U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-94-06

To:	NRC Management Directives Custodians
Subject:	Transmittal of Management Directive 8.10, "NRC Medical Event Assessment Program"
Purpose:	Directive and Handbook 8.10 are being issued (1) to ensure that medical events are reviewed in a manner that is timely, objective, systematic, and technically sound; that factual information pertaining to the events is documented; and that probable causes are ascertained; (2) to ensure that NRC provides the appropriate level and direction for followup of patients who have received an overdose of radiation; and (3) to require that the staff ensures that licensees have complied with the notification requirements of the misadministration rule (10 CFR 35.33) and notification requirements of 10 CFR Parts 19 and 20, if applicable.
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Date Approved:	July 6, 1994
Volume:	8 Licensee Oversight Programs
Directive:	8.10 "NRC Medical Event Assessment Program"
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NRC Medical Event Assessment Program

Directive 8.10

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NRC Medical Event Assessment Program
Directive 8.10

Policy
(8.10-01)

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to establish a Medical Event Assessment (MEA) Program. This directive and handbook specify the scope, objectives, authorities, responsibilities, and basic requirements for the MEA Program.

Objectives
(8.10-02)

- To ensure that medical events are reviewed in a manner that is timely, objective, systematic, and technically sound; that factual information pertaining to the events is documented; and that probable causes are ascertained. (021)

- To ensure that NRC provides the appropriate level and direction for followup of patients who have received a medical misadministration or others who have received an overdose of radiation. (022)

- To ensure that licensees have complied with the notification requirements of the misadministration rule (10 CFR 35.33) and notification requirements of 10 CFR Parts 19 and 20, if applicable. (023)

Organizational Responsibilities and Delegations of Authority
(8.10-03)

The Executive Director for Operations (EDO)
(031)

Determines whether a medical event should be investigated by an Incident Investigation Team (IIT) in accordance with Management Directive (MD) 8.3, "NRC Incident Investigation Program."

The Director, Office of Nuclear Material Safety and Safeguards (NMSS)
(032)

- Develops, approves, and maintains procedures and guidelines governing the MEA Program. (a)
- Oversees regional implementation of the MEA Program. (b)
- Delegates responsibility for establishing and maintaining procedures and instructions for the MEA Program to the Chief, Operations Branch, Division of Industrial and Medical Nuclear Safety. (c)
- Determines if a medical event other than a misadministration will be assessed in accordance with this directive. (d)
- Makes recommendations to and coordinates with the appropriate regional administrator on events that may warrant investigation by an Augmented Inspection Team (AIT). (e)

The Director, Office of Enforcement (OE)
(033)

- Reviews enforcement actions resulting from a review performed under the MEA Program. (a)

Organizational Responsibilities and Delegations of Authority
(8.10-03) (continued)

The Director, Office of Enforcement (OE)
(033) (continued)

- Delegates authority to an NRC regional office administrator in accordance with the Enforcement Manual. (b)

- Reviews an enforcement action resulting from an inspection by an AIT or an IIT under the MEA Program regardless of the severity of the violation(s). (c)

The Director, Office of Personnel (OP)
(034)

Appoints physicians and scientific consultants used in the MEA Program as special Government employees.

The Director, Office for Analysis and Evaluation of Operational Data (AEOD)
(035)

- Maintains a database of medical events. (a)

- Provides formal training for the conduct of investigations. (b)

Regional Administrators
(036)

- Maintain overall responsibility for the implementation of the MEA Program in the regional office. (a)

- Provide personnel to implement the MEA Program in the region. (b)

Organizational Responsibilities and Delegations of Authority
(8.10-03) (continued)

Regional Administrators
(036) (continued)

- Delegate day-to-day responsibility for implementation of the MEA Program to other regional management as authorized by regional procedures. (c)

- Determine whether a medical event should be investigated by an AIT in accordance with MD 8.3. (d)

Applicability
(8.10-04)

Employees
(041)

The provisions of this directive and handbook apply to all NRC employees.

Handbook
(8.10-05)

Procedures for the MEA Program are set forth in Handbook 8.10.

References
(8.10-06)

1. NRC Inspection Manual Chapter 1360, “Use of Physician and Scientific Consultants in the Medical Consultant Program.”

2. Memorandum, W. C. Parler, OGC, to R. M. Bernero, NMSS, “OGC Responses to Questions Concerning NRC's Legal

References

(8.10-06) (continued)

Authorities, Responsibilities, and Liabilities for Follow-up of Patients Subject to Misadministrations," dated September 28, 1993. (Attorney Work-Product Material—Limited to NRC Unless the Commission Determines Otherwise.)

3. Memorandum, M. G. Malsch, OGC, to R. M. Bernero, NMSS, "Guidance on Use of Physician and Scientific Consultants in the Medical Consultant Program," dated September 21, 1993. (Attorney Work-Product Material—Limited to NRC Unless the Commission Determines Otherwise.)

4. Memorandum, S. A. Treby, OGC, to C. J. Paperiello, NMSS, "Request for OGC Guidance on Issues Raised in Licensee Responses to NRC Inquiry on Patient Notification for Prior Therapeutic Misadministrations," March 10, 1994. (Attorney Work-Product Material—Limited to NRC Unless the Commission Determines Otherwise.)

5. NRC Management Directive 8.3, "NRC Incident Investigation Program" (formerly MC 0513).

6. "General Statement of Policy and Procedure for NRC Enforcement Actions," Appendix C to 10 CFR Part 2.

7. NRC Inspection Manual Chapter 610, "Inspection Reports."

8. Memorandum, C. J. Paperiello, NMSS, to Regional Division Directors, "Definition of Referring Physician as Referred To in 10 CFR 35.33, 'Notification, Reports, and Records of Misadministrations,'" dated November 18, 1993.

9. "Technical Training Center Syllabus of Courses," NUREG/BR-0017, Rev. 8, Addendum 1993-1994. (Courses identified as H-304, H-318, and G-202 in Section (E)(2)(a) and Section (F)(2) of Handbook 8.10 are more fully described in this NUREG/BR.)

References

(8.10-06) (continued)

10. Enforcement Manual.

11. "Definitions," 10 CFR 35.2.

12. "Quality Management Program," 10 CFR 35.32.

13. "Notifications, Reports, and Records of Misadministrations," 10 CFR 35.33.

14. Memorandum, J. Taylor, EDO, to Regional Administrators; R. M. Bernero, NMSS; and T. Murley, NRR, "Recommending Third Party Assistance to Licensees," dated July 15, 1993.

15. "Use of Public Office for Private Gain," 5 CFR 2635.702.

NRC Medical Event Assessment Program

Handbook 8.10

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Procedures for the NRC Medical Event Assessment Program

Objective of the NRC Medical Event Assessment Program (A)

The objective of the NRC Medical Event Assessment Program is to conduct a timely, thorough, systematic, and formal assessment of medical events.

Scope of a Medical Event Assessment (MEA) (B)

The MEA should emphasize fact-finding, determination of probable cause(s), and compliance. The review should be sufficiently broad and detailed to ensure that the event and related issues are well defined, the relevant facts and circumstances are identified and collected, and the findings and conclusions are identified and substantiated by the information and evidence associated with the event. The review should consider the adequacy of the licensee's actions during the event. The scope of the MEA will also include NRC's ensuring that the licensee complies with the notification requirements of 10 CFR Parts 19, 20, and 35, as applicable. (1)

All medical misadministrations by NRC licensees will be assessed in accordance with this management directive. Other medical events will be chosen on a case-by-case basis for assessment in accordance with this management directive. Assessments may be conducted by one person or may involve a group. This group will be composed of NRC staff, with support from NRC consultants when warranted. (2)

At the discretion of the Executive Director for Operations (EDO), responsibility for an MEA may be transferred to an Incident

Scope of a Medical Event Assessment (MEA) (B) (continued)

Investigation Team (IIT) as defined in Management Directive (MD) 8.3, "NRC Incident Investigation Program." (3)

At the discretion of a regional administrator, responsibility for an MEA may be transferred to an Augmented Inspection Team (AIT) as defined in MD 8.3. (4)

Criteria for considering transfer of responsibility for an MEA to an IIT or an AIT are provided in Section (C) of this handbook. (5)

Note: If responsibility for an MEA is transferred to an AIT or an IIT, determination of compliance with NRC regulations is outside the scope of MD 8.3 and shall be performed in accordance with this management directive.

Criteria for Determining Whether an Incident Investigation Team (IIT) or an Augmented Inspection Team (AIT) Is Warranted for an MEA (C)

Transfer of Responsibility for an MEA to an IIT (1)

An IIT should be considered for the following events in accordance with MD 8.3:

- A medical event involving a significant number of patients or individuals over a long period (months or years) that may have resulted in deterministic effects. (a)

- A medical event resulting in the potential exposure of a significant number of individuals above occupational or public dose limits. (b)

Criteria for Determining Whether an Incident Investigation Team (IIT) or an Augmented Inspection Team (AIT) Is Warranted for an MEA (C) (continued)

Transfer of Responsibility for an MEA to an IIT (1) (continued)

- A medical event involving circumstances sufficiently complex, unique, or not well enough understood in which an investigation would serve the needs and interests of the Commission. (c)

Transfer of Responsibility for an MEA to an AIT (2)

An AIT should be considered for the following events in accordance with MD 8.3:

- A medical event in which a medical consultant determined that the event directly contributed to a fatality. (a)

- A medical event involving a device failure, including computer software such as treatment planning systems or other support systems, with possible adverse generic implications. (b)

- A medical event that is complicated and whose probable causes are unknown or difficult to understand. (c)

- A medical event whose consequences to the patient(s) or other potentially exposed individuals require headquarters or special contractor support to evaluate. (Examples of specialized contractor support include cytogenetic studies, metallographic examinations, thermal analysis, and microhardness measurements.) (d)

Followup Procedures (D)

The timeframe for initial activation of the procedures in this management directive should be based on the initial assessment

Followup Procedures (D) (continued)

of the severity of the event. This assessment will typically be performed by the regional office with input from the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), as necessary. (1)

The following guidelines may be used when establishing the timeframe for activation: (2)

- Medical event resulting in a fatality — 2 working days (a)
- Medical event (other than a misadministration) that has not resulted in a fatality — 5 working days (b)
- Misadministration resulting in overexposure to a patient* — 5 working days (c)
- Misadministration resulting in underexposure to a patient* — 10 working days (d)

The degree and type of followup are based on the type of medical event. When assessing a medical event, the following items must be addressed: (3)

- NRC will follow up on (track) patients or other exposed individuals until the physician consultant has provided a final report of the probable deterministic effects of any radiation exposures. (a)
- NRC will make available a copy of the NRC inspection report and the consultant's report to the referring physician or the individual's physician. (b)

*The specified timeframe assumes that the misadministration occurred within the last 2 months. If the misadministration occurred in the past, consideration should be given to extending the timeframe.

Followup Procedures (D) (continued)

- NRC will review all facts associated with the medical event and will coordinate activities with State officials and local Government. These activities may include coordination with State Radiological Health Departments and local authorities (i.e., law enforcement). In cases in which a patient has died and the physician consultant finds that the medical event may be a contributing cause of death, NRC will provide facts on the medical event to the appropriate local government or State authority to ensure the accuracy of the death certificate. (c)

- NRC will, if appropriate, take enforcement action based on the circumstances surrounding the event. Action will be based on the NRC enforcement policy specified in 10 CFR Part 2, Appendix C. (d)

- NRC will inform the referring physician or the individual's physician of the Department of Energy's (DOE's) voluntary long-term medical study program in accordance with guidance provided in NRC Inspection Manual Chapter 1360, "Use of Physician and Scientific Consultants in the Medical Consultant Program." (e)

- NRC documents containing a patient's or an exposed individual's identity must be marked with the following statement: (f)

  > "This information must be protected from disclosure pursuant to 10 CFR 2.790 because it contains a patient's or an exposed individual's identity. Disclosure of this document shall not be made since it would result in an unwarranted invasion of the patient's or the individual's privacy."

In addition to the items listed above, the following items must be addressed when assessing a misadministration: (4)

Followup Procedures (D) (continued)

- NRC will verify that the referring physician and the patient have been notified as required by 10 CFR 35.33. (a)

- The licensee's report submitted under 10 CFR 35.33 must not include the patient's name or other information that could lead to the identification of the patient. (b)

- NRC will verify by reasonable means that the licensee has orally notified the referring physician and the patient or a responsible relative or guardian and, when such notification has been made, has provided a copy of a written report of the event and the probable consequences of the event to the patient, or a responsible relative or guardian if either was notified, as required by 10 CFR 35.33. (c)

- If the licensee or the referring physician has not notified the patient or a responsible relative or guardian, the NRC, in consultation with a physician consultant, if necessary, will determine if there is adequate justification for not providing notification. (d)

- When the medical consultant indicates that after a long period the patient may suffer morbidity or mortality (as in the case of a high radioactive dose to the brain or the central nervous system), the Director, NMSS, in consultation with the EDO, will determine whether a long-term medical consultant should be made available. (e)

In addition to the items listed above, when information provided to the NRC indicates that misadministrations may have occurred in the past or NRC identifies that a misadministration has occurred, the NRC will make a reasonable effort to accomplish the following: (5)

- Identify all patients who received a misadministration. (a)

Followup Procedures (D) (continued)

- Require the licensee to meet the notification requirements of 10 CFR 35.33 and if the patient is deceased, to notify the next of kin and the referring physicians of the possible misadministration. (b)

Group Composition and Qualifications (E)

Group Composition (1)

At a minimum, the group reviewing a medical event must be composed of at least one NRC inspector having the qualifications listed below and an NRC medical consultant, if warranted. More than one NRC inspector may be part of the group; however, only one inspector in the group is required to have the qualifications listed in Section (E)(2) of this handbook. (a)

A physician consultant must be a member of the group if the misadministration resulted in an overexposure to the patient. A scientific consultant may be included if NRC regional management (e.g., a division director or designee) determines it is warranted, as in any case in which the misadministration involves complex treatment planning. (b)

Regional management may use their discretion in determining whether a medical consultant will be used in assessing a medical event other than a misadministration that resulted in an overexposure. (c)

A medical consultant is **not** required to go to the licensee's site in all instances. Contracted services may be limited to a review of documentation or to telephone contact. NRC regional management and the group leader should discuss with the medical consultant his or her need to go onsite. NRC regional management will make the final decision as to whether the consultant will go onsite. (d)

Group Composition and Qualifications (E) (continued)

Qualifications (2)

Group or Primary Inspector (a)

The group or primary inspector shall possess specific training or equivalent experience in the treatment modality involved in the medical event. Specific training includes the following:

- Diagnostic and Therapeutic Nuclear Medicine Course (H-304)* (i)
- Teletherapy and Brachytherapy Course (H-313)* (ii)
- Root Cause/Incident Investigation Workshop (G-205)* (iii)

Medical Consultant (b)

The medical consultant shall be a special Government employee who has been appointed by the NRC to serve as a physician member of the Advisory Committee on the Medical Uses of Isotopes or as a medical consultant. (i)

The medical consultant should have expertise in the area being reviewed. (ii)

Qualifications of the Office of Nuclear Material Safety and Safeguards (NMSS) Misadministration Coordinator (F)

At a minimum, the NMSS Misadministration Coordinator shall possess the following qualifications:

- Senior staff member at the level of GG-14 or above (1)

*See Reference 8 in Directive 8.10.

Qualifications of the Office of Nuclear Material Safety and Safeguards (NMSS) Misadministration Coordinator (F) (continued)

- Specific training or equivalent experience in the treatment modality involved in the medical event. Specific training includes the following: (2)
  - Diagnostic and Therapeutic Nuclear Medicine Course (H-304) (a)
  - Teletherapy and Brachytherapy Course (H-313) (b)
  - Root Cause/Incident Investigation Workshop (G-205) (c)
  - Familiarity with the NRC process to appoint and use medical consultants (d)

Conduct of Assessment (G)

The assessment of all medical events should include the tasks identified below. These tasks should be completed by the regional staff, with support from an NRC medical consultant on an as-needed basis or as specified in this management directive or in NRC Inspection Manual Chapter 1360. (1)

- Identify the sequence of events leading to the medical event. (a)
- Identify the root cause(s) and contributing factors of the medical event. (b)
- Assess any probable deterministic effects on the patient and/or other exposed individual(s). (c)
- Identify and determine the adequacy of corrective actions taken. (d)

Conduct of Assessment (G) (continued)

- Determine whether licensee management was aware of the violation(s) of NRC regulations that contributed to the cause of the medical event if violation(s) were identified during the assessment. (e)

- Identify the licensee's immediate and long-term corrective actions. (f)

In addition to the items listed above, the following items must be addressed when assessing a misadministration: (2)

- Determine compliance with the quality management rule (10 CFR 35.32). (a)

- Determine compliance with notification requirements of the misadministration rule (10 CFR 35.33). In particular, the following items should be addressed: (b)

  – Was notification of the incident reported to NRC by the next calendar day after discovery of the incident? (i)

  – Was a written report of the incident provided to NRC within 15 days of the incident? (ii)

  – Was the referring physician and the patient or the responsible relative or guardian (as required) informed of the incident within 24 hours of discovery? (iii)

  – If the patient was informed, was a written report of the incident provided to the patient within 15 days of the incident? (iv)

  – If the patient or the responsible relative or guardian was not informed of the incident, did the licensee provide adequate justification for its actions? (v)

Role of the Medical Consultant (H)

Note: Responsibilities of the medical consultant may vary from case to case, depending on the nature of the medical event. A more involved description of the responsibilities of the medical consultant is provided in NRC Inspection Manual Chapter 1360.

Physician Consultant (1)

The following generic listing details responsibilities of the physician consultant that would be required during the review of a medical event. **Note**: Items (v) through (ix) are specific to the assessment of a misadministration: (a)

- Gather information regarding the circumstances surrounding the medical event to assist in determining the root cause(s). (i)

- Evaluate the promptness and effectiveness of the licensee's immediate actions in response to the incident and corrective actions to prevent recurrence. (ii)

- Assess any probable deterministic effects on the patient or the exposed individual. (iii)

- Prepare a report summarizing evaluations and assessments. The report should be submitted to the NRC within 30 days of completion of the case review and/or site visit unless there are extenuating circumstances. These circumstances should be discussed with regional management. (iv)

- Provide an estimate of the radiation dose to the exposed individual and the probable error associated with the estimation of the dose. (v)

- Gather information regarding the radiation dose received by the patient as compared to the prescribed dose to determine whether the misadministration was medically or biologically significant. (vi)

Role of the Medical Consultant (H) (continued)

Physician Consultant (1) (continued)

- Evaluate the justification, when applicable, for not informing the patient of the misadministration. (vii)

- Evaluate the licensee's plan for patient followup, if available. (viii)

- Review and evaluate the report submitted by the licensee under 10 CFR 35.33. (ix)

The following generic listing details items that the physician consultant should **not** perform under the terms of the contractual agreement with NRC: (b)

- Enter into a physician-patient relationship with the exposed individual. (i)

- Provide medical opinions or recommendations to anyone other than the NRC without the NRC's written permission, unless compelled by legal process to do so. To minimize the risk of liability, any recommendations made by a physician consultant should be accompanied by a disclaimer that the recommendation is not a substitute for the professional judgment of any physician involved with or responsible for the patient's care. (ii)

- Recommend a particular expert. The physician consultant may indicate that the services of an expert are needed, and if asked, the consultant may identify, after consultation with NRC management, sources for identification and location of such experts. Recommendations will be in accordance with 5 CFR 2635.702, which prohibits Federal employees from using public office for the endorsement of any product, service, or enterprise. (See J. Taylor memorandum of 7/15/93 and attachment.) (iii)

Role of the Medical Consultant (H) (continued)

Scientific Consultant (2)

The following examples illustrate duties that a scientific consultant may be asked to perform. Because of the specialization of the scientific consultant, it is likely that the individual or the organization will be asked to perform only one of these tasks. (a)

- Provide an estimate of the delivered radiation dose for internal and external exposure to the exposed individual and the probable error associated with the estimation of the dose(s). (i)

- Perform and/or evaluate the results of cytogenetic studies. (ii)

- Interpret bioassay results. (iii)

- Prepare a report summarizing evaluations and assessments. The report should be submitted to the NRC within 30 days of completing the requested tasks unless there are extenuating circumstances. These circumstances should be discussed with NRC regional management. (iv)

The following generic listing details items that the scientific consultant should **not** perform: (b)

- Provide medical or technical opinions or recommendations to anyone other than the NRC without the NRC's written permission, unless compelled by legal process to do so. To minimize the risk of liability, any recommendations made by a scientific consultant should be accompanied by a disclaimer that the recommendation is not a substitute for the professional judgment of any physician involved with or responsible for the patient's care. (i)

- Recommend a particular expert. The scientific consultant may indicate that the services of an expert are needed, and if asked, the consultant may identify, after consultation with NRC

Role of the Medical Consultant (H) (continued)

Scientific Consultant (2) (continued)

management, sources for identification and location of such experts. Recommendations will be in accordance with 5 CFR 2635.702, which prohibits Federal employees from using public office for the endorsement of any product, service, or enterprise. (See J. Taylor memorandum of 7/15/93 and attachment.) (ii)

Liability of the Medical Consultant (I)

Medical consultants who are appointed as special Government employees are considered to be Federal employees. When a Federal employee is personally sued for a common law tort committed within the scope of employment, the United States will be substituted as the defendant pursuant to the Federal Tort Claims Act. Government counsel will defend the suit on behalf of the United States. The United States will be responsible for any damages that might be awarded. In addition, the consultant would have absolute personal immunity for injury or damage arising from common law torts. A Federal employee (including present and former employees) may also be provided personal representation by the Government in a proceeding in which he or she is sued, subpoenaed, or charged in his or her individual capacity, provided the actions for which representation is requested reasonably appear to have been performed within the scope of the employee's appointment and representation is in the interest of the United States. (1)

The consultant's provision of professional opinions and recommendations to the NRC does not constitute "practice of medicine" within the scope of State licensing laws, provided the consultant does not enter into a physician-patient relationship with the patient. (2)

Reports and Documentation of an MEA (J)

NRC Inspection Report (1)

The inspection report should be prepared in accordance with NRC Inspection Manual Chapter 610, "Inspection Reports." In addition to the requirements of Inspection Manual Chapter 610, the inspection report should include, at a minimum, the following: (a)

- The sequence of events. (i)
- The immediate and root cause. (ii)
- The probable consequence to the patient and other exposed individuals. (iii)
- The licensee's actions, including compliance with the quality management rule and the notification requirements of the misadministration rule if the medical event was a misadministration. If the medical event was not a misadministration, the licensee's actions, including compliance with the Quality Management Rule (10 CFR Part 35) and the notification requirements of 10 CFR Parts 19 and 20. (iv)

In addition, violations identified as a result of the medical event should be listed in a separate section from other violations. (b)

The report should be distributed in accordance with regional policy for inspection report distribution. (c)

The NRC regional office responsible for reviewing a medical event should provide the inspection report to the referring physician or the individual's physician. (d)

Reports and Documentation of an MEA (J) (continued)

Medical Consultant's Report (2)

The consultant should prepare the inspection report in accordance with guidance provided in NRC Inspection Manual Chapter 1360. (a)

The consultant should provide the final report to the NRC contact. (NRC should supply the name of the NRC contact during its first communication with the consultant.) (b)

The NRC regional office responsible for reviewing a medical event should provide the consultant's report to the referring physician or the individual's physician. (c)

MEA Report Package (3)

The MEA report package contains the inspection report, the licensee's report (required by 10 CFR 35.33), and the medical consultant's report (if required). The lead or primary NRC inspector is responsible for assembling the package. (a)

The NRC inspector should ensure that a copy of the MEA report package is placed in the docket files and is provided to the NMSS Misadministration Coordinator. (b)

The NMSS Misadministration Coordinator should submit one copy of the MEA report package to the Office of Enforcement and one copy to the Office for Analysis and Evaluation of Operational Data (AEOD) to ensure that the medical event is entered into the AEOD nonreactor event database. (c)

Glossary

Authorized User. Physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Deterministic Effect. Health effect, the severity of which varies with the dose and for which a dose threshold is believed to exist. (Also called nonstochastic effect.) Examples of deterministic effects are cataracts, hypothyroidism, erythema, blood dyscrasia, radiation pneumonitis, and epilation.

Guardian. Person legally responsible for a patient.

Medical Consultant. Generic term intended to address the physician or the scientific consultant.

Medical Event. All medical misadministration events and any other event occurring at a medical licensee's facility that is believed by the Director, Office of Nuclear Material Safety and Safeguards, to indicate a significant programmatic breakdown in the licensee's Quality Management Program required by 10 CFR 35.32, or an event that raises a significant question concerning issues such as the adequacy of a device, a regulation, a licensing/certification practice, or an exposure to a patient that did not exceed the radiation dose threshold for a misadministration but did exceed the prescribed dose.

Misadministration. The definition for misadministration can be found in 10 CFR 35.2.

Physician Consultant. A licensed physician, trained or experienced in the use of radioactivity in medical diagnosis and therapy and/or experienced in the evaluation of the medical effects resulting from radiation injuries, whose services are retained by the NRC to provide expert opinion and independent evaluation of the medical information related to radiation exposures of individuals.

Glossary (continued)

Referring Physician. A physician who refers the patient to a radiation oncologist, a nuclear medicine physician, or other category of authorized user and requests treatment, consultation, or diagnostic tests for the patient. In most cases, the referring physician will not be the authorized user.

Responsible Relative. A relative who would make decisions regarding the patient when the patient cannot (e.g., the patient is a minor; the patient is unconscious or incapable of comprehending the information; or the patient has died) or who would make decisions for the patient if telling the patient of a misadministration would be harmful to the patient (based on medical judgment). The responsible relative is usually the next of kin.

Scientific Consultant. A medical or health physicist, radiobiologist, or other specialist who is retained by the NRC to provide expert opinion and independent evaluation of the circumstances surrounding a radiation exposure incident, resulting doses, and dose consequences.