(6)

September 30, 1997

PATIENT NOTIFICATION OF REPORTABLE EVENT

NOTE

Following Commission approval of the staff's program to revise 10 CFR Part 35 and associated guidance documents, the NRC staff initiated development of draft rule language, using a modality-based approach. As directed by the Commission, the staff has developed alternatives, with draft rule text, for the more significant issues associated with the regulation of the medical use of byproduct material. These alternatives to regulation in specific areas are intended to help focus the discussion during the NRC's public meetings and the meetings with medical professional societies during the Fall of 1997 and to assist the staff in developing the proposed rule language. The alternatives represent a broad range of possibilities and are being provided to stimulate input from members of the public in an effort to encourage all interested parties to provide input into the development of the revised regulation. The NRC staff has not selected any alternative at this time, and is open to additional alternatives which might be proposed that are consistent with the guidance provided by the Commission.

9/30/97

PART 35 - PATIENT NOTIFICATION OF REPORTABLE EVENT

Summary of Alternatives

1. Status Quo: Licensee to notify NRC, referring physician, and patient or responsible relative, unless referring physician personally informs the licensee that he or she will inform the patient or that, based on medical judgment, telling the patient or a responsible relative would be harmful.

2. Licensee to notify NRC only, but not referring physician or patient.

3. Licensee to notify NRC and referring physician, but not patient.

4. Licensee to always notify NRC, referring physician, and patient or guardian.

5. Licensee to notify NRC and referring physician, but not patient or guardian (or responsible relative) unless based on medical judgment there would be detrimental effects on patient due to the reportable event.

NOTE: Item 4 of the SRM, March 20, 1997, states:
[Staff should consider...]

Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

Use of term "guardian" in Alternative 4 & 5 is intended to encompass guardian, individual having "medical power of attorney" or "next-of-kin" but not all individuals who have been considered to be "responsible relative."

ALTERNATIVE 1: Status Quo: Licensee to notify NRC, referring physician, and patient or responsible relative, unless referring physician personally informs the licensee that he or she will inform the patient or that, based on medical judgment, telling the patient or a responsible relative would be harmful.

Pros

1. Is consistent with other NRC requirements (e.g., 10 CFR §§ 19.13(d) and 20.2205) requiring licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC.

2. Is consistent with other Federal legislation (e.g., Privacy Act) recognizing the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector. See Statements of Consideration for misadministration rule at 45 Fed. Reg. 31701 (35-SC-10) and 55 Fed. Reg. 1439, at 1444 (January 16, 1990).

3. Enables patients, in consultation with their personal physicians, to make timely decisions regarding remedial and prospective medical care. 56 Fed. Reg. 23360.

4. Enables NRC to identify the causes of misadministrations and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally) and preserves patients right to know.

5. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report Abnormal Occurrences (AOs) to Congress.

6. Is consistent with present NRC guidance regarding medical events (e.g., Management Directive 8.10 Handbook regarding medical event reporting).

Cons

1. Current rule language lacks definition of "responsible relative," which may not be well understood by the medical community. Also, there appears to be multiple and sometimes conflicting interpretations of the extent to which and circumstances in which the "responsible relative" must be notified.

2. Patient notification requirement could be viewed as an unnecessary intrusion into the practice of medicine.

Current Rule Text

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center[1] no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

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[1] The commercial telephone number of the NRC Operations Center is (301) 816-5100.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

ALTERNATIVE 2: Licensee to notify NRC only but not referring physician or patient.

Pros

1. Would not directly result in what some view as NRC intrusion into the practice of medicine.

2. Enables NRC to identify the causes of reportable events and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally).

3. Continues to enable NRC to fulfill statutory obligation to report AOs to Congress.

4. Relies on ethical standard of care to present medical facts to patients. (SRM DSI-7)

5. May support more consistent compliance with the rule.

Cons

1. Is not consistent with other NRC requirements in Parts 19 and 20 regarding reporting radiation exposures to individuals when such reports are made to NRC.

2. NRC and licensee potentially aware of patient information (e.g., potential consequences to patient health) when referring physician and patient are not aware for future informed decisions and medical histories by other physicians.

3. Does not effectuate specific Commission determination that patients have a right to know when they have been involved in a misadministration. 55 Fed. Reg. 1444 (January 16, 1990).

4. Recognizes inconsistent application of ethical standard of care.

5. If patients are not notified and need follow-up care, NRC may have, at minimum, an ethical obligation to either notify patients itself or find another entity (such as a state) to do so.

6. In order for NRC to comply with Section 208 of Energy Reorganization Act requirement to include "nature and probable consequences" in AO reports, NRC's action to obtain such information may inject NRC into patient-physician relationship and result in patient notification without explicit notification requirement in regulations.

Draft Rule Text

(a) For a reportable event:

(1) The licensee shall notify by telephone the NRC Operations Center [2] no later than the next calendar day after discovery of the reportable event.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the reportable event. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual.

(b) Each licensee shall retain a record of each reportable event for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the reportable event, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals involved in the reportable event, or to that individual's responsible relatives or guardians.

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[2] The commercial telephone number of the NRC Operations Center is (301) 816-5100

ALTERNATIVE 3: Licensee to notify NRC and referring physician.

Pros

1. Does not involve NRC in what some view as intrusion into the practice of medicine.

2. Enables NRC to identify the causes of reportable events and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally) and preserves patient's right to know.

3. Continues to enable NRC to fulfill statutory obligation to report AOs to Congress.

4. Less prescriptive than current rule by relying on ethical standard of care to present medical facts to patients.

5. May support more consistent compliance with the rule.

6. Relies on ethical standard of care to present medical facts to patients. (SRM DSI-7)

Cons

1. Is not consistent with other NRC requirements in Parts 19 and 20 regarding reporting radiation exposures to individuals when such reports are made to NRC.

2. Unless referring physician follows ethical standard to inform patients of medical facts, does not effectuate specific Commission determination that patients have a right to know when they have been involved in a misadministration. 55 Fed. Reg.1444 (January 16, 1990).

3. NRC actions to obtain information to comply with Section 208 of Energy Reorganization Act of 1974, requirement to include "nature and probable consequences" in AO reports, could result in patient notification without explicit notification requirement in regulations.

4. Recognizes inconsistent application of ethical standard of care.

5. If patients are not notified and need follow-up care, NRC may have, at minimum, an ethical obligation to either notify patients itself or find another entity (such as a state) to do so.

Draft Rule Text

(a) For a reportable event:

(1) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the reportable event.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the reportable event. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence. The report must not contain the individual's name or any other information that could lead to identification of the individual.

(3) The licensee shall notify the referring physician of the reportable event no later than 24 hours after its discovery. If the referring physician cannot be reached within 24 hours, the licensee shall notify the referring physician as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the reportable event, because of any delay in notification.

(4) If the referring physician was notified, the licensee shall also furnish, within 15 days after discovery of the reportable event, a written report to the referring physician by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each reportable event for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the reportable event, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals involved in the reportable event, or to that individual's responsible relatives or guardians.

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[3] The commercial telephone number of the NRC Operations Center is (301) 816-5100.

ALTERNATIVE 4: Same as status quo but licensee must always notify patient or guardian (does not provide for licensee reliance on referring physician to do so, or no notification based on medical judgment).

Pros

1. Is consistent with other NRC requirements (e.g., 10 CFR §§ 19.13(d) and 20.2205) requiring licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC.

2. Is consistent with other Federal legislation (e.g., Privacy Act) recognizing the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector. See Statements of Consideration for misadministration rule at 45 Fed. Reg. 31701 (35-SC-10) and 55 Fed. Reg. 1439, at 1444 (January 16, 1990).

3. Enables patients or guardian in consultation with their personal physician, to make timely decisions regarding remedial and prospective medical care. 56 Fed. Reg. 23360.

4. Enables NRC to identify the causes of reportable event and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally) .

5. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report Abnormal Occurrences (AOs) to Congress.

6. Patient or guardian would always be required to be notified because there is no provision for referring physician to inform patient in lieu of licensee doing so or for withholding notification based on medical judgment of harm to patient.

Cons

1. Determining who is "guardian" may be difficult without a definition.

2. Not consistent with "therapeutic privilege" of physician to withhold certain information from the patient which could adversely affect the patient's condition.

3. Not consistent with Medical Policy Statement to minimize intrusion into the practice of medicine.

4. May not require notification of individual (responsible relative) who under current rule would have been notified.

Draft Rule Text

(a) For a reportable event:

(1) The licensee shall notify by telephone the NRC Operations Center[4] no later than the next calendar day after discovery of the reportable event.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the reportable event. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual may be made instead to that individual's guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual (or guardian) of the reportable event no later than 24 hours after its discovery. If the referring physician or the individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the reportable event, because of any delay in notification.

(4) The licensee shall furnish, within 15 days after discovery of the reportable event, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each reportable event for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the reportable event, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals involved in the reportable event , or to that individual's guardian.

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[4] The commercial telephone number of the NRC Operations Center is (301) 816-5100.

ALTERNATIVE 5: Licensee to notify NRC and referring physician, but not patient or guardian (or responsible relative) unless, based on medical judgement, there would be detrimental effects on patient due to the reportable event.

Pros

1. Enables NRC to identify the causes of reportable events and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally) .

2. Continues to enable NRC to fulfill statutory obligation to report AOs to Congress.

3. Is consistent with Medical Policy statement to minimize intrusion into the practice of medicine.

4. Is consistent with SRM direction to revise Part 35 to be risk-based.

5. Is consistent with SRM direction to rely on industry standard [here, ethical standard of care], except for required notification of reportable events causing "detrimental" effects.

Cons

1. Not consistent with Parts 19 and 20 regarding reporting to individuals radiation exposure information furnished to NRC, which do not require threshold of "detrimental" effects.

2. Determining what is "detrimental" may be difficult without definition of this term (e.g., some effects may be delayed in time).

3. NRC has previously rejected threshold of "clinically detectable adverse effect" (for reporting misadministrations) as not well understood by the medical community and a "moving target" for patient notification of misadministration. 45 Fed. Reg. 31701.

4. NRC and referring physician may possess information regarding patient's medical treatment and consequences of misadministration without patient being aware of that information, which is not consistent with patient's "right to know" (55 Fed. Reg. 1444, January 16, 1990).

5. Recognizes inconsistent application of ethical standard of care for reportable events not having detrimental effects.

6. May not require notification of all patient's (or guardians) who under current rule would have been notified.

7. Determining who is "guardian" may be difficult without a definition.

Draft Rule Text

(a) For a reportable event:

(1) The licensee shall notify by telephone the NRC Operations Center[5] no later than the next calendar day after discovery of the reportable event.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the reportable event. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual may be made instead to that individual's guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual (or guardian) of the reportable event no later than 24 hours after its discovery if, based on medical judgment, there are or would be detrimental effects on the individual due to the reportable event. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual(s) cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the reportable event, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the reportable event, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each reportable event for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals involved in the reportable event, or to that individual's guardian.

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[5] The commercial telephone number of the NRC Operations Center is (301) 816-5100.

PATIENT NOTIFICATION OVERVIEW

KEY ITEMS FOR CONSIDERATION	ALTERNATIVES 1	2	3	4	5
Consistent with other NRC requirements (e.g., 10 CFR §§ 19.13(d) and 20.2205) requiring licensees to provide reports to individuals receiving radiation exposure when licensees are required to report such exposure to NRC.	X			X	
Consistent with other Federal legislation (e.g., Privacy Act) recognizing the right of individuals to know information about themselves which is contained in records both inside and outside the Federal sector. See Statements of Consideration for misadministration rule at 45 Fed. Reg. 31701 (35-SC-10) and 55 Fed. Reg. 1439, at 1444 (1/16/90).	X			X	
Rule clearly defines who must be informed.		X	X	X	
Requirement minimizes intrusion into medical judgements affecting patients.	X	X	X		X
Notification requirement enables patients, in consultation with their personal physicians, to make timely decisions regarding remedial and prospective medical care. 56 Fed. Reg. 23360.	X			X	X
Enables NRC to identify the causes of reportable events and help identify precursor events (SRM DSI-7) in order to correct them and prevent recurrence (isolated incidents can reveal a generic problem when compared nationally).	X	X	X	X	X
Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report Abnormal Occurrences (AOs) to Congress.	X	X	X	X	X
Consistent with present NRC guidance regarding medical events (e.g., Management Directive 8.10 Handbook regarding medical event reporting).	X				
Relies solely on physician ethical standard of care to present medical facts to patients.		X	X		
Consistent with Commission SRM directive to rely on voluntary standards if such meets NRC needs.		X	X		
Requires definition of "detrimental" effects.					X
Allows physician discretion, based on medical judgement, in deciding whether to inform patient of medical event.	X	X	X		X
Preserves patient right to know.	X			X	
Requires definition of "guardian" or "responsible relative".	X			X	X