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September 30, 1997

THRESHOLD FOR 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.

9/29/97

PART 35 - THRESHOLD FOR REPORTABLE EVENT

Summary of Alternatives

1. Thresholds for reportable event (misadministration) and recordable event remain as listed in the current §35.2, with the addition of a statement in the reportable definition to address precursor events that are outside the area defined by the term "misadministration."

2. Threshold for reportable event is raised to the level of the NRC abnormal occurrence reporting criteria. In addition, the definition for reportable event will include a statement to address precursor events that are outside the area currently defined by the term "misadministration." Threshold for recordable event is raised to the current threshold for "misadministration."

3. Threshold for reportable event is raised to the level of the NRC abnormal occurrence reporting criteria. In addition, the definition for reportable event will include a statement to address precursor events that are outside the area currently defined by the term "misadministration." (No requirement for recordable event.)

4. Threshold for reportable event is lowered to the current level of recordable event, with the inclusion of items such as wrong patient, route, or dosage that are not covered by the current "recordable event" definition. In addition, the definition for reportable event will include a statement to address precursor events. (No requirement for recordable event.)

5. Thresholds for reportable event and recordable event, if applicable, would be set according to the outcome of discussions on Alternatives 1, 2, 3, and 4. Licensees would voluntarily report precursor events that are outside of the area currently defined by the term "misadministration."

NOTE 1: The term "misadministration" has been replaced with "reportable event" in this document.

NOTE 2: In the Staff Requirements Memorandum dated March 20, 1997, the Commission directed the staff to address how to capture not only relevant safety-significant events, but also precursor events. Staff is considering the development of a regulatory requirement designed to capture precursor events having programmatic implications for radiation safety. This requirement would be intended to identify events, incidents, and situations which have implications for that facility or implications for similar facilities (generic incidents) that may adversely affect the dose to the patient or the public. The objective of this requirement is to identify information that would be useful to avoid potentially significant problems and to improve the radiation safety program at licensed facilities. This requirement should include, but not necessarily be limited to, incidents resulting from mechanical, structural or electrical malfunction of a system, as well as events resulting from procedural errors or human error. Examples of

precursor events might include failure of an interlock system, malfunction of a timer system, failure of a brachytherapy treatment device to contain a source, or mislabelling of a radiopharmaceutical.

NOTE 3: Several of the alternatives presented in this document would base the reportable level on the NRC abnormal occurrence (AO) reporting criteria. The AO statement of policy contains criteria that are set at a level required to keep Congress and the public informed of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety. Therefore, AO levels are set above the normal level of reporting to NRC to exclude those events that involve some variance from regulatory limits, but are not significant from the standpoint of public health and safety. If the AO criteria are used as a basis for the reportable threshold, the actual reportable threshold would have to be some percentage of the AO criteria.

CURRENT DEFINITIONS/REQUIREMENTS

	Status Quo Recordable (Recordable Event §35.2)	Status Quo Reportable (Misadministration §35.2)
All diagnostic radio pharmaceuticals (including < 30μC NaI, I-125 or I-131).	.....	. Wrong patient, radiopharm., route, or dosage; *and* . Dose >5 rem EDE or 50 rem to organ.
Sodium iodide radio pharmaceuticals (where >30 μCi NaI-125 or I-131).	. Admin.dosage differs by >10% prescr. dosage *and* >15μCi. . W/o written directive. . W/o daily dosage record.	. Wrong patient. . Wrong radiopharmaceutical. . Admin. dosage differs by >20% prescr. dosage *and* >30 μCi.
Therapeutic radio pharmaceuticals.	. Admin. dosage differs by >10% prescr. dosage . . W/o written directive..... . W/o daily dosage record.....	. Wrong patient. . Wrong mode of transport. . Wrong route of admin. . Admin. dosage differs by >20% prescr. dosage.
Teletherapy.	. Calculated weekly dose 15% > prescr. dose. . W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong mode of treatment. . Wrong treatment site. . Calculated weekly dose 30% > prescr. dose. . Calculated total dose differs by >20% total prescr. dose. . If <3 fractions, calc. total dose differs by >10% total prescr. dose.
Brachytherapy.	. Calc. dose differs by >10% prescr. dose. . W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong radioisotope. . Wrong treatment site. . Leaking source. . Failure to remove source for a temporary implant. . Calculated admin. dose differs by >20% prescr. dose.
Gamma stereotactic radiosurgery.	. W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong treatment site. . Calculated total admin. dose differs by >10% total prescr. dose.

Abnormal occurrence event criteria - Misadministration (Management Directive 8.1):

a. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; AND

b. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that is (i) the wrong pharmaceutical, (ii) delivered by the wrong route of administration, (iii) delivered to the wrong treatment site, (iv) delivered by the wrong treatment mode, or (v) from a leaking source(s).

ALTERNATIVE 1: Thresholds for reportable event (misadministration) and recordable event remain as listed in the current §35.2, with the addition of a statement in the reportable definition to address precursor events that are outside the area defined by the term "misadministration."

Pros

1. Regulatory requirement for licensee to identify and/or report or record, as appropriate, events. This information may be used to increase the overall effectiveness of the radiation safety program.

2. Provides licensee with tiered approach to event reporting or recording depending on the nature of the event.

3. Enables NRC to identify the causes of 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).

4. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report abnormal occurrences (AOs) to Congress.

5. Licensees are familiar with current definition, therefore it would only be necessary to change current operating procedures to identify and report precursor events.

Cons

1. Requirement for multiple action points (reportable and recordable) may be considered prescriptive.

2. Requirement may be considered as intruding into the area of patient confidentiality if the patient's name or identification is included in the report or record.

3. Reporting of precursor events may not be justified by risk associated with the potential for exposure and may result in an increased burden on licensees.

4. Reporting of precursor events may result in a large volume of reports, requiring a significant expenditure of NRC resources for evaluation of low risk events.

5. Specific rule language and guidance (examples) will need to be developed to identify precursor events.

Suggested Rule Text

	Status Quo Recordable (Recordable Event §35.2)	Status Quo Reportable (Misadministration §35.2)
All diagnostic radio pharmaceuticals (including < 30μC NaI, I-125 or I-131).	.....	. Wrong patient, radiopharm., route, or dosage; *and* . Dose >5 rem EDE or 50 rem to organ.
Sodium iodide radio pharmaceuticals (where >30 μCi NaI-125 or I-131).	. Admin.dosage differs by >10% prescr. dosage *and* >15μCi. . W/o written directive. . W/o daily dosage record.	. Wrong patient. . Wrong radiopharmaceutical. . Admin. dosage differs by >20% prescr. dosage *and* >30 μCi.
Therapeutic radio pharmaceuticals.	. Admin. dosage differs by >10% prescr. dosage . . W/o written directive. . W/o daily dosage record.	. Wrong patient. . Wrong mode of transport. . Wrong route of admin. . Admin. dosage differs by >20% prescr. dosage.
Teletherapy.	. Calculated weekly dose 15% > prescr. dose. . W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong mode of treatment. . Wrong treatment site. . Calculated weekly dose 30% > prescr. dose. . Calculated total dose differs by >20% total prescr. dose. . If <3 fractions, calc. total dose differs by >10% total prescr. dose.
Brachytherapy.	. Calc. dose differs by >10% prescr. dose. . W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong radioisotope. . Wrong treatment site. . Leaking source. . Failure to remove source for a temporary implant. . Calculated admin. dose differs by >20% prescr. dose.
Gamma stereotactic radiosurgery.	. W/o written directive. . W/o daily dose record.	. Wrong patient. . Wrong treatment site. . Calculated total admin. dose differs by >10% total prescr. dose.

Additional requirement for reportable events:

Statement to address precursor events (reference NOTE 2, page 1).

ALTERNATIVE 2: Threshold for reportable event is raised to the level of the NRC abnormal occurrence reporting criteria. In addition, the definition for reportable event will include a statement to address precursor events that are outside the area currently defined by the term "misadministration." Threshold for recordable event is raised to the current threshold for "misadministration."

Pros

1. Regulatory requirement for licensee to identify and/or report or record, as appropriate, events. This information may be used to increase the overall effectiveness of the radiation safety program.

2. Provides licensee with tiered approach to event reporting and recording, depending on the nature of the event.

3. Enables NRC to identify the causes of 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).

4. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report abnormal occurrences (AOs) to Congress.

5. Abnormal occurrence event reporting criteria are risk-based.

Cons

1. Requirement for multiple action points (reportable and recordable) may be considered prescriptive.

2. Requirement may be considered as intruding into the area of patient confidentiality if the patient's name or identification is included in the report or record.

3. Reporting of precursor events may not be justified by risk associated with the potential for exposure and may result in an increased burden on licensees.

4. Reporting of precursor events may result in a large volume of reports, requiring a significant expenditure of NRC resources for evaluation of low risk events.

5. Specific rule language and guidance (examples) will need to be developed to identify precursor events.

6. Licensees would have to change current operating procedures to identify and report precursor events.

Suggested Rule Text

Recordable Event:

All diagnostic radio pharmaceuticals (including < 30μC NaI, I-125 or I-131).	. Wrong patient, radiopharm., route, or dosage; and . Dose >5 rem EDE or 50 rem to organ.
Sodium iodide radio pharmaceuticals (where >30 μCi NaI-125 or I-131).	. Wrong patient. . Wrong radiopharmaceutical. . Administered dosage differs by >20% prescribed dosage *and* >30 μCi.
Therapeutic radio pharmaceuticals.	. Wrong patient. . Wrong mode of transport. . Wrong route of admin. . Administered dosage differs by >20% prescribed dosage.
Teletherapy.	. Wrong patient. . Wrong mode of treatment. . Wrong treatment site. . Calculated weekly dose 30% > prescribed dose. . Calculated total dose differs by >20% total prescribed dose. . If <3 fractions, calculated total dose differs by >10% total prescribed dose.
Brachytherapy.	. Wrong patient. . Wrong radioisotope. . Wrong treatment site. . Leaking source. . Failure to remove source for a temporary implant. . Calculated administered dose differs by >20% prescribed dose.
Gamma stereotactic radiosurgery.	. Wrong patient. . Wrong treatment site. . Calculated total administered dose differs by >10% total prescribed dose.

Reportable Event:

a. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; AND

b. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that is (i) the wrong pharmaceutical, (ii) delivered by the wrong route of administration, (iii) delivered to the wrong treatment site, (iv) delivered by the wrong treatment mode, or (v) from a leaking source(s).

c. Statement to address precursor events (reference NOTE 2, page 1).

ALTERNATIVE 3: Threshold for reportable event is raised to the level of the NRC abnormal occurrence reporting criteria. In addition, the definition for reportable event will include a statement to address precursor events that are outside the area defined by the term "misadministration." (No requirement for recordable event.)

Pros

1. Regulatory requirement for licensee to identify and/or report, as appropriate, events. This information may be used to increase the overall effectiveness of the radiation safety program.

2. Enables NRC to identify the causes of 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. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report abnormal occurrences (AOs) to Congress.

4. Abnormal occurrence event reporting criteria are risk-based.

5. The regulation would be simplified because there would be only one paperwork requirement, i.e., only reportable events.

Cons

1. Requirement may be considered as intruding into the area of patient confidentiality if the patient's name or identification is included in the report.

2. Reporting of precursor events may not be justified by risk associated with the potential for exposure and may result in an increased burden on licensees.

3. Reporting of precursor events may result in a large volume of reports, requiring a significant expenditure of NRC resources for evaluation of low-risk events.

4. Misadministrations that do not meet the reporting criteria or the criteria for a precursor event will no longer be reported to NRC.

5. Specific rule language and guidance (examples) will need to be developed to identify precursor events.

6. Licensees would have to change current operating procedures to identify and report precursor events.

Suggested Rule Text:

Reportable Event:

a. Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; AND

b. Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (I) is the wrong pharmaceutical, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

c. Statement to address precursor events (reference NOTE 2, page 1).

ALTERNATIVE 4: Threshold for reportable event is lowered to the current level of recordable event, with the inclusion of items such as wrong patient, route, or dosage that are currently not covered by the current "recordable event" definition. In addition, the definition for reportable event will include a statement to address precursor events. (No requirement for recordable event.)

Pros

1. The regulation would be simplified because there would be only one paperwork requirement i.e., only reportable events.

2. Regulatory requirement for licensee to identify and/or report events. This information may be used to increase the overall effectiveness of the radiation safety program.

3. Enables NRC to identify the causes of 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).

4. Enables NRC to fulfill its statutory obligation (in Section 208 of The Energy Reorganization Act of 1974) to report abnormal occurrences (AOs) to Congress.

Cons

1. Requirement may be considered as intruding into the area of patient confidentiality if the patient's name or identification is included in the report.

2. Lowering the threshold for reporting events and reporting of precursor events may not be justified by risk associated with the potential for exposure and may result in an undue burden on licensees.

3. Lowering the threshold for reporting events and reporting of precursor events may result in a large volume of reports, requiring a significant expenditure of NRC resources for evaluation of low risk events.

4. Specific rule language and guidance (examples) will need to be developed to identify precursor events.

5. Licensees would have to change current operating procedures to identify and report precursor events.

Suggested Rule Text

Reportable Event:

All diagnostic radiopharm (including < 30μC NaI, I-125 or I-131).	. Wrong patient, radiopharm., route, or dosage.
Sodium iodide radiopharm (where >30 μCi NaI-125 or I-131.	. Wrong patient. . Wrong radiopharmaceutical. . Admin.dosage differs by >10% prescr. dosage *and* >15μCi. . W/o written directive. . W/o daily dosage record.
Therapeutic radioparm.	. Wrong patient. . Wrong mode of transport. . Wrong route of administration. . Admin. dosage differs by >10% prescribed dosage. . W/o written directive. . W/o daily dosage record.
Teletherapy.	. Wrong patient. . Wrong mode of treatment. . Wrong treatment site. . Calculated total dose differs by >20% total prescribed dose. . If <3 fractions, calculated total dose differs by >10% total prescribed dose. . Calculated weekly dose 15% > prescribed dose. . W/o written directive. . W/o daily dose record.
Brachytherapy.	. Wrong patient. . Wrong radioisotope. . Wrong treatment site. . Leaking source. . Failure to remove source for a temporary implant. . Calc. dose differs by >10% prescribed dose. . W/o written directive. . W/o daily dose record.
Gamma stereotactic radiosurgery.	. Wrong patient. . Wrong treatment site. . Calculated total admin. dose differs by >10% total prescribed dose. . W/o written directive. . W/o daily dose record.

Additional requirement for reportable events:

Statement to address precursor events (reference NOTE 2, page 1).

ALTERNATIVE 5: Thresholds for reportable event and recordable event, if applicable, would be set according to the outcome of discussions on Alternatives 1, 2, 3, and 4. Licensees would voluntarily report precursor events that are outside of the area currently defined by the term "misadministration."

Pros

1. Relies on voluntary standard for reporting of precursor events that do not meet the dose threshold for reportable or recordable events.

2. Voluntary reporting system may permit NRC to capture precursor events reported to other agencies or organizations and thus reduce duplicative reporting by licensees.

3. Consistent with SRM on DSI-7 to rely on voluntary standards when .....appropriate.

Cons

1. NRC and licensee resources would be required to develop a mechanism to capture precursor events.

2. Inconsistent application of voluntary standard may result in NRC not being informed of some precursor events.

Suggested Rule Text

The rule text would either be the suggested text in alternative 1, 2, 3, or 4, but with a statement to address voluntary reporting of precursor events.

OVERVIEW OF THRESHOLD FOR REPORTABLE EVENT

Key Items for Consideration	Alt. 1	Alt. 2	Alt. 3	Alt. 4
Regulatory requirement for licensee to identify and/or report or record, as appropriate, events.	x	x	x	x
Enables NRC to identify the causes of 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
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
Requirement for multiple action points (reportable and recordable) may be considered prescriptive.	x	x		
Requirement may be considered as intruding into the area of patient confidentiality if the patient's name or identification is included in the report or record.	x	x	x	x
Reporting of precursor events may not be justified by risk associated with the potential for exposure and may result in an increased burden on licensees.	x	x	x	x
Reporting of precursor events may result in a large volume of reports, requiring a significant expenditure of NRC resources for evaluation of low risk events.	x	x	x	x
Specific rule language and guidance (examples) will need to be developed to identify precursor events.	x	x	x	x

*Key items are not identified for Alternative 5 because the exact pros & cons will depend on which Alternative is used with the voluntary reporting of precursor events.