials (diagnostic nuclear medicine);

(2) High-dose unsealed materials (nuclear medicine therapy);

(3) Low-dose sealed source applications;

(4) Teletherapy;

(5) High-dose rate remote afterloaders;

(6) Gamma stereotactic surgery; and

(7) Emerging technologies.

This list is not viewed as all-inclusive. Additional categories may be developed, depending on the breadth of the areas to be covered, and the similarity of requirements in a given area.

Development of rule text alternatives, including draft guidance documents, would be done using a working group (or groups) and steering group approach. State participation in the process will be enhanced through the inclusion of State individuals in both the working group and the steering group.

The NRC staff plans to solicit public input on the revision to Part 35, associated guidance, and the 1979 Medical Policy Statement on an informal and formal basis during the rulemaking process. It is expected that the first version of the draft rule language will be available to the public on the INTERNET and through the NRC Public Document Room, in August 1997. During the development process, the NRC staff will make drafts publicly available, but will need to cut off consideration of comments at a point approximately two to three months before providing the draft rule language and associated documents to the Commission for approval. (Currently the draft rule and associated documents are scheduled to be provided to the Commission in May 1998.) Comments received after that time would be considered as part of the ongoing interaction process, and as part of the comments received during the formal public comment period on the proposed rule after Commission approval. The NRC staff plans to interact with professional societies on an ongoing basis to solicit comments. The NRC staff will conduct facilitated public meetings in the Fall of 1997. These meeting will

be used to focus discussion on the specific rule text and alternatives. Discussions would also be held in meetings with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the Organization of Agreement States in the Fall of 1997.

After Commission approval of the draft rule language and associated documents, the proposed rule and draft documents will be published in the Federal Register for public comment for a minimum of 75 days. The NRC staff will also make the drafts available on the INTERNET, and will accept comments electronically. The NRC staff plans to hold two public meetings during the formal comment period, to facilitate comment submittal.

Development of the final rule, associated documents, and final guidance will be done using a working group(s) and steering group. The NRC staff will continue to make draft documents available, but would not be able to consider further external input, beginning approximately four months before the submission of the final documents for Commission approval (currently scheduled for May 1999). The NRC staff plans to discuss the final documents with the ACMUI and the Agreement States before submitting them to the Commission.

Reference Information

1. Strategic Assessment Direction-Setting Issues Paper Number 7 is available by writing to the U.S. Nuclear Regulatory

Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

2. The memorandum "Management Review of Existing Medical Use Regulatory Program (COMIS-92-026)" (dated June 16, 1993) is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

3. "Radiation in Medicine: A Need for Regulatory Reform" (1996) is available from the National Academy Press at 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055.

4. Summary minutes and transcripts of the ACMUI April 1997 meeting or transcripts of the May 8, 1997, Commission briefing are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

Transcripts of the May 8, 1997, briefing are also available by Internet at http://www.nrc.gov.

5. The NRC Medical Policy Act Statement of 1979 was published in the Federal Register, Volume 44, page 8242, on February 9, 1979.

6. SECY-97-115, Program for Revision of 10 CFR Part 35, "Medical Uses of Byproduct Material" and Associated Federal Register Notice; SECY-97-131, Supplemental Information on SECY-97-131, Supplemental Information on SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material,' and Associated Federal Register Notice; and the associated SRM (dated June 30, 1997) are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

Copies are also available on the Internet at http://techconf.llnl.gov/noframe.html.

Dated at Rockville, Maryland, this_____day of July, _____ 1997.

For the U. S. Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission.

DOCUMENT NAME: frn35.rdb

No legal objection

OFC	IMOB	IMAB	NMSS	IMNS	OGC
NAME	DFlack/ll	CHaney	EKraus	DCool	SATreby for WOlmstead
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DATE	7/ /97	7/ /97	7/ /97	7/ /97	7/ /97	7/ /97

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OFC	IMOB	IMAB	NMSS	IMNS	OGC
NAME	DFJack/II	CHaney	EKraus	DCool	STreby no legal objection
DATE	7/28/97	7/ /97	7/23/97	7/29/97	7/24/97

OFC	OSP	ADM	NMSS	DEDR	EDO	SECY
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DATE	7/24/97	7/25/97	7/29/97	7/ /97	7/30/97	7/ /97

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