

USE OF PHYSICIAN AND SCIENTIFIC CONSULTANTS IN THE MEDICAL CONSULTANT PROGRAM

1360-01 PURPOSE

This chapter establishes policy and procedures for the use of physician and scientific consultants in the Medical Consultant Program and incorporates current policy as given in Management Directive 8.10, "NRC Medical Event Assessment Program."

1360-02 OBJECTIVE OF MEDICAL CONSULTANT PROGRAM

The objective of the Medical Consultant Program is to have qualified medical and technical individuals available to: (1) assist U.S. Nuclear Regulatory Commission (NRC) staff in evaluating radiation exposure incidents (including medical events); and (2) provide technical support in areas such as radiation biology and medical physics. Assistance/support may include, but is not limited, to the following areas:

- a. Expert and independent medical evaluations of the probable deterministic effects of radiation exposures.
- b. Interpretation of bioassay results and other data related to a radiation exposure.
- c. Calculation of internal and external radiation doses, as necessary.
- d. Participation in NRC inspections and investigations to determine the root cause of the radiation exposure incident and the nature and probable deterministic effects of the radiation exposure on the exposed person(s).
- e. Evaluation of reports the licensee submits to NRC and to the exposed individual after a radiation exposure incident or medical event.
- f. Provision of expert testimony regarding inquiries or hearings, and as requested by the NRC, participation in selected conferences on the biological effects of radiation and radioactive materials.
- g. Provide technical support to NRC as necessary (e.g., rulemaking activities, validation and verification of research results).

1360-03 DEFINITIONS

03.01 Deterministic Effect. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.02 Guardian. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.03 Medical Consultant. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.04 Medical Consultant Program. Program established to provide physician and scientific consultants to NRC.

03.05 Medical Event. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.06 Misadministration. (See 10 CFR 35.2, "Definitions," "Misadministration.")

03.07 NMSS Coordinator. Individual appointed by the Director, IMNS, NMSS, to function as the NMSS Coordinator for the Medical Consultant Program.

03.08 Patient's Physician or Individual's Physician. A physician who is retained by the patient or exposed individual to provide medical care to that patient or individual. In the case of a medical misadministration, the patient's or individual's physician may, or may not, be the referring physician and/or the physician authorized user.

03.09 Physician Consultant. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.10 Radiation Exposure Incident (Incident). Generic term intended to address any situation where an individual or embryo/fetus may have been or has been exposed to radiation levels that may warrant use of a medical consultant.

03.11 Referring Physician. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.12 Responsible Relative. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

03.13 Scientific Consultant. (See NRC Management Directive 8.10, "NRC Medical Event Assessment Program.")

1360-04 POLICY ON USE OF MEDICAL CONSULTANTS

04.01 The time frame for initial activation of the procedures in this Manual Chapter should be based on the initial assessment of the severity of the event. This assessment will typically be performed by the regional office with input from IMNS/NMSS, as necessary.

The following guidelines may be used when establishing the time frame for activation¹:

- a. Radiation Exposure Incident resulting in a fatality - 2 working days after NRC is informed of the event.

¹The specified time frame assumes that the misadministration/medical event occurred within the last 2 months. If the misadministration/medical event occurred in the past, consideration should be given to extending the time frame.

- b. Radiation Exposure Incident (other than a misadministration/medical event) that has not resulted in a fatality - 5 working days after NRC is informed of the event.
- c. Radiation Exposure Incident (determined to be a misadministration/medical event) with the potential to result in unintended permanent functional damage to an organ or a physiological system as determined by a physician - 5 working days after the event is determined to be a misadministration by NRC.

04.02 Medical Consultants must be used under the following circumstances:

- a. Incidents where an individual has received one or more of the following doses:
 - 1. A suspected total effective dose equivalent of 0.25 sievert (Sv) (25 rem) or more.
 - 2. A suspected eye dose equivalent of 0.75 Sv (75 rem) or more.
 - 3. A shallow-dose equivalent to the skin or extremities of 2.5 Gray (250 rad or more).
 - 4. A suspected committed effective dose of 2.5 Sv (250 rem) or more to any individual organ or tissue other than the lens of the eye.
- b. Incidents where an individual is demonstrating physical symptoms (erythema, nausea, vomiting, etc.) consistent with radiation syndromes, and the source of the radiation may be attributable to NRC-licensed radioactive material.
- c. Incidents where NRC staff believe permanent functional damage to an organ or a physiological system is possible.
- d. Incidents where a nursing infant or an embryo/fetus may have been inadvertently exposed to radiation or radioactive material as a result of the intentional or unintentional exposure of the mother of the nursing infant or an embryo/fetus to radiation or radioactive material.
- e. A medical consultant shall be contacted for all misadministration/medical events involving an overexposure in accordance with Management Directive 8.10, "NRC Medical Event Assessment Program." With the exception of cases identified in items c. and d. above (for which site visits are required), a site visit by the medical consultant will not normally be required. A site visit by the medical consultant would be appropriate if the region and consultant agree that a site visit is necessary for NRC to understand the event, its causes, and its ramifications to the NRC's programs.

04.03 Medical Consultants may be used under the following circumstances:

- a. Incidents where members of the public or occupationally exposed individuals may have been exposed to radiation during a radiation exposure incident.
- b. Incidents where the staff believes that the assistance of a medical consultant would be beneficial to fulfilling the NRC mission.

1360-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, IMNS, NMSS

- a. Establish and maintain procedures and instructions for the Medical Consultant Program.
- b. Designate an NMSS Coordinator for the Medical Consultant Program.
- c. Approve the use of physician or scientific consultants under NRC's Medical Consultant Program by: (1) NRC organizations/offices other than regional materials branches; (2) organizations in Headquarters other than IMNS; and (3) Agreement States.
- d. Establish and maintain a list of physician and scientific consultants appointed by the Office of Human Resources as Special Government Employees to provide consultative services to NRC.

05.02 NMSS Coordinator

- a. Determine the number and type of medical consultants necessary to satisfy NRC needs and coordinate with the Coordinator for the Advisory Committee on Medical Uses of Isotopes (ACMUI), appropriate program managers, and the Program Management, Policy Development, and Analysis (PMDA) staff, NMSS, to ensure that NRC's medical consultant needs are met.
- b. Centrally maintain, for each medical consultant, a copy of Form 50-B, "Notification of Personnel Action." (NOTE: Responsibility in this area may be delegated to NRC project managers for specific contracts.)
- c. Prepare, update, and provide to the regional Directors, Division of Nuclear Material Safety, on at least an annual basis, the master list of appointed consultants per Policy and Guidance Directive 9-13, "Use of Consultants."
- d. Act as liaison between the IMNS Director and NRC organizations/offices, other than regional materials branches, that have requested permission to use physician or scientific consultants.
- e. In those cases where the NRC medical consultant has not provided the information, as indicated in the Medical Consultant Report (see Enclosure 2), forward information on the U. S. Department of Energy's (DOE's) Long-Term Medical Study Program (see Enclosure 10 for a summary of DOE's Long-term Medical Study Program) to the exposed individual's physician or referring physician, if applicable. This program is maintained for DOE by Radiation Emergency Assistance Center/Training Site of the Oak Ridge Institute of Science and Education, Oak Ridge, Tennessee.
- f. Coordinate any information transfer for DOE's Long-Term Medical Study program with DOE's Office of Epidemiology and Health Surveillance, in which the NRC medical consultant provides a summation and evaluation of case data.
- g. Provide Agencywide Document Access and Management System (ADAMS) location information (Accession number) for the inspection and medical consultant's and licensee's reports as required by 10 CFR 35.33, if applicable, to the Office of Enforcement. The regional contact person for each case should review all documents and reports for personal, privacy and confidential information before entering the information into ADAMS.

05.03 Director, PMDA, NMSS

- a. Oversee the administration of the Medical Consultant Program.

- b. Coordinate with the NMSS Medical Consultant and ACMUI Coordinators to ensure that appropriate numbers and types of medical consultants are available.
- 05.04 NRC Regional Office and All Headquarters Offices
- a. Implement Management Directive 8.10 and the Medical Consultant Program in their respective offices.
 - b. Evaluate the need to use a medical consultant.
 - c. Follow established procedures provided in Section 1360-07 of this document for retaining the services of a medical consultant.
 - d. Distribute copies of the inspection report, in accordance with NRC policy for inspection report distribution, and provide the ADAMS accession number of the inspection report to the NMSS Coordinator. The copies should include the Nuclear Materials Event Database tracking number. For misadministration/medical events, provide copies of the inspection report and the medical consultant's report to the referring physician or the individual's physician, if possible.
 - e. Ascertain whether a conflict of interest or an appearance of a conflict-of-interest situation exists if the consultant provides consulting services on a particular case.
 - f. If the medical consultant and the region determine that a site visit is not warranted based on the specifics of the case, obtain a written statement from the medical consultant explaining why a site visit nor additional consulting services are not necessary. This written report may be in the form of a letter, facsimile, or an e-mail.
 - g. If the consultant declines to assist on the case for reasons other than discussed above, the region should provide documentation by memorandum, facsimile, or e-mail to the NMSS Coordinator, identifying the regional contact and stating the reason that the consultant declined to assist on the case. The region should then contact another consultant to review the case.
 - h. On receipt of the consultant's report, send written confirmation and NRC Form 148, "Voucher for Professional Services," to the consultant and provide the ADAMS accession number for the consultant's report to the NMSS Coordinator.
 - i. Approve vouchers submitted by the consultants, after verifying that the vouchers are complete and accurate, and complete NRC Form 449, "Statement of Services of Consultant, Expert, or Member." Forward the approved vouchers and completed NRC Form 449 to the Management Analyst, Administrative Support, Program Management, Policy Development and Analysis Staff (PMDA), NMSS, for processing and reimbursement.
 - j. Provide information to the NMSS Coordinator for referral to DOE's Long-Term Medical Study Program.
- 05.05 Medical Consultant. The medical consultant's responsibilities begin after s(he) has been contacted by NRC and has agreed to assist NRC in the evaluation of a particular radiation exposure incident.
- a. Perform requested tasks, as specified in the NRC Medical Consultant Charter (see Enclosure 6).
 - b. Submit final written reports of findings to the appropriate NRC regional office within 30 days of completing the requested task(s).

- c. Complete NRC Form 148, "Voucher for Professional Services," within 30 days of completion of requested tasks. If the service requested by NRC resulted in travel, complete NRC Form 64/64A, "Travel Voucher," for non-local travel, or SF1164, "Claim for Reimbursement for Expenditures on Official Business," for local travel. If miscellaneous expenses were incurred, complete form SF1034, "Public Voucher for Purchases and Services Other Than Personal." All vouchers should be completed within 30 days of the travel or expenditures and forwarded to the regional contact.

1360-06 FUNDING FOR MEDICAL CONSULTANT PROGRAM

Medical consultant time will be charged against IMNS, NMSS, full-time equivalent allocations. Travel expenses shall be charged against regional travel funds or, in the case of use by another NRC office, against that office's travel funds.

1360-07 NRC PROCEDURES FOR THE MEDICAL CONSULTANT PROGRAM

07.01 General Guidance. These are general administrative procedures for the Medical Consultant Program. For non-reactor incidents, this Chapter should be used in conjunction with incident response procedures in Manual Chapter 1301, where applicable.

07.02 Specific Guidance. (Actions to be taken by the NRC Regional Office unless otherwise noted)

- a. Decide, based on the evaluation of available information on a radiation exposure incident and on the criteria established in Manual Chapter 1360, Section 1360-04, whether the services of a physician and/or scientific consultant are needed.
- b. Select a consultant(s) from the list distributed by the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS). This list will be an enclosure to the latest revision of the Policy and Guidance Directive (P&GD) 9-13, "Use of Consultants." In selecting a consultant, regional or Headquarters management (i.e., branch chief or delegate) should ensure that there will be no conflict of interest nor an appearance of a conflict of interest between the consultant and the licensee and that the consultant's expertise is appropriate to the nature of the incident and beneficial to the evaluation of the incident.

It is recommended that, if possible, a consultant from a region other than the one in which the event occurred should be chosen. If a medical consultant is required, the requesting Regional or Headquarters Staff will work with the NMSS Coordinator to obtain an appropriate individual.

If the services of a particular medical consultant are to be procured under a U. S. Nuclear Regulatory Commission (NRC) task order contract (an individual contract for services under the broad scope base contract), the Project Manager for that specific contract is to arrange for the consulting services. All interactions with medical consultants, working under a task order contract, should be through the contract project manager. Do not continue with the procedures described in this part for medical consultants who are working under a task order contract.

- c. Request approval to use a physician or medical consultant from the Division Director, IMNS/NMSS, in the case of an incident involving non-NRC licensed byproduct material; Agreement State licensed material in an Agreement State, or naturally occurring radioactive material; or a situation where the consultant will be

used by an NRC group outside IMNS or the regional materials branches. This approval should be requested in writing. A sample memorandum requesting use of a specific consultant can be found in Enclosure 1.

- d. Contact the selected medical consultant, by telephone, to obtain an oral agreement for his/her services; provide him/her with a description of the incident and the tasks to be performed; and discuss, based on available information, whether an on-site visit appears necessary. The oral agreement should include an agreed-on date when services will be performed/completed.

If the medical consultant and the region conclude that a site visit is not warranted, the region shall do the following:

Obtain a written statement from the medical consultant, based on the specifics of the case, as to why a site visit is not needed. The written statement may be in the form of a letter, facsimile, or an e-mail. An example form to be sent to the consultant may be found in Enclosure 2. This statement should be placed in the docket file. Provide the ADAMS accession number for the medical consultant's statement to the NMSS Coordinator.

If the consultant declines to assist on the case for reasons other than discussed above, the region should provide documentation by memorandum, facsimile, or e-mail to the NMSS Coordinator, identifying the regional contact and stating the reason that the consultant declined to assist on the case. The region should then contact another consultant to review the case.

- e. Inform the NMSS Coordinator by telephone, e-mail, and/or facsimile that a consultant has been contacted. If not done previously, provide a brief description of the incident (e.g., preliminary notification (PN), draft PN, or draft inspection report) to the NMSS Coordinator at this time. If the NMSS Coordinator is not available, notify the Section Leader of the Materials Safety and Inspection Branch, Section B, IMNS/NMSS.
- f. Send the consultant a letter of confirmation. Provide the ADAMS accession number for the letter of confirmation to the NMSS Coordinator.

A sample letter of confirmation is provided in Enclosure 3. Enclosed with the letter should be the following documents, as necessary:

- Preliminary Description of Incident Form (Enclosure 4) or PN, if available
- Medical Consultant Charter (Enclosure 6)
- Medical Consultant Liability (Enclosure 7)
- Restrictions on Service with Other Federal Departments or Agencies (Enclosure 8)
- Medical Consultant Report Form (Enclosure 9)
- NRC Procedure for Notifying the Referring or Individual's Physician of the U. S. Department of Energy Long-Term Medical Study Program (Enclosure 12)
- NRC Form 148, Voucher for Professional Services
- NRC Form 64/64A, Travel Voucher (non-local travel)
- SF1164, Claim for Reimbursement for Expenditures on Official Business (local travel)
- SF1034, Public Voucher for Purchases and Services Other Than Personal

- g. If applicable, arrange for the consultant's travel.
- h. In coordination with the medical consultant, finalize a schedule for completion of all tasks, including the final report.

- i. Inform the licensee that a medical consultant has been retained by NRC and describe, as appropriate, the consultant's role in the inspection or investigation of the incident. Provide the consultant's name to the licensee and suggest that the licensee inform the involved individual's physician(s) and/or referring physician of the NRC consultant's identity and function.
- j. Continue the NRC inspection or investigation, to include gathering information on: (1) the licensee's actions, to include individual(s) notifications, as required by applicable provisions in 10 CFR Parts 19, 20, 21, and 35; and (2) the medical status of the involved individual.
- k. Forward a copy of the report submitted by the licensee under 10 CFR 20.2203 or 10 CFR 35.3045 to the medical consultant for review.
- l. Obtain a final report from the consultant within 30 calendar days of completion of the case review and/or site visit, unless there are extenuating circumstances. (NOTE: The medical consultant should have informed the regional contact of extenuating circumstances before the 30-day period has expired.)
- m. Send a copy of the consultant's report to the referring physician or the individual's physician (as applicable) and provide the NMSS Coordinator with the ADAMS accession number for the consultant's report. The NMSS Coordinator will forward the ADAMS accession number of the medical consultant's report to the Regional Coordinator.
- n. Complete and issue the final NRC inspection/investigation report. The report should be prepared in accordance with NRC Inspection Manual Chapter 0610, "Inspection Reports," and Management Directive 8.10, "NRC Medical Event Assessment Program."

NOTE: Send a copy of the final inspection report to the referring physician or the individual's physician and provide the NMSS Coordinator with the ADAMS Accession number for the final inspection report.

- o. NMSS Coordinator will provide information of NRC's procedures for notifying the individual's physician or referring physician, per procedures found in Enclosure 12.
- p. NMSS Coordinator will provide ADAMS accession numbers for the inspection, medical consultant's, and licensee's reports, if applicable, to OE.
- q. Receive the following voucher, NRC Form 148, "Voucher for Professional Services," submitted by the consultant and verify the hours/days claimed by the consultant, sign the approval block, and forward the voucher and completed NRC Form 449, "Statement of Services of Consultant, Expert, or Member" to the Management Analyst, Administrative Support, Program Management, Policy Development and Analysis Staff (PMDA), NMSS, for processing and reimbursement. A copy of the voucher should also be provided to the NMSS Coordinator.

NOTE: All consultant time will be charged against IMNS/NMSS full-time equivalent allocations.

- r. Receive the voucher for miscellaneous expenses, SF 1034, "Public Voucher for Purchases and Services Other Than Personal," submitted by the consultant, and verify the expenses claimed by the consultant. Forward the voucher to the Division of Accounting and Finance, Office of the Chief Financial Officer, for processing and reimbursement. A copy of the voucher should also be provided to the NMSS Coordinator.

- s. Receive the voucher for consultant's travel, NRC Form 64/64A or SF 1164, "Travel Voucher," verify and process the completed NRC Form 64/64A or SF 1164 for travel performed while working in the region. A copy of the voucher should also be provided to the NMSS Coordinator.

NOTE: Travel expenses will be charged against regional program support (travel) funds or, in the case of use by a Headquarter's office, against the user office's travel funds.

- t. Enclosure 5 provides a check list containing the criteria and procedures for the use of medical consultants.
- u. If the medical consultant does not make the referral, the NMSS Coordinator will inform the referring or individual's physician of the DOE study, if applicable.

Enclosures

1. Sample Memorandum Requesting Consultant Services
2. Medical Consultant Report (Short Form)
3. Sample Letter of Confirmation To Medical Consultants
4. Preliminary Description of Incident Form
5. Check List: Use of Medical Consultants
6. Medical Consultant Charter
7. Medical Consultant Liability
8. Restrictions on Service with Other Federal Departments or Agencies
9. Medical Consultant Report
10. Summary of U.S. Department of Energy, Office of Epidemiology and Health Surveillance Long-Term Medical Study Program
11. Criteria for Selection of Cases for Long-Term Medical Study Program
12. NRC Procedure for Notifying the Referring or Individual's Physician of the U.S. Department of Energy (DOE) Long-Term Medical Study Program
13. Sample Letter Providing Information to the Referring or Individual's Physician on U.S. Department of Energy Long-Term Medical Study Program
14. Sample Letter Providing Information to the Licensed Facility on U.S. Department of Energy Long-Term Medical Study Program

END

SAMPLE MEMORANDUM REQUESTING CONSULTANT SERVICES

[For Use by Offices Other Than Regional Materials Branches, or within Division of Industrial and Medical Nuclear Safety (IMNS)/Nuclear Materials Safety and Safeguards (NMSS)]

MEMORANDUM TO: _____, Director
IMNS, NMSS

FROM: _____

SUBJECT: REQUEST FOR USE OF MEDICAL CONSULTANTS

The [Office] requests authorization to use one of the [physician or scientific] consultants who are under contract to your Division. This written request is being made pursuant to Nuclear Regulatory Commission Manual Chapter 1360, "Use of Physician and Scientific Consultants." The following is a brief description of the task to be performed.

Consultant requested: _____ [name] _____

Description of service: _____

Estimated hours needed to complete task: _____

Site visit anticipated? Yes No

CONTACT: [name]
[telephone number]

cc: NMSS Coordinator

END

MEDICAL CONSULTANT REPORT (SHORT FORM)
(To Be Completed By Medical Consultant, If Site Visit Is Not Necessary)
Official Use Only

Medical Consultant Name: _____ Report Date: ___ / ___ / ___

Signature: _____
(If mailed or faxed)

Licensee Name: _____ License No. _____

Facility Name: _____ Incident Date: ___ / ___ / ___

Estimated Dose to Individual or Target Organ: _____

Probable Error Associated with Estimation: _____

Prescribed Dose (Medical Misadministration Only): _____

Method Used to Calculate Dose: _____

Description of Incident:

Why Site Visit Is Not Required:

Assessment of probable deterministic effects of the radiation exposure on the individual:

SAMPLE LETTER OF CONFIRMATION TO MEDICAL CONSULTANTS

[Medical Consultant]
[Street address]
[City, State, Zip code]

Dear _____:

This letter is to confirm our telephone agreement of [date] that you will assist this U. S. Nuclear Regulatory Commission (NRC) regional office by serving as a [physician or scientific] consultant with respect to the [incident or misadministration] described in Attachment 1. A Charter detailing the tasks that should be completed under this contract is provided in Attachment 2. (For Medical Events only, it is not the intent of the Medical Consultant Program to evaluate the appropriateness of the prescribed treatment, its medical effectiveness, or provide an opinion as to how the facility should operate.) If you encounter difficulty in completing these tasks or identify additional tasks that should be performed, please contact your NRC regional contact for this matter. This individual should also be contacted if you believe that your involvement in the case would result in a possible conflict-of-interest situation. In addition, please note the information in Attachments 3 and 4 regarding medical consultant liability and service with other Federal departments or agencies. Please notify your NRC regional contact if you are currently performing work for other Federal departments or agencies.

It is our understanding, based on our telephone agreement of [date], that you [will/will not] conduct an on-site visit. Your evaluation of the incident shall include a review of all pertinent documents available, regardless of whether an on-site visit is conducted.

The licensee [name] has been notified by our office of your participation in this incident evaluation and has been asked to contact the individual's physician(s) and/or the referring physician, regarding your involvement in NRC activities.

Attachment 5 contains a brief summary of the U.S. Department of Energy (DOE), Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program. DOE sponsors this life-time morbidity study of personnel involved in radiation incidents through the Radiation Emergency Assistance Center/Training Site of the Oak Ridge Institute of Science and Education. NRC will provide information on the study to the individual's physician or referring physician, after it has investigated the incident. However, you may want to discuss this information with the individual's physician or the referring physician.

Please inform your NRC regional contact when you have completed the tasks specified in the Charter. A report of your findings and conclusions (Attachment 6) shall be provided to us within 30 calendar days of the completion of the case review unless there are extenuating circumstances that have been discussed with your NRC regional contact before the 30-day period ends. Please note that your report will be an official Agency record, and will be released to the public. Thus, it is important that all confidential information be kept out of your report.

Please follow the instructions provided in the Charter when preparing and submitting claims for reimbursement. These claims should be submitted on a monthly basis but no later than

30 days after the completion of your report. You should submit your voucher to your NRC regional contact.

[Medical Consultant]

Thank you for your assistance in this matter. The NRC regional contact for this case is [name]. [Mr./Miss/Ms. (Name)] can be reached by telephone at (XXX) XXX-XXXX, FAX (XXX) XXX-XXXX, or by e-mail at [e-mail address].

Sincerely,

NRC Regional Administrator (or Designee)

Attachments: ***ONLY FORWARD APPLICABLE ATTACHMENTS***

1. Preliminary Description of Incident Form (see Enclosure 4)
2. Medical Consultant Charter (see Enclosure 6)
3. Medical Consultant Liability (see Enclosure 7)
4. Restrictions on Service with Other Federal Departments or Agencies (see Enclosure 8)
5. Summary of U.S. Department of Energy, Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program (see Enclosure 10)
6. Medical Consultant Report (see Enclosure 9)

END

PRELIMINARY DESCRIPTION OF INCIDENT FORM
(provide additional information on separate sheet)

*******IMPORTANT*******
REDACT INFORMATION FROM DOCUMENT
(WHICH IS EXEMPT FROM DISCLOSURE UNDER 10 CFR 2.790)
THEN RELEASE THE DOCUMENT

Nuclear Regulatory Commission Regional Office: RI RII RIII RIV

Date of Incident: ___ / ___ / ___ Date of Notification: ___ / ___ / ___

NRC Inspector (Regional Contact): _____
telephone number: _____

Medical Consultant: _____
Specialty: _____

Licensee Involved (If more than one licensee is involved, provide a separate enclosure for each):

Name: _____

Address: _____

Telephone Number: _____

NRC License No. _____

Docket No. _____

Name and Title of Licensee contact: _____

Telephone Number: _____

Provide a preliminary description of the incident(s) and a summary of the known circumstances resulting in radiation exposure, including all known radionuclides and activities:

Dates of Incident: _____

Description of Incident: _____

Individual(s) exposed:

Name: _____

Home Address: _____

Home Telephone: _____

Estimated Radiation Dose: _____

Name: _____

Home Address: _____

Home Telephone: _____

Estimated Radiation Dose: _____

Name: _____

Home Address: _____

Home Telephone: _____

Estimated Radiation Dose: _____

END

*****IMPORTANT*****

**REDACT INFORMATION FROM DOCUMENT
(WHICH IS EXEMPT FROM DISCLOSURE UNDER 10 CFR 2.790)
THEN RELEASE THE DOCUMENT**

CHECK LIST
USE OF MEDICAL CONSULTANTS

Medical Consultant Must Be Used When: (Check the Appropriate Item)

- Suspected total effective dose equivalent of 0.25 sievert (Sv) (25 rem) or more.
- Suspected eye dose equivalent of 0.75 Sv (75 rem) or more.
- Shallow-dose equivalent to the skin or extremities of 2.5 Sv (250 rem) or more.
- Suspected committed effective dose of 2.5 Sv (250 rem) or more to any individual organ or tissue other than the lens of the eye.
- Individual is demonstrating physical symptoms (erythema, nausea, vomiting, etc) and the source of the radiation may be attributable to NRC-licensed radioactive material.
- NRC staff believes permanent functional damage to an organ or a physiological system is possible.
- Nursing infant or an embryo/fetus may have been inadvertently exposed as a result of exposure of the mother to radiation or radioactive material.

Medical Consultant May Be Used When: (Check the Appropriate Item)

- Members of the public or occupationally exposed individuals exposed during a radiation exposure incident.
- Staff believes that the assistance of a medical consultant would be beneficial to fulfilling the NRC mission.

NRC PROCEDURES FOR THE USE OF MEDICAL CONSULTANTS

(the following tasks are performed by the regional office unless otherwise noted)

- Determine need for and select medical consultant.
- Obtain approval to use medical consultant from Division Director, IMNS/NMSS, if necessary.
- Obtain oral agreement from selected medical consultant and provide preliminary description of incident.
- Obtain written statement from medical consultant if site visit is not needed.

(Procedures continued)

- Inform NMSS Consultant if medical consultant declines to assist on the case and then contact another consultant to review the case.
- Inform NMSS Coordinator that a medical consultant has been contacted and provide description of incident.

- ___ Provide NMSS Coordinator with ADAMS accession numbers of any licensee reports, including health and dose assessments, of the event.
- ___ Send letter of confirmation to consultant. Provide ADAMS accession number to NMSS Coordinator.
- ___ Arrange for consultant's travel, if applicable.
- ___ Finalize schedule for completion of tasks, including final report.
- ___ Inform licensee about medical consultant and provide consultant's name and role.
- ___ Perform/continue inspection or investigation.
- ___ Forward copy of report submitted by licensee to consultant.
- ___ Obtain final report from consultant and send a copy to the referring physician or the individual's physician. Provide ADAMS accession number to NMSS Coordinator.
- ___ Complete and issue inspection/investigation report.
- ___ Obtain, verify, and sign voucher (NRC Form 148) submitted by consultant and forward with completed NRC Form 449 to PMDA for processing and reimbursement. Forward a copy of voucher to NMSS Coordinator.
- ___ Obtain and verify voucher for miscellaneous expenses, SF 1034, submitted by consultant and forward to the Division of Accounting and Finance, OCFO, for processing and reimbursement. Forward a copy of voucher to NMSS Coordinator.
- ___ Obtain, verify and process voucher for consultant's travel, NRC Form 64/64A or SF 1164. Forward a copy of voucher to NMSS Coordinator.

MEDICAL CONSULTANT CHARTER**A. GENERAL INFORMATION**

The U. S. Nuclear Regulatory Commission's (NRC's) authority and responsibility for conducting special inspections of radiation exposure incidents are provided under the Atomic Energy Act of 1954, as amended, and under the Energy Reorganization Act of 1974. The purpose of these inspections is to ascertain the facts and other related information surrounding the incident. This may involve the following tasks: determining the circumstances surrounding the incident and the root cause of the incident; evaluating the actions taken by the licensee at the time of the incident, in providing medical care to exposed persons; evaluating corrective actions taken by the licensee; to preclude future similar incidents; verifying or estimating dose(s), to the exposed individual(s); evaluating the probable deterministic effects of the exposure; evaluating the notifications made by the licensee, and the licensee's follow-up plan, if available; and gathering evidence to support any necessary enforcement actions by NRC.

B. SPECIFIC GUIDANCE AND TASKS TO BE PERFORMED

1. The medical consultant shall not do the following (as applicable to the specific situation):
 - a. Enter into a physician-patient relationship with the exposed individual.
 - b. Provide medical opinions or recommendations to anyone other than NRC, without NRC's written permission, unless compelled by legal process to do so. To minimize the risk of liability, any recommendations made by a medical 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 or individual's care.
 - c. Recommend a particular expert. The medical 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. Information on 5 CFR 2635.702 is available from the regional contact listed in the cover letter.
 - d. Divulge or make known to the licensee, individual, individual's physician, or referring physician any official findings or conclusions resulting from the NRC inspection, without NRC's permission.
 - e. Evaluate the appropriateness of the prescribed treatment or its medical effectiveness (medical events), or provide an opinion on how the facility should operate.
 - f. Volunteer advice to the licensee about corrective actions to be taken by the licensee.

2. The medical consultant shall do the following (as applicable to the specific situation):
 - a. Act for, and on behalf of, the Commission, to gather medical information for the evaluation of the effects of radiation exposure on those exposed to radiation.
 - b. Assist in NRC inspection/investigative activities related to radiation exposure incidents.
 - c. Provide the date of any on-site visits at the licensee's facility, to the NRC regional contact, as soon as a visit has been scheduled.
 - d. Gather information regarding the circumstances surrounding the incident, to assist in determining the root cause(s).
 - e. Provide a professional opinion/estimate on the magnitude of the radiation dose to the exposed individual(s), and the probable error associated with the estimation of the dose. If necessary, request that the licensee and/or individual's physician furnish information on bioassays, medical history, written directive, physical examinations, and other pertinent laboratory work, etc.
 - f. Assess any probable deterministic effects on the exposed individual.
 - g. Evaluate the medical data provided by each exposed individual's physician and interpret the results for the NRC regional office staff; keep the NRC regional or Headquarters staff informed (as appropriate) of the medical condition of the individual.
 - h. Evaluate the promptness and effectiveness of the licensee's immediate actions, in response to the incident, and corrective actions to prevent recurrence.
 - i. For medical events, gather information regarding the radiation dose actually received by the patient, as compared with the prescribed dose, to determine whether the misadministration was medically or biologically significant.
 - j. For medical events, evaluate the licensee's notification to the exposed individual or individual's responsible relative or guardian or, alternatively, the licensee's reason for not informing the individual or individual's responsible relative of the misadministration.
 - k. Review and evaluate the report (to individuals of exceeding dose limits) submitted by the licensee under 10 CFR 20.2205 (non-medical event) or 10 CFR Part 35 (medical event) to include an evaluation of the licensee's description of the incident, immediate actions taken in response to the incident, steps taken or proposed regarding long-term corrective actions to prevent recurrence, and the probable effects on the exposed individual.
 - l. Evaluate the licensee's plan for exposed individual follow-up, if available.
 - m. Prepare and submit, to the NRC regional office, a report of findings and conclusions, within 30 calendar days of completion of the case review and/or site visit, unless there are extenuating circumstances. These circumstances should be communicated to NRC regional management as soon as they are discovered. If information is discovered that is directly relevant to a potential violation of NRC regulations, it should be promptly communicated to NRC.

The report may be submitted on the "Medical Consultant Report" form. If the form is not used to submit the findings, you shall, at a minimum, address the items listed on the form.

- n. Promptly prepare and submit NRC Form 148, "Voucher for Professional Services," to the NRC regional contact, indicating days/hours claimed. Per NRC Management Directive 10.6, "Use of Consultants and Experts," these vouchers should be submitted monthly when work is performed.
- o. Prepare and submit NRC Form 64/64A, "Travel Voucher" (non-local travel) or SF1164, "Claim for Reimbursement for Expenditures on Official Business" (local travel) to the NRC regional contact for expenses incurred during days/hours worked in the region or Headquarters.

NOTE: The regional offices shall make travel arrangements through an NRC travel request (NRC Form-279).

- p. Prepare and submit SF 1034, "Public Voucher for Purchases and Services Other Than Personal," to the NRC regional contact, for administrative expenses other than those associated with salary and travel.
- q. Furnish expert testimony at inquiries or hearings and participate in selected conferences on bioeffects of radiation and radioactive materials.

- 3. The medical consultant may consider doing the following:

Informing the individual's physician of the U.S. Department of Energy, Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program. This life-time morbidity study of personnel involved in radiation incidents is maintained by the Radiation Emergency Assistance Center/Training Site of the Oak Ridge Institute of Science and Education. Information on the study is attached to the confirmation letter.

NOTE: NRC will make the referring or individual's physician aware of the study if the consultant does not inform the physician.

END

MEDICAL CONSULTANT LIABILITY

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.

The consultant's provision of professional opinions and recommendations to the U.S. Nuclear Regulatory Commission 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 [omit this paragraph for non-medical events].

END

**RESTRICTIONS ON SERVICE WITH OTHER FEDERAL
DEPARTMENTS OR AGENCIES**

U.S. Nuclear Regulatory Commission policies and procedures for obtaining the services of consultants are defined in Management Directive Chapter 4139, "Utilization of Consultants, Members, and Other Advisory and Assistance Services," Part 1, Appendix D. The following information is contained in the Directive and has direct implications for the physician and scientific consultant.

Service with Other Agencies

An employee who serves two or more Federal Departments or agencies is required to inform each of his or her arrangement(s) with the other. If the individual's appointments are made on the same date, the aggregate of the estimates of the days of services will determine the decision, by each agency, as to whether the individual is "Regular" or "Special." If, after being employed by one department or agency, a Special Government Employee is appointed by another agency, the second agency must make an estimate of the individual's days of service for the remaining portion of the 365-day period which was initiated by the first appointment. The sum of the estimate and of the actual number of days of service to other departments or agencies, during the prior portion of such 365-day period, will determine whether the individual is "Regular" or "Special." Close coordination between the agencies and the appointee must be maintained to ensure that the 130-day limitation is not inadvertently exceeded.

END

MEDICAL CONSULTANT REPORT

(To Be Completed By Medical Consultant

Official Use Only)

Medical Consultant Name: _____
Signature: _____

Report Date: ___ / ___ / ___

Licensee Name: _____
License No. _____ Docket No. _____
Facility Name: _____

Incident Date: ___ / ___ / ___

Individual's Physician Name: _____

Address: _____

Referring Physician's Name: _____

(Medical Misadministration Only)

Address: _____

Individuals Contacted During Investigation: _____
(Name and Title) _____

Records Reviewed: (General Description)

Estimated Dose to Individual or Target Organ: _____

Probable Error Associated with Estimation: _____

Prescribed Dose (Medical Misadministration Only): _____

Method Used to Calculate Dose: _____

Official Use Only

Factual Description of Incident:
(Attach a copy of any reports, documents, etc. used/referenced in this description.)

Assessment of probable deterministic effects of the radiation exposure on the individual:

Briefly describe the current medical condition of the exposed individual:

**Was individual or individual's physician informed of Department of Energy (DOE)
Long-Term Medical Study Program? Yes No**

If yes, would the individual like to be included in the Program? Yes No

Official Use Only

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to Nuclear Regulatory Commission (NRC), pursuant to 10 CFR 35.3045, in the following areas:
- a. Why the event occurred: Yes No
 - b. Effect on the patient: Yes No
 - c. Licensee's immediate actions on discovery: Yes No
 - d. Improvements needed to prevent recurrence: Yes No

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 20.2205 or 10 CFR 35.3045), provide the basis for your opinion:

3. Did the licensee notify the referring physician of the misadministration? Yes No
- Did the licensee notify the patient or the patient's responsible relative or guardian? Yes No
4. If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification, consistent with 10 CFR 35.3045? Yes No

Briefly explain the licensee's response:

5. Provide an opinion of the licensee's plan for exposed individual follow-up, if available.

**SUMMARY OF U. S. DEPARTMENT OF ENERGY, OFFICE OF EPIDEMIOLOGY
AND
HEALTH SURVEILLANCE'S LONG-TERM MEDICAL STUDY PROGRAM**

The Office of Epidemiology and Health Surveillance of the U. S. Department of Energy (DOE) sponsors a voluntary life-time morbidity study of personnel involved in radiation incidents, which is maintained by the Radiation Emergency Assistance Center/Training Site (REAC/TS). This study includes the gathering of clinical and epidemiological data at an early stage, after a significant exposure to radiation, and continues throughout the lifetime of the individual involved. The purpose of this study is to compile the best human radiobiological data available for improving immediate medical care, to develop the best prophylactic and anticipatory care for possible late effects, and to upgrade the bases for radiation risk estimates.

Personnel sought to participate in the study are those involved in a radiation incident or misadministration during which one or more persons received radiation exposure that equals or exceeds the selection criteria listed in the accompanying table. If an individual is willing to participate in the study, direct contact with the individual will be made by the DOE contractor, at which time the details of the program will be explained fully, a consent form will be signed, and a schedule for future contacts will be arranged.

Generally, the follow-up program will consist of obtaining copies of all medical records associated with the treatment of the individual immediately after the incident and then annual contacts with the individual to follow his/her medical history. Initially, the types of information sought will include a complete medical history before and after the incident or misadministration and copies of all relevant hospital, laboratory, and physicians' records covering the period of observation. The annual contact will be made to determine whether the individual has had any illnesses or physical examinations during the year and to obtain additional medical records as they appear to relate to the radiation exposure.

Participation in the follow-up program is totally voluntary and individuals may stop their participation at any time. The medical information obtained during participation is covered by legal constraints to protect the identity and privacy of living participants. Any expenses involved in providing medical records to the follow-up program are borne by the DOE long-term medical study program, not the individual. Any expenses for either short- or long-term medical care of the individual are the responsibility of the program participant and not the responsibility of DOE, Oak Ridge Institute for Science and Education, or REAC/TS.

**REAC/TS Contact: Dr. Robert C. Ricks, Director REAC/TS
(865) 576-3131**

**CRITERIA FOR SELECTION OF CASES FOR
LONG-TERM MEDICAL STUDY PROGRAM**

<u>Condition</u>	<u>Criteria</u>
Dose to whole body, active blood-forming organs or gonads	Greater than or equal to 0.25 Sievert (Sv) (25 rem).
Dose to skin of whole body or extremities	Greater than or equal to 6 Sv (600 rem).
Dose to other tissues or organs from external source	Greater than or equal to 0.75 Sv (75 rem).
Internal burdens	Greater than or equal to 50% of NCRP* Permissible Body Burden.
Medical misadministration	Misadministrations as defined in 10 CFR 35.2 where the patient has received an administered dose greater than that prescribed.

*National Council on Radiation Protection and Measurement

END

**NRC PROCEDURE FOR NOTIFYING THE REFERRING OR INDIVIDUAL'S
PHYSICIAN OF THE U. S. DEPARTMENT OF ENERGY (DOE)
LONG-TERM MEDICAL STUDY PROGRAM**

This procedure should be initiated by the Nuclear Material Safety and Safeguards (NMSS) Coordinator immediately after receipt of the medical consultant's report. The NMSS Coordinator has the overall responsibility for performing these tasks.

1. Review the medical consultant's report to determine if the consultant made the referring or individual's physician aware of the Department of Energy (DOE) Long-Term Medical Study Program and marked the appropriate box on the Medical Consultant Report. If the consultant has made the physician aware of the program, no further action is necessary. If the consultant has not made the physician aware of the program, continue with the procedure.
2. Review the medical consultant's report and determine if the estimated dose to the individual exceeds the criteria established by DOE for selection of cases for the Long-Term Medical Study Program. No further action is needed if the dose does not exceed the threshold. If the threshold is exceeded, continue with the procedure.
3. Inform the referring or individual's physician of the DOE Study by using the sample letters, "Sample Letter Providing Information to the Referring or Individual's Physician on U.S. Department of Energy Long-Term Medical Study Program," and "Sample Letter Providing Information to the Licensed Facility on U.S. Department of Energy Long-Term Medical Study Program." The letters should be sent together, by certified mail, with a request for return receipt. The latter is necessary to provide assurance that the letters were received by the physician.

A copy of the letters and the return receipt should be maintained by the NMSS Coordinator.

END

ENCLOSURE 13

**SAMPLE LETTER PROVIDING INFORMATION
TO THE REFERRING OR INDIVIDUAL'S PHYSICIAN
ON U. S. DEPARTMENT OF ENERGY LONG-TERM MEDICAL STUDY PROGRAM**

Dear [Name]:

On [date], one of your patients received a [Identify event (e.g, misadministration, overexposure, etc.)] of radioactive material during [Describe event (e.g. teletherapy using _____ source, brachytherapy using _____ from a remote afterloader, radiographic source disconnect, etc.)] at [licensee name],[city, state]. The U.S. Nuclear Regulatory Commission (NRC) does not routinely retain the names of individuals involved in radiation incidents or the names of their referring physicians. I have therefore asked [licensee] to add the name of the patient, [individual's name] and your name and address to this letter.

NRC would like to make you aware of a voluntary life-time morbidity follow-up program of personnel involved in radiation incidents. The follow-up program is being conducted by the Radiation Emergency Assistance Center/Training Site (REAC/TS) for the U.S. Department of Energy, Office of Health.

We ask you to review the attached, Summary of U.S. Department of Energy, Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program, and if you believe it appropriate, provide the information to the patient involved. If your patient is interested in participating in the follow-up program or would like additional information on the follow-up program, he or she should contact Dr. Robert C. Ricks, Director REAC/TS, at (865) 576-3131. If you have any questions regarding this transmittal letter, please contact me by telephone at [Telephone Number], by Fax at [Fax Number], or by e-mail at [e-mail address].

Sincerely,

NMSS Coordinator
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Attachment: As Stated

END

ENCLOSURE 14

**SAMPLE LETTER PROVIDING INFORMATION TO THE LICENSED FACILITY ON U. S.
DEPARTMENT OF ENERGY LONG-TERM MEDICAL STUDY PROGRAM**

[Licensee]
ATTN: [Person's name]
[Person's position]
[Street address]
[City, State, Zip code]

Dear [Name]:

On [date], a(n) patient/individual at your facility received a [Identify event (e.g. misadministration, overexposure, etc.)] of radioactive material during [Describe event (e.g. teletherapy using _____ source, brachytherapy using _____ from a remote afterloader, radiographic source disconnect, etc.)] The U.S. Nuclear Regulatory Commission (NRC) would like to make that patient's/individual's referring physician and, if the referring physician deems it appropriate, that patient/individual aware of a voluntary life-time morbidity follow-up program for personnel involved in radiation incidents. The program is being conducted by the Radiation Emergency Assistance Center/Training Site (REAC/TS) for the U.S. Department of Energy, Office of Health.

NRC does not routinely retain the names of patients/individuals involved in radiation incidents or the names of their referring physicians. We ask, therefore, that you add the name of the patient/individual involved in the [date], [List event] and the name and address of the patient's/individual's referring physician to the attached letter and transmit that letter, along with its enclosure, to the referring physician. The letter and its enclosure provide information about the follow-up program being conducted by REAC/TS and ask the referring physician to inform the patient/individual about the REAC/TS program. If you have any questions regarding NRC's request, please contact me by telephone at [Telephone Number], by Fax at [Fax Number], or by e-mail at [e-mail address] .

Sincerely,

NMSS Coordinator
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Docket No.
License No.

Enclosure:
Letter dtd XX/XX/XX to referring physician

cc: Dr. Robert C. Ricks, Director REAC/TS

Issue Date: 04/24/02

E14-1

1360, Enclosure 14