March 20, 1998 SECY-98-054

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: COMMISSION RESOLUTION OF SIGNIFICANT ISSUES ASSOCIATED WITH THE REVISION OF 10 CFR PART 35, “MEDICAL USES OF BYPRODUCT MATERIAL”

PURPOSE:

To obtain Commission direction on: (1) retaining the current requirement for medical use licensees to notify individuals and referring physicians of a medical event,[1] pursuant to 10 CFR 35.33(a)(3) and (a)(4); and (2) capturing precursor events.

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

[1] The Part 35 Working Group has replaced the term "misadministration" with "medical event," based on SRM - COMSECY-96-057, "Materials/Medical Oversight (DSI-7)," March 20, 1997 (Attachment 1), in which the Commission said the staff should consider ". . . changing the nomenclature from ’misadministration’ to ’medical event’ or comparable terminology." However, in historical discussions, the term "misadministration" is still used.

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BACKGROUND:

The Commission, in its Staff Requirements Memorandum (SRM) of June 30, 1997, SECY-97-115, "Program for Revision of 10 CFR Part 35, 'Medical Uses of Byproduct Material' and Associated Federal Register Notice," approved the staff's proposed plan for the revision of 10 CFR Part 35 (Attachment 2). The staff implemented that plan by establishing a U.S. Nuclear Regulatory Commission Working Group and Steering Group, and by actively soliciting input from the public, the medical professional societies, States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The staff has benefitted from these interactions with the regulated community and the public and has received many useful comments.

The Working Group considered the input from the public and the medical community in developing the "strawman" revision of the Part 35 rule that was placed on the INTERNET and in the Public Document Room on January 30, 1998. That "strawman" revision included: (1) the current requirements for notifying NRC, referring physicians, and individuals of medical events, because of the controversy associated with individual (patient) notification; and (2) a proposed definition of a "significant precursor" (and related recordkeeping and reporting requirements).

DISCUSSION:

Notification Following a Medical Event

The current regulations in 10 CFR 35.33(a) and (b) require, in part, that NRC medical use licensees inform NRC, the referring physician, and the individual receiving the misadministration (medical event) within 24 hours of its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual, or that, based on medical judgment, telling the individual would be harmful. Background information on 10 CFR 35.33(a) and (b) is presented in Attachment 3.

Staff is not requesting guidance on whether licensees should notify NRC of a medical event. Staff and licensees recognize that this notification is needed, at a minimum, for NRC to comply with Section 208 of the Energy Reorganization Act for reporting "Abnormal Occurrences" to Congress. However, because of medical community and public comments, staff has been evaluating whether the current regulations should be revised to require notification of NRC only, or of NRC and the referring physician.

The majority of the comments received on notification following a medical event (including those
of two "patient rights advocates"[2]), indicated that there should not be an NRC requirement for patient and/or referring physician notification in the case of a medical event. Individuals who do not favor patient notification assert that there are no other areas of medicine in which there is a Federal requirement for patient notification and that an NRC requirement for patient

[2] However, a patient's right advocate at the ACMUI meeting on March 2, 1998, expressed concern about the risk to the patient, if the patient or referring physician is not notified.

notification is contrary to the 1979 Medical Policy Statement. According to some of the ACMUI members and the NRC medical consultant advising the Working Group, patient notification of medical events should occur as part of the patient-physician "fiduciary" relationship, in which it is the "standard of care" for a physician to provide the patient with complete and accurate information.[3] Members of the medical community have pointed out that they view the "fiduciary" relationship between the patient and physician as different from that between a licensee and an individual receiving a dose in excess of the 10 CFR Part 20 limits. In addition, some members of the medical community particularly object to the requirement, in 10 CFR 35.33(a)(I)-(ii), for licensees to provide the informed individual with a copy of the licensee's report to the Commission (or a similar report), believing that the report greatly magnifies the significance of the event when, in fact, a medical event could be of minimal safety significance.

Although patient (and referring physician) notification of medical mistakes or events is the "standard of care," that practice may not be uniformly followed. Based on recent articles in a professional medical journal and the national news media (Attachment 5), the issue of whether physicians should notify patients of medical "events" is the subject of considerable debate and is not at all well-settled. Thus, reliance on physicians to follow either the "standard of care" or the AMA ethical standards,[3] may result in patients not receiving information necessary for their medical care.

Those opposing and those favoring retention of the requirement to notify the individual, referring physician and NRC agree that the issue is not whether patients should be notified of medical events. Rather, the issue is whether, in light of existing medical ethical and practice standards obligating physicians to make such notifications, NRC should retain the provisions in Part 35 requiring licensees to do so.[4]

Staff has identified three possible alternatives for notification of NRC, referring physician, and individuals, in the case of a medical event. Attachment 6 provides a detailed discussion of these alternatives.

Alternative 1: Retain the current reporting requirements in Part 35, with minor changes intended to clarify the term "responsible relative."

Alternative 2: Revise the current reporting requirement to require a licensee to inform NRC and the referring physician (but not the patient) of the medical event.

Alternative 3: Revise the current reporting requirement to require a licensee to inform only

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[3] A patient's right to receive information from physicians is an element of the patient-physician relationship and is also part of "informed consent," based on American Medical Association (AMA) "Principles of Medical Ethics." (See Attachment 4).

[4] If there is such a requirement, the Working Group/Steering Group agree that the rule should retain the provision permitting the referring physician to inform the patient and for the licensee not to notify the patient, if, based on medical judgment, telling the patient would be harmful. 10 CFR 35.33(a)(3).

NRC of a medical event.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of notifying only NRC (Alternative 3).

Precursor Events

The Commission, in COMSECY- 96-057, directed staff to determine the best way to capture precursor events. Staff's objectives in capturing precursor events are to identify and analyze incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities.

Alternative pathways for capturing precursor events were discussed with the ACMUI at the September and March semi-annual meetings, and with the public during two facilitated public workshops (October and November 1997). In September 1997, the ACMUI recommended that NRC make reporting of precursor events voluntary. Participants in the facilitated public workshops, as well as members of the public, believe that: (1) there are already adequate mechanisms in place for identifying precursor events; (2) additional NRC requirements for notification of precursor events could result in a significant financial burden for both NRC and licensees, without an associated incremental increase in safety; (3) because of the nature of precursor events, it will be hard to precisely define a precursor event in rule language; and (4) inclusion of a requirement for reporting of precursor events could lead to an additional basis for enforcement action.

Staff believes that identification and reporting of precursor events at some level is warranted, given that a "significant precursor" may have future implications for that facility or for similar facilities (generic incidents), and thus such reporting could lead to improved radiation safety programs at licensed facilities. Therefore, staff identified three possible alternatives for capturing precursor events. Attachment 7 provides a detailed discussion of these alternatives.

Alternative 1: Revise Part 35 to require reporting of "significant precursors."

Alternative 2: Revise Part 35 to require reporting of deficiencies in equipment (hardware and/or software), byproduct material, or procedures supplied by a manufacturer or vendor that, in the opinion of the radiation safety officer, could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility.

Alternative 3: Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding with the Food and Drug Administration and monitor/establish a system with U. S. Pharmacopeia to review its database.

On March 2, 1998, the ACMUI voted 8-0, with one abstention, in favor of Alternative 2.

RECOMMENDATIONS:

The staff is seeking Commission guidance on the preferred alternative for notification of individuals and referring physicians of a medical event. This guidance is necessary because of the sensitivity associated with medical event reporting, the differences of opinion that exist among the staff, patient right's advocates, and the regulated community, and the fact that this is a major policy issue.

Staff recommends that Alternative 2 be chosen as the preferred alternative for identification of precursor events because it: (1) clearly states the types of incidents and conditions that NRC needs to identify and analyze events and incidents that could lead to medical events, significant errors, or systematic problems that could have health and safety implications at the licensee's facility or at similar facilities; (2) requires licensees to submit reports of precursor events; and (3) should not significantly increase the regulatory burden on licensees and the NRC.

COORDINATION:

OGC reviewed this paper and has no legal objection. The Office of the Chief Information Officer has no objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections; resources to implement the rule will be considered in developing the FY 2000 budget.

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. SRM-COMSECY-96-057, dtd 3/20/97
2. SRM-SECY-97-115, dtd 6/30/97
3. Background Info on 10 CFR 35.33(a) and (b)
4. AMA, "Code of Medical Ethics, Current Opinions with Annotations"
5. Journal and Media Articles
6. Notification Following a Medical Event
7. Precursor Events

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File in PDR: ____Yes ____No Pending SECY Review. *SEE PREVIOUS CONCURRENCE

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