March 20, 1998

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.

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).

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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 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 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

ATTACHMENT 3

BACKGROUND INFORMATION ON 10 CFR 35.33(a) and (b)

The provision for notifying patients or the patient's "responsible relative" of a misadministration has been a feature of the misadministration rule since it was first proposed in 1973. "Medical Uses of Radioisotopes (Byproduct Material)," 38 Fed. Reg. 6399, 6400 (March 9, 1973). That proposed rule would have required medical use licensees to report to a patient (or responsible relative) a misadministration that could cause ". . . a demonstrably adverse effect, unless in the physician's professional judgment, such notification would be contrary to the best interests of the patient or a surviving relative of the patient." 38 Fed. Reg. 6400, 6401. No explicit explanation was provided in the Statements of Consideration (SOC) of the purpose of such a requirement. However, the Commission's discussion of an exception in 10 CFR Part 20 for intentional exposure of patients to radiation for medical purposes and Part 20 requirements for reporting radiation exposures to other individuals,(5) implied as a goal, achieving consistency between reporting requirements in Parts 35 and 20.(6) Specifically, the Commission cited former 10 CFR 20.107 (1973), which provided that nothing in the regulations in Part 20 ". . . shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy." Based on former 10 CFR 20.107, notifications had not been required ". . . of incidents involving the exposure of patients to radiation if the patient were receiving any intentional medical exposure." 38 Fed. Reg. 6399-6400. According to the Commission, since the incidents involving medical exposure that had been brought to its attention ". . . generally involved accidental or erroneous exposures of patients to radiation in amounts or forms other than intended, it does not seem appropriate to continue . . . not requiring reports of such misadministrations to patients." 38 Fed. Reg. 6400.

The Commission withdrew the 1973 proposed rule in 1978 (citing as a reason the passage of a five-year period) and proposed new misadministration record keeping and reporting requirements. It changed, without explanation, the threshold for reporting a diagnostic misadministration to NRC, to the patient's referring physician, and the patient's responsible relative. "Human Uses of Byproduct Material, Misadministration Reporting Requirements," 43 Fed. Reg. 29297 (May 7, 1978). The threshold of "a demonstrably adverse effect" became a "clinically detectable adverse effect." 43 Fed. Reg. at 29297-98. Noting that a purpose of the misadministration rule ". . . is to inform the patient or a patient's responsible relative(7) so that corrective action can be taken," the Commission expressed ". . . concern about the possibility of undue intrusion into the patient-physician relationship." 43 Fed. Reg. 29297. Consequently, the Commission specifically sought comment about "those portions of the proposed amendments which deal with the manner in which referring physicians and their patients are informed of misadministrations." Id.

Ninety percent of the comments were opposed to the proposed rule, with most citing it as ". . . an unprecedented intrusion into medical practice." Misadministration Reporting Requirements," 45 Fed. Reg. 31701 (May 14, 1980). A majority of the commenters who opposed the rule were opposed to the requirement for reporting diagnostic misadministrations to patients. 45 Fed. Reg. at 31703. The Commission determined that the threshold of a "clinically detectable adverse effect" in the proposed rule for reporting a diagnostic misadministration was a "moving target" and ". . . not well understood in the medical community." 43 Fed. Reg. at 31703. Therefore, In the final rule, although the Commission required licensees to report to NRC all diagnostic and therapeutic misadministrations, it required that only therapy misadministrations be reported to the referring physician and the patient or a responsible relative.(8) Id.

Many of the objections to the patient notification provisions specifically addressed by the Commission (as described above) have been raised again over the years, and those objections, as well as the Commission's response, warrant discussion here. Although the Commission recognized, in promulgating the rule in 1980, that the misadministration reporting requirement may be unique to medical practice, ". . . it is necessary to protect patients." 45 Fed. Reg. at 31702. The Commission also recognized the rule's intrusion into the physician-patient relationship ". . . in the sense that the rule does affect, to a limited degree, the nature of the physician's obligation to his or her patient." Id. Noting that some physicians supported the rule, the Commission did not, however, believe that objections warranted abandoning the rule. Id.

As explained by the Commission:

> The "physician-patient" relationship is a concept that was developed to advance the needs of the patient. The relationship involves duties of reasonable care and skill, confidentiality, and good faith owed by the physician to the patient. Nothing in the rule would detract from these duties. Thus, in a strict sense, the rule would not interfere with the relationship.

Id.

As to the comment noting the lack of a similar requirement in aspects of radiation medicine not regulated by the Commission (e.g., x-rays, accelerator-produced isotopes), the Commission stated that it ". . . must operate under the assumption that Congress intended a disproportionate degree of Federal regulatory control be exercised over nuclear materials as opposed to . . . other sources of radiation." 45 Fed. Reg. at 31702. As the Commission pointed out, the U.S. Nuclear Regulatory Commission was not the only Federal agency with requirements or policies to which the medical community objected on the ground of unwarranted interference in the physician-patient relationship. Id. According to the Commission, the Food and Drug Administration (FDA) had recently rejected an objection on that basis to its request for assistance in developing a policy on labeling of prescription drugs to promote patient understanding of drugs prescribed for them. Id. The FDA determined that patients have a right to know about a drug's benefits, risks, and directions for

use. Id.

Although the Commission acknowledged possible truth to the comment that the patient notification provisions would invite unwarranted malpractice suits and thereby boost medical costs, the Commission stated that ". . . there is nothing in the rule that would in any way modify the legal rules governing malpractice suits arising out of misadministrations." 45 Fed. Reg.

at 31703. "The requirement . . . to report therapy misadministrations to patients or a responsible relative is important." 45 Fed. Reg. at 31702. "Patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them." Id. The Commission's response also cited ". . . parallel requirements for licensee reports to workers on occupational overexposures" and the trend at the time in Federal legislation recognizing the right of individuals to know information about themselves that is contained in the records of institutions both inside and outside of the Federal sector." Fed. Reg. at 31702-03.

In a major revision of 10 CFR Part 35 (effective in 1987), the Commission changed the misadministration rule to require a report to NRC and the referring physician for a misadministration resulting ". . . in a dose to a patient greater than the dose to a member of the public permitted under [former] 10 CFR 20.105(a)." "Medical Use of Byproduct Material," 51 Fed. Reg. 36932, 36942 (October 16, 1986). The Commission responded to renewed objections to misadministration reporting by agreement with assertions that the misadministration rate for radiopharmaceuticals is much lower than that for other drugs, that there is no reporting requirement for non-Atomic Energy Act radiopharmaceuticals and other drugs, and that the risk to patients, workers, and the public is small. 51 Fed. Reg. at 36942. Nevertheless, the Commission concluded that ". . . the fact that there are other greater potential hazards found in the medical arena does not relieve NRC of its responsibility to assure public health and safety as it may be affected by material under its jurisdiction." Id.

The Quality Management rulemaking retained provisions for patient notification of misadministrations, but added events of arguably lesser significance ("recordable events") for which reporting to NRC or others was not required. "Quality Management Program and Misadministrations," 56 Fed. Reg. 34104 (July 25, 1991). In proposing to retain the patient notification provisions, the Commission reaffirmed the two primary purposes of those provisions, discussed above: (1) to effectuate the rights of patients to know about misadministrations unless that information would be harmful to them, and (2) to achieve consistency with parallel requirements that NRC licensees report to an individual certain radiation exposure data pertaining to that individual. "Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 Fed. Reg. 1439, 1444 (January 16, 1990).

Most recently, as part of the "wrong patient" rulemaking,[9] the Commission amended the definition of "misadministration" in 10 CFR 35.2, and the reporting requirements in 10 CFR 35.33 to substitute the word "individual" for the phrase "patient or human research subject." 60 Fed. Reg. at 48624. (The latter term had been added in another rulemaking[10] to reflect inclusion of research subjects in the definition of "medical use" in 10 CFR 35.2). The Commission noted that if a misadministration occurs because the material was administered to the wrong individual, there may be no referring physician, in which case the licensee is relieved of complying with that portion of 10 CFR 35.33. Id. However, the licensee must comply with all other requirements in 10 CFR 35.33. Id.

ATTACHMENT 6

NOTIFICATION FOLLOWING A MEDICAL EVENT

The January 30, 1998, "strawman" version of the proposed revision of 10 CFR Part 35, which was put on the Internet for public comment, included the following draft rule text for reporting medical events:

(a) A licensee shall report any administration of byproduct material or radiation therefrom that:
(1) Results in a dose that is greater than 5 rem effective dose equivalent or 50 rem to an organ, and
(2) Represents either:
(I) A total dose or dosage that differs by at least 20 percent from that prescribed in a written directive;
(ii) A fractioned dose that differs by at least 30 percent from that prescribed in a written directive; or
(iii) A prescribed dose or dosage that is the wrong pharmaceutical; delivered to the wrong patient; delivered by the wrong route of administration; delivered to the wrong treatment site;
(iv) delivered by the wrong treatment mode; or from a leaking source(s); and
(3) Is not the direct result of patient intervention that could have been reasonably prevented by the licensee.

That version stated that the issue of whom should be notified following a medical event was still under discussion, and therefore, the current notification requirements were included. As noted in the Commission paper, staff has identified three possible alternatives for notification of the U.S. Nuclear Regulatory Commission, the referring physician, and individuals in the case of a medical event.

Alternative 1 Retain the current reporting requirements in 10 CFR Part 35 with minor changes intended to clarify the term "responsible relative."

The requirement to inform individuals about a medical event is consistent with other NRC requirements (e.g., 10 CFR 19.13(d) and 20.2205) for licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC. As articulated by the Commission at the time the misadministration rule was promulgated (and later modified), patient notification "... recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector." "Misadministration Reporting Requirements," 45 Federal Register 31701, at 31702 (May 16, 1980) and "Basic Quality Assurance Program, Records, and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material," 55 Federal Register 1439, at 1444 (January 11, 1990). This alternative recognizes

physician discretion to withhold information from the patient if, based on medical judgment, such information would be "harmful" to the patient. Patient notification also enables patients, in consultation with their personal physicians, to make timely decisions regarding their remedial and prospective medical care. "Quality Management Program and Misadministrations," 56 Federal Register 34104, at 34117 (July 25, 1991). In addition, this alternative codifies existing industry standards [American Medical Association (AMA) Principles of Medical Ethics](11) obligating physicians to provide complete and accurate information to their patients.

As stated on numerous occasions, the medical community perceives the current requirements to be an unnecessary intrusion into the practice of medicine and asserts that this is the only area of medicine where there are Federal Government requirements for notifying individuals of medical errors.

If the Commission prefers this alternative, staff recommends that the current rule text be revised to clarify the provision for notifying the individual's "responsible relative," in lieu of the individual, in certain circumstances (e.g., the individual is a minor or unconscious) because that term is not defined legally, and therefore may be subject to different interpretations by the medical community.

The 1996 OMB submittal estimated that the regulatory burden: for NRC and Agreement State licensees to report misadministrations (medical events) to NRC or the appropriate Agreement State, the referring physician, and the individual is approximately $214,200/year (based on 105 misadministrations/year); and for NRC to respond to and follow-up on the events, and to review the written reports is approximately $288,000/year. Staff does not anticipate any change in the regulatory burden for licensees and the NRC if this alternative is pursued.

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

This alternative would rely on the authorized user or referring physician's voluntary compliance with "ethical principles" and "standards of care" to present complete and accurate medical facts to patients. This approach, as compared with Alternative 1, could be viewed as intruding less into the practice of medicine. Staff believes that requiring licensees to inform the referring physician of the medical event would help to assure that individuals, in consultation with their personal physicians (referring physicians), will have the needed information to make timely decisions about their remedial and prospective medical care. Staff does recognize that in some cases there will be not be a referring physician and the responsibility to inform the individual will fall to the authorized user physician.

This alternative does not ensure that individuals will be informed of a medical event and, therefore, might not receive information, viewed necessary by NRC, to make informed medical care decisions. This alternative is not consistent with other NRC requirements, in 10 CFR Parts 19 and 20, regarding reporting radiation exposures to individuals when such reports are made to NRC. Also, if the referring physician does not follow the "ethical principles," this approach would not effectuate the specific Commission determination that individuals have a right to know when they have been involved in a misadministration. 45 Fed. Reg. at 31702.

Regulatory burden would be approximately the same as Alternative 1 if this alternative is pursued. Although the Federal government would no longer require licensees to provide information to individuals or responsible relatives, there would still be a requirement for licensees to report to NRC, notify the referring physician, and document the event.

ALTERNATIVE 3:	Revise the current reporting requirement to require a licensee to inform only NRC of a medical event.

This alternative has many of the benefits previously discussed under Alternative 2: (1) it is consistent with NRC's policy of recognizing that physicians have the primary responsibility for the protection of patients and that they will act in the best interest of their patients, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy," 44 Fed. Reg. 8242, at 8244 (February 9, 1979); (2) it would not require that the referring physician be informed of a medical event; and (3) it reflects the viewpoint of the medical community members noted in the Commission paper under the general discussion of patient notification.

This alternative does not contain a Federal requirement that would ensure that patients are informed of a medical event; therefore, individuals may not have information necessary for making informed medical care decisions. In addition, individuals who are the subject of medical events would not be accorded the same protection as occupational workers and members of the public, in terms of the requirements to be informed of radiation exposures when licensees are required to report such exposures to NRC (see discussion following Alternative 1 above). Also, this alternative does not effectuate a specific Commission determination that patients have a right to know when they have been involved in a misadministration.

The regulatory burden on licensees would be decreased if this alternative is pursued. Licensees would no longer be required, by the Federal government, to provide information to individuals or responsible relatives and the referring physician. No change in burden on staff is anticipated.

ATTACHMENT 7

PRECURSOR EVENTSThe staff has identified three possible alternatives for capturing precursor events.

Alternative 1: Revise 10 CFR Part 35 to require reporting of "significant precursors."

Part 35 would be revised to: (1) define "significant precursor" in 10 CFR 35.2; (2) require that licensees report "significant precursors" to the U.S. Nuclear Regulatory Commission; and (3) require that licensees keep records of significant precursors. In addition, the statements of consideration for the revised rule would contain examples of conditions and incidents that staff would consider to be "significant precursors" [e.g., failure of computer hardware or software, interlock systems, or source containment systems (afterloaders)]; malfunction of a treatment timer system; or mislabeling of a therapeutic radiopharmaceutical).

This alternative was included in the "strawman rule" that was made publicly available January 1998 and was based on the definitions used by the Food and Drug Administration (FDA) in the medical device reporting area. A significant precursor was defined as "a condition or incident, except for a medical event, related to the use of radionuclides in medicine that caused or could cause serious injury to a patient, human research subject, worker, or the public." Although "serious injury" was not defined in the January 1998 version, subsequent versions of the draft rule text have defined it to mean an injury or illness that: (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

This alternative would capture a range of precursor events and, therefore, would fully meet the objective of the Staff Requirements Memorandum (SRM) COM-SECY-96-057, "Materials/Medical Oversight," March 20, 1997, to "capture" precursor events. However, if the intent of identifying precursor events is to improve licensees' radiation protection programs, then this alternative could potentially go beyond the intended objective (e.g., NRC would receive reports involving certain human errors that could not be applied to improvements in other licensees' programs). This alternative is risk-based, in that a reporting threshold is set, for significant precursors, that is similar to the FDA's threshold for medical device reporting.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, staff did attempt to limit reporting of precursors to only those events that could have a significant impact on public health and safety, and, consequently limit the increase in regulatory burden. Licensees may need to revise operating procedures and would need to report and record "significant precursors." NRC resources would be needed to process, review, and investigate reported precursor events. (NOTE: If Alternative 1 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

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 (RSO), could lead to a medical event at that facility or could have detrimental health and safety implications beyond the licensee's facility.

Part 35 would be revised to require reporting of deficiencies in equipment (e.g., hardware and/or software failures), byproduct material (e.g., the wrong material in a container), or procedures supplied by a manufacturer or vendor (e.g., vendor-supplied operating procedures that could result in a source being exposed for a time period beyond that anticipated by the licensee) that, in the opinion of the licensee, could lead to a medical event at that facility or could have implications beyond the licensee's facility. Licensees would be required to keep records of incidents reported to NRC.

This alternative would limit the number of precursor events reported to NRC, but would still meet the objective of capturing precursor incidents or conditions that could improve licensees' radiation protection programs.

It is anticipated that this alternative will increase the regulatory burden on licensees and NRC. However, it is expected that the increase for licensees and NRC will be about the same as that associated with Alternative 1 because, although the types of reports to be submitted in Alternative 2 are more limiting, the threshold for reporting events is set lower than the level in Alternative 1, i.e., NRC would receive approximately the same number of reports under Alternatives 1 and 2. (NOTE: If Alternative 2 is preferred, the estimated resources for this alternative will be addressed in the Regulatory Analysis.)

Enforcement action under Alternative 2 would only occur if it is demonstrated that the RSO concluded that the requisite standard was met. Where individual licensee employees believed the standard was met, investigations might be needed to determine if the RSO had reached the same conclusion and did not report it. This would be similar to enforcement of 10 CFR 30.9(b).

Alternative 3 Rely on current NRC reporting requirements in 10 CFR Parts 20, 21, and 30, and the Memorandum of Understanding (MOU) with the FDA and monitor/establish system with U.S. Pharmacopeia (USP) to review its database.

This alternative relies on the existing regulatory framework in Parts 20, 21, and 30 and 21 CFR Part 803 to capture precursor events. Staff recognizes that all precursor events may not be captured under this alternative. This alternative captures: (1) precursors that would have significant implications for public health and safety or common defense and security, pursuant to 10 CFR 30.9; (2) events that prevent taking immediate protective actions necessary to avoid exceeding the regulatory limits because of exposures to radiation or radioactive materials, and certain other events involving licensed material pursuant to 10 CFR 30.50; (3) information provided to the FDA, which is currently available to NRC via the FDA/NRC MOU, pursuant to 21 CFR Part 803, "Medical Device Reporting"; and (4) reporting requirements pursuant to Parts 20 and 21. In addition, staff would recommend that NRC monitor, on an ongoing basis, information errors that are available via voluntary reporting systems, such as the voluntary Medication Errors Reporting Program at USP (see Enclosure for information on USP). Note, staff discussions with both USP and the medical community have noted that voluntary reporting systems do not capture all events.

There is no increased burden on licensees associated with this alternative. NRC medical use licensees are already required to report specified events to NRC and the FDA, and many of them already participate in the USP voluntary reporting system. It is not anticipated that this approach would result in an significant increase in expenditure of NRC resources. Some minor resources (less than 0.1 full time equivalent) would be required to monitor information provided by USP. If this alternative is pursued, staff believes that an Information Notice should be issued describing the NRC position on capturing precursor events, using existing mechanisms.

Enclosure: 1. Information on USP and Its Initiatives and Programs

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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.

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.

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).

5. 10 CFR 20.405(c) (1973) required that "Any exposure of an individual to radiation which is required to be reported to the Commission shall also be reported to the individual." This provision has been carried over in current 10 CFR 20.2205, "Reports to Individuals of exceeding dose limits," under which, when a licensee is required, pursuant to 10 CFR 20.2203, 2204, or 20.2206, to report the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Commission to the individual.

6. 10 CFR 20.1002 states the scope of present Part 20 as not applying ". . . to doses due to background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with [10 CFR] 35.75, or to exposure from voluntary participation in medical research programs."

7. The Commission explained that:

> [I]t is expected that the licensee would report to the patient's responsible relative rather than the patient when, for example, the referring physician tells the licensees that in his medical judgment informing the patient would be harmful to the patient; the patient is a minor; or the patient is unconscious and incapable of comprehending the information.

43 Fed. Reg. at 29297.

8. The Commission also made two changes to the rule regarding patient notification of the patient or "responsible relative": First, it added a parenthetical "(or guardian)" to "responsible relative" to cover persons who do not have relatives. 45 Fed. Reg. at 31704. Secondly, as amended, the rule would permit referring physicians, if they wish, to inform the patient of the misadministration. Id.

9. "Medical Administration of Radiation and Radioactive Materials," 60 Fed. Reg. 48623, (September 20, 1995).

10. "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 59 Fed. Reg. 61767 at 61772, 61781, 61783, (December 2, 1994).

11. Although AMA discusses patients' rights to receive information from physicians as "Fundamental Elements of the Patient-Physician Relationship" and to effectuate "informed consent," AMA ethical standards for informing patients of physicians' mistakes reflect a threshold of "significant complications" to the patient that may have resulted from the physician's mistake or judgment. "AMA Council on Ethical and Judicial Affairs, Code of Medical Ethics," Current Opinions with Annotations at xxxix, 120, 125 (8.12), 1996-1997.