U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 8.10	NRC ASSESSMENT PROGRAM FOR A MEDICAL EVENT OR AN INCIDENT OCCURRING AT A MEDICAL FACILITY	DT-14-07
Volume 8	Licensee Oversight Programs	
Approved By:	Mark A. Satorius Executive Director for Operations	
Date Approved:	March 28, 2014	
Expiration Date:	March 28, 2019	
Issuing Office:	Office of Federal and State Materials and Environmental Management Programs Division of Materials Safety and State Agreements	
Contact Name:	Penny Lanzisera 610-337-5169	Sophie Holiday 301-415-7865

EXECUTIVE SUMMARY

Management Directive (MD) and Handbook 8.10 are being revised to reflect the changes in the medical regulations made to Title 10 of the *Code of Federal Regulations*, Part 35, "Medical Use of Byproduct Material," to include the following:

- Unintended radiation exposures to an embryo/fetus in excess of the limits specified for reporting as an Abnormal Occurrence,
- Medical equipment failures that could result in unusual exposures,
- Changes in the agency's organizational structure, and
- Definition for the term "incident," for the purposes of the NRC Assessment Program, which is an event other than a "medical event" as defined in 10 CFR 35.2, occurring at a medical facility that may warrant assessment by NRC.

The name of this MD has been changed from "NRC Medical Event Assessment Program" to "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility," to clarify the intent as well as the objectives of the program.

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to establish an assessment program for a medical event or incident occurring at medical facilities (Assessment Program) for responding to medical events and incidents at medical facilities. Management Directive (MD) 8.10 specifies the scope, objectives, authorities, responsibilities, and basic requirements for the Assessment Program.

II. OBJECTIVES

- Ensure that medical events and incidents at medical facilities are reviewed in a manner that is timely, objective, systematic, and technically sound; that factual information pertaining to the medical event or incident is documented; that probable causes are ascertained; and that corrective actions are implemented to prevent recurrence.
- Ensure that the appropriate level and direction for followup is provided to patients who have experienced a treatment that meets the medical event reporting criteria.
- Ensure that the appropriate level and direction for followup is provided to patients who are parents of an embryo/fetus or a nursing child who has received a dose that meets

the Abnormal Occurrence reporting criteria. However, NRC will not intrude into medical judgments affecting patients.

- Ensure that licensees have complied with the notification and reporting requirements of 10 *Code of Federal Regulations* (CFR) 35.3045, "Report and Notification of a Medical Event"; 10 CFR 35.3047, "Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child"; 10 CFR 30.50, "Reporting Requirements"; 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation"; 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; and 10 CFR Part 20, "Standards for Protection Against Radiation," if applicable.
- Ensure that the NRC Medical Policy Statement is applied appropriately. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public, and to ensure radiation safety of patients primarily by assuring that the use of radionuclides is in accordance with the physician's directions.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Executive Director for Operations (EDO)

Determines whether a medical event or incident at a medical facility constitutes a significant operational occurrence, and therefore, should be investigated by an Incident Investigation Team (IIT) in accordance with MD 8.3, "NRC Incident Investigation Program."

B. Director, Office of Federal and State Materials and Environmental Management Programs (FSME)

1. Establishes and maintains procedures and guidelines governing the Assessment Program.
2. Oversees regional implementation of the Assessment Program and directs that all medical events, as defined in 10 CFR Part 35, "Medical Use of Byproduct Material," be assessed in accordance with this directive.
3. Delegates responsibility to the regional office to determine if incidents, which do not meet the definition of a medical event occurring at a medical facility, are assessed in accordance with this directive. These may include an overdose to a worker, member of the public, embryo/fetus, or nursing child as a result of activities conducted at a medical facility, or medical equipment failures.

4. Appoints a coordinator within the office to oversee the agencywide medical consultant program.
5. Maintains a database of medical events and other reportable incidents occurring at medical facilities. Currently the system maintained for this purpose is the Nuclear Material Events Database (NMED).
6. Makes recommendations to and coordinates with the appropriate regional administrator on medical events or incidents that may warrant investigation by an Augmented Inspection Team (AIT) or IIT.
7. Obtains Executive Director of Operations concurrence for an IIT on medical events or incidents that may warrant investigation.

C. Director, Office of Enforcement (OE)

1. Reviews escalated enforcement actions resulting from a review performed under the Medical Event Assessment Program (MEA Program).
2. Reviews escalated enforcement actions resulting from an inspection by an AIT or an IIT under the MEA Program.
3. Delegates authority to an NRC regional administrator in accordance with the Enforcement Manual.

D. Chief Human Capital Officer (CHCO)

1. Appoints physicians and scientific consultants used in accordance with the Medical Consultant Program as special Government employees, based on recommendations provided by FSME.
2. Establishes training courses applicable to responding to medical events and incidents at medical facilities.

E. Regional Administrators (RAs)

1. Maintain overall responsibility for the implementation of the Assessment Program in the regional office.
2. Provide personnel to implement the Assessment Program in the region.
3. Make recommendations to and coordinate with the Director of FSME on medical events and incidents occurring at medical facilities that may warrant an investigation by an AIT or IIT in accordance with MD 8.3.

IV. APPLICABILITY

The policy and guidance in MD 8.10 apply to all NRC employees.

V. DIRECTIVE HANDBOOK

Handbook 8.10 provides guidance for the Assessment Program.

VI. REFERENCES

Code of Federal Regulations

5 CFR 2635.702, "Use of Public Office for Private Gain," at http://www.gpo.gov/fdsys/pkg/CFR-2008-title5-vol3/xml/CFR-2008-title5-vol3-sec2635-702.xml.

10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/.

10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/part002-0390.html.

10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part019/.

10 CFR 19.13, "Notifications and Reports to Individuals," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part019/part019-0013.html.

10 CFR Part 20, "Standards for Protection Against Radiation," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

10 CFR 20.2203, "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-2203.html.

10 CFR Part 21, "Reporting of Defects and Noncompliance," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/.

10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/part021-0021.html.

10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/.

10 CFR 30.50, "Reporting Requirements," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/part030-0050.html.

10 CFR Part 35, "Medical Use of Byproduct Material," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/.

10 CFR 35.33, "Notifications, Reports, and Records of Misadministrations," at http://www.gpo.gov/fdsys/pkg/CFR-2001-title10-vol1/pdf/CFR-2001-title10-vol1-sec35-33.pdf.

10 CFR 35.40, "Written Directive," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0040.html.

10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0041.html.

10 CFR 35.3045, "Report and Notification of a Medical Event," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html.

10 CFR 35.3047, "Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child," at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3047.html.

Nuclear Regulatory Commission Documents

Enforcement Manual at http://www.nrc.gov/about-nrc/regulatory/enforcement.html.

Enforcement Policy at http://www.nrc.gov/about-nrc/regulatory/enforcement.html.

Inspection Manual Chapters—

0610, "Nuclear Material Safety and Safeguards Inspection Reports," at http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/mc0610.pdf.

1360, "Use of Physician and Scientific Consultants in the Medical Consultant Program," at http://pbadupws.nrc.gov/docs/ML0631/ML063120385.pdf.

2800, "Materials Inspection Program," at http://pbadupws.nrc.gov/docs/ML1028/ML102800160.pdf.

Inspection Procedures—

87103, "Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing," at http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/ip87103.pdf.

87132, "Brachytherapy Programs," at http://pbadupws.nrc.gov/docs/ML1200/ML12006A148.pdf.

NRC Management Directives—

7.1, "Tort Claims Against the United States," at http://www.internal.nrc.gov/policy/directives/toc/md7.1.htm

8.3, "NRC Incident Investigation Program," at http://www.internal.nrc.gov/ADM/DAS/cag/Management_Directives/md8.3.pdf.

"NRC Medical Policy Statement," at http://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf.

United States Code

Federal Tort Claims Act (28 U.S.C. Part VI, Chapter 171).

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I. NRC ASSESSMENT FOR A MEDICAL EVENT OR INCIDENT OCCURRING AT A MEDICAL FACILITY

A. Purpose of the Handbook

This handbook contains the procedures for responding to and documenting a medical event or incident occurring at a medical facility, the qualifications for group members responding to the event or incident, and the process for selecting and assigning a medical consultant, if necessary. Upon notification of a significant operational event, the regional administrator (RA) and staff should perform the initial review to assess the safety significance of the event in order to assess the level of response required.

B. Scope of Assessment

1. The assessment should emphasize fact-finding, determination of probable cause(s), and compliance with NRC reporting and notification requirements. The review should be sufficiently broad and detailed to ensure that the medical event or incident 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 medical event or incident.

2. The review should consider the adequacy of the licensee's actions during the medical event or incident. Objectives of the assessment are to determine the proximate and ultimate causes of the event and the programmatic weaknesses or shortcomings that permitted these conditions to exist. The scope of the assessment will also include ensuring that the licensee complies with the notification requirements of 10 *Code of Federal Regulations* (CFR) Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; and 10 CFR Part 35, "Medical Use of Byproduct Material," as applicable.

3. All medical events reported in accordance with 10 CFR 35.3045, "Report and Notification of a Medical Event," will be evaluated under the Assessment Program for a Medical Event or Incident Occurring at Medical Facilities (Assessment Program).

   (a) Other incidents occurring at medical facilities, including a dose to an embryo/fetus or nursing child in excess of the regulatory limits, an overdose to a worker or member of the public (not including patients), and medical equipment failures, will be chosen on a case-by-case basis, as determined by management, for assessment in accordance with Management Directive (MD) 8.10.

(b) In addition, any incident that raises a significant question concerning issues such as the adequacy of a device, the applicability of a regulation, a licensing and/or certification practice, a breakdown in the licensee's program implemented in accordance with 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," or an exposure to a patient that did not exceed the radiation dose threshold for a medical event but did exceed the prescribed dose may warrant implementation of the procedures described in MD 8.10 on a case-by-case basis, as determined by management.

(c) Assessments may be conducted by one person or may involve a group composed of NRC employees, with support from NRC consultants when warranted.

4. At the direction of the Executive Director for Operations (EDO), responsibility for assessing a medical event or incident at a medical facility may be transferred to an Incident Investigation Team (IIT) as defined in MD 8.3, "NRC Incident Investigation Program."

5. In addition, at the direction of the RA, responsibility for assessing a medical event or incident at a medical facility may be transferred to an Augmented Inspection Team (AIT) as defined in MD 8.3.

6. Regional management may direct their staff to commence a reactive or special inspection, as defined in NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program," until an AIT or IIT can be initiated.

7. Criteria for considering transfer of responsibility for assessing a medical event or incident at a medical facility to an AIT or an IIT are provided in Section II of this handbook. If responsibility for assessing a medical event or incident at a medical facility is transferred to an AIT or an IIT, determining compliance with NRC regulations is performed in accordance with MD 8.10.

II. CRITERIA FOR DETERMINING WHETHER AN INCIDENT INVESTIGATION OR AUGMENTED INSPECTION IS WARRANTED FOR A MEDICAL EVENT OR INCIDENT OCCURRING AT A MEDICAL FACILITY

A. Transfer of Responsibility for Assessing a Medical Event or Incident at a Medical Facility to an Incident Investigation Team (IIT)

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

1. A medical event in which a medical consultant determines that the event directly contributed to a fatality. Since this determination may take several weeks, a medical

consultant should be contacted immediately for all medical events involving a patient fatality to determine whether the event may have been a contributing factor in the patient death.

2. An incident at a medical facility resulting in the potential exposure of a significant number of individuals above occupational or public dose limits.

3. A medical event or other incident at a medical facility involving circumstances sufficiently complex, unique, or not well enough understood in which an investigation would serve the needs and interests of the Commission.

4. An event at a medical facility involving the medical use of byproduct, source, or special nuclear material that may result or may have resulted in deterministic effects to a significant number of patients or individuals over a long period (months or years).

B. Transfer of Responsibility for Assessing a Medical Event or Incident at a Medical Facility to an Augmented Inspection Team (AIT)

An AIT should be considered for the following medical events or incidents in accordance with MD 8.3.

1. A medical event or other incident at a medical facility involving possible adverse generic implications that require special contractor support to evaluate.

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

3. A medical event or other incident at a medical facility that is complicated and whose probable causes are unknown or difficult to understand and for which special contractor support may be necessary to evaluate.

4. A medical event or other incident at a medical facility 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.)

III. FOLLOWUP PROCEDURES

A. Timeframe to Activate Procedure

1. The timeframe for initial activation of the procedures in MD 8.10 should be based on the initial assessment of the severity of the medical event or incident. This assessment will typically be performed by the regional office with input from the Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), as necessary.

2. For medical events or incidents that meet the criteria for an IIT or AIT, the response time may need to be adjusted to ensure a timely response. The following guidelines may be used to establish the timeframe for activation following notification of the medical event or incident to NRC:

   (a) Two (2) working days for a medical event or an incident resulting in a fatality;

   (b) Five (5) working days for a medical event resulting in an overexposure to a patient; and

   (c) Ten (10) working days for all other medical events or incidents, including:

      (i) A medical event resulting in an underexposure to a patient; or

      (ii) An incident at a medical facility, not resulting in a fatality, determined by regional and/or FSME management to warrant activation of this procedure. For example, exposures to an embryo/fetus potentially in excess of the limits in 10 CFR 35.3047, “Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child,” or possible generic medical equipment failures that could result in unusual patient exposures may warrant activation of this procedure.

3. For medical events, the specified timeframe assumes that the medical event occurred within the last 2 months. If the medical event occurred in the past, consideration may be given to extending the timeframe. In addition, in coordination with FSME, the specified timeframes may either be extended or the activation may be determined unnecessary. For instance, if the medical event involves exposures not significantly in excess of the regulatory limits, FSME may authorize extension of the response timeframe. Additionally, if the medical event is the result of an underexposure, FSME may determine that activation is unnecessary when the licensee is appropriately addressing the patient’s treatment and the root cause of the underdose. In any case, the FSME agreement to any changes in the timeframes listed above will be documented by the appropriate region in a request from the regional division director to the division director of MSSA. FSME must maintain this

request in the official recordkeeping system, the Agencywide Documents Access and Management System (ADAMS).

B. Items to Address in Followup

1. The degree and type of followup are based on the type of medical event or incident occurring at the medical facility. In addition, a database for tracking nuclear material medical events and incidents, designated as the Nuclear Material Events Database (NMED), includes medical events and incidents that occur at medical facilities. This database should contain sufficient information to allow for analysis of medical events and incidents occurring at medical facilities. Enclosure 3 of IMC 2800 provides a listing of data that is entered into NMED.

2. When assessing a medical event or an incident at a medical facility, the following items must be addressed, where applicable:

   (a) NRC will collect information on the medical status of involved individuals (e.g., patients or other exposed individuals) until the physician consultant has provided a final report of the probable deterministic effects of any radiation exposures.

   (b) NRC will make available a copy of the NRC inspection report to the referring physician or the individual's physician for medical events. In addition, if the medical consultant's report is not summarized in the NRC inspection report, NRC will make available a copy of the medical consultant's report, or a summary of the pertinent information.

   (c) NRC will review all facts associated with the medical event or incident at the medical facility and will coordinate activities with State officials and local government, if applicable. 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.

   (d) NRC will, if appropriate, take enforcement action based on the circumstances surrounding the medical event or incident. Action will be based on the NRC enforcement policy (10 CFR Part 2, Subpart B).

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

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

> This information must be protected from disclosure pursuant to 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," because it contains a patient's or an exposed individual's identity. Disclosure of this document will not be made since it would result in an unwarranted invasion of the patient's or the individual's privacy.

(g) The licensee's report submitted under 10 CFR 35.3045 must not include the individual's name or other information that could lead to the identification of the individual. However, the licensee will provide an annotated copy of the report provided to NRC to the referring physician, if other than the licensee, with the individual's name and social security number (or other identification number).

(h) NRC will verify that the licensee has notified the referring physician and the patient or a responsible relative or guardian if required under 10 CFR 35.3045(e). Note: The requirements in 10 CFR 35.3045(e) provide specific exceptions to the requirement for the licensee to make these notifications. If verbal notifications are made, NRC will verify that the licensee has informed the patient or responsible relative or guardian that a written description of the event can be obtained, as required by 10 CFR 35.3045.

(i) 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 of FSME, in consultation with the EDO, will determine whether a long-term medical consultant should be made available.

(j) When information provided to NRC indicates that medical events may have occurred in the past or NRC identifies that a medical event has occurred, NRC will make a reasonable effort to identify all patients who were involved in a medical event and require the licensee to meet the notification requirements of 10 CFR 35.3045. If the patient is deceased, NRC will require the licensee to notify the referring physician of the medical event. In addition, the responsible relative or guardian notification required by 10 CFR 35.3045 will be considered to be met when the next of kin has been notified of the medical event.

(k) NRC will verify that medical equipment failures connected with the medical event or incident at the medical facility are reported, if necessary, in accordance with 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and 10 CFR 30.50, "Reporting Requirements." NRC will also ensure

that the licensee is aware that other medical equipment failures not resulting in a medical event or incident may also require reporting. In addition, NRC will ensure that the manufacturer of the medical equipment has been notified of the failure. Finally, NRC will ensure that all licensees possessing similar equipment are informed of the equipment failure by a generic communication (e.g., Information Notice, Regulatory Issue Summary).

(l) NRC will verify that overexposures to workers or members of the public from activities conducted at medical facilities are reported in accordance with 10 CFR 19.13, "Notifications and Reports to Individuals," and 10 CFR 20.2203, "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits," with appropriate notification to the worker.

(m) To ensure proper tracking of medical events and incidents occurring at medical facilities and to facilitate incident/event analysis for types of incidents/events, NRC will ensure that each medical event and incident is entered into NMED.

IV. GROUP COMPOSITION AND QUALIFICATIONS

A. Group Composition

1. At a minimum, the group reviewing a medical event or an incident at a medical facility must be composed of at least one NRC inspector having the qualifications listed below and an NRC medical consultant, if warranted. The medical consultant's review may be limited to records review remotely or the consultant may arrange to go onsite in accordance with IMC 1360. 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 this handbook.
2. In general, a physician consultant must be a member of the group if a medical event resulted in an overexposure to a patient or a nursing infant or if an embryo/fetus may have been inadvertently exposed to radiation or radioactive material in excess of the regulatory limits. However, in some cases, FSME management may document its agreement that a medical consultant is not needed for a medical event involving an overexposure. For instance, a medical event involving an overexposure not significantly exceeding the regulatory limits with no adverse health effects noted may not warrant a medical consultant.
3. A scientific consultant may be included if regional management (e.g., a division director or designee) determines it is warranted, as in any case in which the medical event or incident involves complex issues.

4. Regional management may use discretion based on the criteria detailed in IMC 1360 in determining whether a medical consultant will be used in assessing an overexposure incident at a medical facility other than to a patient, nursing infant, or embryo/fetus. In addition, regional management may use discretion in determining whether a scientific consultant is warranted for medical equipment failure.

5. A medical consultant is **not** required to go to the licensee's site in most instances. Contracted services may be limited to a review of documentation or to telephone contact. Regional management or designee should discuss with the medical consultant his or her need to go onsite. Regional management will make the final decision as to whether the consultant will go onsite.

B. Qualifications of Inspector, Medical Consultant, and FSME Coordinator

1. The inspectors and FSME coordinator will possess specific training or equivalent experience in the treatment modality involved in the medical event or incident at the medical facility. Inspectors must be qualified inspectors for the modality being inspected. Specific training includes the following, which may also be met by equivalent experience:

   (a) Diagnostic and Therapeutic Nuclear Medicine Course (H-304);

   (b) Brachytherapy, Gamma Knife, and Emerging Technologies Course (H-313);

   (c) Root Cause/Incident Investigation Workshop (G-205); and

   (d) Familiarity with the NRC process to appoint and use medical consultants as outlined in IMC 1360.

2. The medical consultant will be a special Government employee who has been appointed by NRC to serve as a physician member of the Advisory Committee on the Medical Uses of Isotopes or as a medical consultant. The medical consultant should have expertise in the area being reviewed.

V. CONDUCT OF ASSESSMENT

A. NRC Inspection Procedure (IP) for the specific modality being reviewed (e.g., IP 87132, "Brachytherapy Programs," and NRC IP 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing,") may be useful in preparing for the assessment.

B. The tasks to be completed during an assessment are identified below, as applicable. These tasks should be completed by the regional staff, with support from an NRC medical consultant and headquarters on an as-needed basis or as specified in MD 8.10 or in IMC 1360.

1. Notify the licensee's management that an inspection is to be conducted. When notifying the licensee, make sure that the medical event or incident has terminated and that there are no ongoing safety issues. If ongoing safety issues are identified, immediately notify regional management of the situation.

   (a) Request that the licensee preserve any physical evidence connected with the medical event or incident, if possible.

   (b) Request in advance that the licensee be prepared to submit any necessary documents at the initial licensee meeting. For instance, for medical events involving patient overexposures, request that all treatment planning documentation and device calibrations, as applicable, be provided.

2. Assess any deterministic effects that may occur to the patient and/or any other exposed individual(s). Initially this assessment will be based on the licensee's data collected on the patient's/individual's medical condition, with subsequent review by NRC employees and the medical consultant.

3. Inspect equipment, tools, work areas, and anything else directly or indirectly involved in the medical event or incident. Interview all personnel directly or indirectly involved in the medical event or incident. Consider having licensee personnel perform a reenactment of the medical event or incident.

4. Identify the sequence of events leading to the medical event or incident.

5. Identify the root cause(s) and contributing factors of the medical event or incident. Relay any generic causes that may be applicable to other licensees to regional management.

6. Identify and determine the adequacy of the licensee's immediate and long-term corrective actions.

7. Determine compliance with 10 CFR 35.41.

8. Determine compliance with notification requirements for a medical event (10 CFR 35.3045). In particular, the following items should be addressed:

   (a) Was notification of the event reported to NRC by the next calendar day after discovery of the event?

(b) Was a written report of the event provided to NRC within 15 days of the event?

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

(d) If the patient was informed, was a written description of the event provided to the patient upon request?

9. Determine compliance with other reporting/notification requirements, as applicable (i.e., 10 CFR 19.13, 10 CFR 20.2203, 10 CFR 21.21, and 10 CFR 30.50).

10. With assistance from FSME, obtain the services of a medical consultant or scientific consultant, if warranted. (See Section IV.A of this handbook for guidance.) Follow the procedures in IMC 1360 for contracting a consultant.

11. Request headquarters assistance when special headquarters support is necessary to evaluate a medical event or incident. For instance, dose reconstructions may require headquarters assistance.

12. Collect information required by NMED, as described in Enclosure 3 of IMC 2800, for input into the NMED database.

VI. ROLE OF THE MEDICAL CONSULTANT

Responsibilities of the medical consultant may vary from case to case, depending on the nature of the medical event or incident. Additional details can be found in IMC 1360.

A. Physician Consultant

1. Responsibilities of the physician consultant include:

(a) Gathering information regarding the circumstances surrounding the medical event or incident to assist in determining the root cause(s).

(b) Evaluating the promptness and effectiveness of the licensee's immediate actions in response to the medical event or incident and corrective actions to prevent recurrence.

(c) Assessing any probable deterministic effects on the patient or the exposed individual.

(d) Providing an estimate of the radiation dose to the exposed individual and the probable error associated with the estimation of the dose.

(e) Gathering information regarding the radiation dose received by the patient as compared to the prescribed dose to determine whether the medical event was medically or biologically significant.

(f) Evaluating the licensee's plan for individual followup, if available.

(g) Reviewing and evaluating the report submitted by the licensee under 10 CFR 35.3045, 10 CFR 35.3047, and 10 CFR 20.2203, as applicable.

(h) Preparing a report summarizing evaluations and assessments. The report should be submitted to 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.

2. The physician consultant should **not** do the following:

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

(b) Provide medical opinions or recommendations to anyone other than 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.

(c) Recommend a particular expert. The physician consultant may indicate that the service of an expert is needed, and if asked, the consultant may identify, after consultation with NRC management, sources for identification and location of an expert. Recommendations will be in accordance with 5 CFR 2635.702, "Use of Public Office for Private Gain," which prohibits Federal employees from using public office for the endorsement of any product, service, or enterprise.

B. Scientific Consultant, Including Physicist Consultant

1. The following examples illustrate duties that a scientific consultant, including a physicist 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).

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

(c) Interpret bioassay results.

(d) Evaluate medical equipment failures.

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

2. A scientific consultant, including a physicist consultant, should **not** do the following:

(a) Provide medical or technical opinions or recommendations to anyone other than 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.

(b) 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 management, sources for identification and location of an expert. 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.

VII. LIABILITY OF THE MEDICAL CONSULTANT

Medical consultants who are appointed as special Government employees are considered to be Federal employees. Claims of liability for negligent or wrongful acts or omissions of the medical consultant within the scope of his or her duties will be processed in accordance with the Federal Tort Claims Act, 28 U.S.C. Part VI, Chapter 171, 10 CFR Part 14, and NRC MD 7.1, “Tort Claims Against the United States.” The consultant's provision of professional opinions and recommendations to 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.

VIII. REPORTS AND DOCUMENTATION OF ASSESSMENT

A. NRC Inspection Report

1. The inspection report should be prepared in accordance with IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports." In addition to the requirements of IMC 0610, the inspection report should include, at a minimum, the following:

   (a) The sequence of events.

   (b) The root cause and contributing causes.

   (c) The probable consequence to the patient and other exposed individuals.

   (d) The licensee's actions, including compliance with 10 CFR 35.40, “Written Directives”; 10 CFR 35.41, “Procedures for Administrations Requiring a Written Directive”; and the notification requirements of the medical event (10 CFR 35.3045). In addition, if applicable, compliance with notification requirements of 10 CFR Parts 19, 20, 21, and 30.

   (e) Documentation of violations identified.

2. The report should be distributed in accordance with regional policy for inspection report distribution.

3. The NRC regional office responsible for reviewing a medical event should provide the inspection report to the referring physician or the individual's physician, if they are not members of the licensee’s organization.

B. Medical Consultant’s Report

1. The consultant should prepare the inspection report in accordance with guidance provided in IMC 1360.

2. The consultant should provide the final report to the NRC contact documented in the contract letter.

3. The NRC regional office responsible for reviewing the medical event or incident should provide the consultant's report to the referring physician or the individual's physician, if the medical consultant's report is not summarized in the NRC inspection report provided to them.

C. Assessment Report Package

1. The assessment report package contains the inspection report, the licensee's report (required by 10 CFR 35.33, “Notifications, Reports, and Records of

Misadministrations"), and the medical consultant's report (if required). The lead or primary NRC inspector is responsible for assembling the package.

2. The NRC inspector should ensure that a copy of the assessment report package is placed in ADAMS and in the docket files.
3. The NRC inspector should ensure that a copy is provided to the FSME coordinator for all medical events and incidents that require a medical consultant.
4. The FSME coordinator should submit one copy of the assessment report package to the Office of Enforcement. The FSME coordinator should also submit one copy of the assessment report to NMED or assure that sufficient information is described in NMED regarding the medical event or incident.

IX. 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 or meets the other criteria described in 10 CFR 35.2, "Definitions."

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.

Incident at a Medical Facility (as Used in Management Directive 8.10)

An event, other than one that meets the definition of "medical event" in 10 CFR 35.2, occurring at a medical facility, that may warrant assessment by NRC. These events include a dose to an embryo/fetus or nursing child in excess of the regulatory limits, an overdose to a worker or member of the public at a medical facility (not including patients), and medical equipment failures. In addition, any event that raises a significant question concerning issues such as the adequacy of a device, the applicability of a regulation, a licensing or certification practice, a breakdown in the licensee's program implemented in accordance with 10 CFR 35.41, or an exposure to a patient that did not

exceed the radiation dose threshold for a medical event but did exceed the prescribed dose may warrant activation of MD 8.10.

Medical Consultant

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

Medical Event

The definition for medical event involving patients 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 NRC to provide expert opinion and independent evaluation of the medical information related to radiation exposures of individuals.

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 some cases, the referring physician will not be the authorized user. In other cases, the referring physician will 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 medical event 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 NRC to provide expert opinion and independent evaluation of the circumstances surrounding a radiation exposure incident, resulting doses, and dose consequences.