

Advanced Medical Systems, Inc.

RADIATION PROTECTION RECORDS	Procedure: RSP-004	Revision No.: 000
	Page: 1 of 11	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

This procedure describes the records necessary to document implementation of the Advanced Medical Systems, Inc. (AMS) Radiation Protection Program Plan and to demonstrate compliance with USNRC license requirements.

2 SCOPE

- 2.1 This procedure applies to records generated during implementation of the Radiation Protection Program Plan and Radiation Safety Procedures (RSPs).
- 2.2 Records that pertain to operations, facilities or personnel that do not involve license requirements and Radiation Protection Program Plan provisions are exempt from the requirements of this Radiation Safety Procedure.

3 REFERENCES

- 3.1 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.
- 3.2 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan".
- 3.3 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-003, "Control of Radiation Safety Procedures".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be found in RSP-002, "Definitions".

5 PROCEDURE

5.1 Responsibilities

5.1.1 The Vice President and the RSC shall oversee the implementation of this RSP.

5.1.2 The Radiation Safety Officer (RSO) shall

- 5.1.2.1 Maintain copies of records generated during implementation of the radiation protection program and RSPs.
- 5.1.2.2 Periodically review the radiation protection records to ensure compliance with the requirements of this procedure.

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5.1.2.3 Remain knowledgeable of the type, quantity and location of all radiation protection records.

5.1.2.4 Ensure backup copies of radiation protection records exist.

5.1.3 Radiation Protection Technicians, Authorized Users, contractors and visitors that provide radiation protection services shall submit records generated during implementation of the Radiation Protection Program and RSPs to the RSO.

5.2 Form and Storage of Records

5.2.1 Records shall remain legible through the retention period specified in Section 5.9.

5.2.2 Records may consist of the original or a reproduced copy or a microfilm copy, provided the microfilm is authenticated by the RSO.

5.2.3 Occupational radiation exposure records shall be kept confidential, and the following controls shall be in place:

5.2.3.1 Records shall be kept in a secured cabinet except when in use.

5.2.3.2 There shall be a primary and backup custodian for the records.

5.2.3.2.1 The primary custodian shall be the RSO.

5.2.3.2.2 The backup custodian shall be the Vice President.

5.2.4 Safeguards against tampering with and the loss of records should be implemented.

5.3 Records from Purchased Services

5.3.1 If AMS or the RSO purchases radiation protection services from another firm, records clearly delineating responsibilities both during and subsequent to the performance of the services should be specified on the Request for Purchase Order.

Note: Common examples of purchased services include personnel dosimetry (TLD) services, bioassay analyses, radiation surveyor (health physics technician) support, instrument calibrations, and consulting services.

5.3.2 The RSO should ensure that pertinent records requirements are being met during contract administration.

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5.3.3 Records requirements should include:

- 5.3.3.1 Retention of written information of sufficient scope to define the procedure and method of evaluation; and
- 5.3.3.2 Data and computed results.

5.4 Records Related to an Individual

5.4.1 The purpose of individual records is to enable the RSO to provide an accurate, quantitative description of the occupational radiation exposure received by monitored individuals.

5.4.2 Examples of individual records are:

- 5.4.2.1 External radiation monitoring results;
- 5.4.2.2 Internal radiation monitoring results;
- 5.4.2.3 Supplementary information on individual exposures (e.g., radiation incident investigation reports); and
- 5.4.2.4 Documentation of proficiency in radiological training and qualification requirements.

5.4.3 Identification of the individual:

- 5.4.3.1 Positive identification of the individual employee, visitor, or contractor shall be required.
- 5.4.3.2 Due to such factors as multiple employment, duplication of common names, and legal changes of names, the Social Security number shall be used for individual identification.
- 5.4.3.3 For those cases where Social Security numbers are not available (e.g., foreign nationals), the birth date and sex of the individual shall accompany the individual's employee number on all records.

5.4.4 Radiation exposure received during prior employment:

- 5.4.4.1 A summary of the occupational radiation exposure received by a monitored employee during previous employment shall be obtained.

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5.4.4.2 The RSO shall attempt to secure and record the following information when radiation exposure is indicated for previous employment:

5.4.4.2.1 Period(s) of employment and identification of employer.

5.4.4.2.2 The nature and magnitude of prior occupational exposure, both internal and external, for the periods in question.

5.4.5 Exposure Received by Individuals at Other Installations or Facilities During Employment by AMS:

5.4.5.1 The RSO shall attempt to secure and record the radiation exposure received by monitored employees at facilities other than AMS.

5.4.5.2 When necessary, in order to maintain continuity in exposure data, the RSO may provide dosimetry devices to employees during official visits to other facilities.

5.4.5.3 The RSO shall encourage employees to report when radiation exposure is being incurred at other facilities.

5.4.6 Records of External Exposure

5.4.6.1 The following information shall be retrievable either directly or indirectly from personnel dosimetry records:

5.4.6.1.1 Identification of the wearer of the dosimeter;

5.4.6.1.2 Period of exposure or deployment;

5.4.6.1.3 Type(s) of phosphor, lot number, or processing batch identifiers;

5.4.6.1.4 Control dosimeter readings and confidence limits;

5.4.6.1.5 Personnel dosimeter readings and confidence limits;

5.4.6.1.6 Notation of abnormalities;

5.4.6.1.7 Identification of individual processing the dosimeter;

5.4.6.1.8 Computed dose for each type of radiation for the specified period;

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5.4.6.1.9 Appropriate summation to facilitate comparison with permissible limits; and

5.4.6.1.10 Identification of the individual performing dose computations.

Note: This information is typically maintained by the vendor and should be requested in purchase orders

5.4.6.2 When the dosimeter is the primary means of external dose assessment, the records shall be continuous for the period in question.

5.4.6.3 If a valid measurement result cannot be obtained from the personnel dosimeter, an estimate of the radiation exposure shall be recorded after performance of an investigation. The record of investigation may include, but is not limited to:

5.4.6.3.1 Identification of the individual;

5.4.6.3.2 Dates involved;

5.4.6.3.3 Nature of the abnormality (e.g., contaminated dosimeter, lost dosimeter);

5.4.6.3.4 Location and tasks to which the individual was assigned;

5.4.6.3.5 Readings from other dosimeters worn by the individual;

5.4.6.3.6 Dose received by others working under similar conditions;

5.4.6.3.7 Results of time-and-motion studies;

5.4.6.3.8 Conclusions as to magnitude and type of occupational exposure actually incurred; and

5.4.6.3.9 Signature of the RSO.

5.4.7 Records of Internal Exposure

5.4.7.1 When bioassay analyses are performed the following information should be directly or indirectly retrievable from the records:

5.4.7.1.1 Identification of the individual;

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- 5.4.7.1.2 Purpose of the sample/measurement and, if applicable, date of suspected intake;
- 5.4.7.1.3 Collection period for the sample and the date submitted for analysis or the measurement date;
- 5.4.7.1.4 Type of sample and size of aliquot or type of measurement (e.g., whole body count, specific organ count);
- 5.4.7.1.5 Type of radioactivity (e.g., alpha, beta);
- 5.4.7.1.6 Gross and net activity observed, and the counting time;
- 5.4.7.1.7 Identity of all radionuclides detected;
- 5.4.7.1.8 Cross reference to calibration and control data and confidence limits; and
- 5.4.7.1.9 Identification of the laboratory technicians performing the analysis.

Note: This information is typically maintained by the analytical laboratory or bioassay vendor and should be requested in purchase orders

- 5.4.7.2 Records of bioassay interpretation shall include the following:
 - 5.4.7.2.1 A listing of the bioassay data used in the interpretation and the identity of the radionuclide;
 - 5.4.7.2.2 Reference to the method of interpretation;
 - 5.4.7.2.3 Assumptions used in arriving at the conclusion including the known or assumed date of intake;
 - 5.4.7.2.4 Conclusion as to the magnitude and location of the body burden, expressed in units of activity (i.e., curies or becquerels); and
 - 5.4.7.2.5 Identification of the individual making the conclusion.

5.4.8 Other Individual Exposure Records

- 5.4.8.1 Completed Form USNRC Form-5

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- 5.4.8.2 Completed Form USNRC Form-4
- 5.4.8.3 Accident Reports
- 5.4.8.4 Personnel Decontamination Records
- 5.4.8.5 Radiation Work Permits
- 5.4.8.6 Dose estimates and justifications for those estimates

5.5 Radiation Safety Training Records

5.5.1 The RSO shall maintain records associated with delivery of general employee training in radiation protection, radiation worker training, authorized user training, and special briefings.

5.5.2 Specific training records should include:

- 5.5.2.1 Outline or course lesson plan indicating the name of the instructor, the company that provided the training, the date and time the training was conducted, the name or number of the test used for the class, employee test results, and course critiques.
- 5.5.2.2 Training Attendance Records
- 5.5.2.3 Performance Verification Sheets completed pursuant to RSP-006.

5.6 Medical Services Provided to an Individual

5.6.1 In certain cases, medical services (i.e., periodic chest x-rays, examinations following occupational injuries, medical qualification for respirator usage, etc) may be provided to AMS employees.

5.6.2 These records shall be forwarded to the RSO.

5.7 Records to be Maintained by the RSO

5.7.1 Program Administration

- 5.7.1.1 Records Index
- 5.7.1.2 Minutes of the Radiation Safety Committee Meetings

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- 5.7.1.3 Statement of RSO, Radiation Protection Technician, Authorized User and Instructor Qualifications
- 5.7.1.4 Training records
- 5.7.1.5 USNRC Form-5 for individuals
- 5.7.1.6 Medical records
- 5.7.2 Radioactive Material License
 - 5.7.2.1 Application
 - 5.7.2.2 License and Amendments
 - 5.7.2.3 Inspections by the USNRC
 - 5.7.2.4 Correspondence with the USNRC
- 5.7.3 USNRC Regulations
 - 5.7.3.1 Title 10, Code of Federal Regulations, Parts 19 and 20.
 - 5.7.3.2 Referenced USNRC Regulatory Guides
 - 5.7.3.3 Information Notices from the USNRC
- 5.7.4 Program Documentation
 - 5.7.4.1 Current revision of active RSPs
 - 5.7.4.2 Procedure Manual Transmittal Forms
 - 5.7.4.3 Procedure Transmittal Forms
- 5.7.5 Contamination Control Records
 - 5.7.5.1 Radiation Work Permits
 - 5.7.5.2 Contamination Survey Records
 - 5.7.5.3 Equipment/Area Decontamination Records

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5.7.6 Licensed Material Inventory Records

5.7.7 Site Monitoring Records

- 5.7.7.1 Radiological survey results including ambient surveys, contamination surveys, airborne rad activity surveys, and environmental monitoring surveys.
- 5.7.7.2 Calibration and maintenance records for radiological survey equipment
- 5.7.7.3 Radiological survey instrument user manuals

5.7.8 Waste Disposal Records

- 5.7.8.1 Names, quantity, and release survey results of the radioactive material deemed waste
- 5.7.8.2 Location, method and date of disposal

5.8 Documentation to be Maintained by the RSO

- 5.8.1 The signed original of the RSP and each revision, including PCN's and signed original of each Minor Change.
- 5.8.2 The signed original of each Minor Change.

5.9 Retention and Storage of Records

- 5.9.1 AMS legal counsel should be consulted prior to disposal or transfer of records generated pursuant to the radiation protection program plan.
- 5.9.2 Individual employee records and analyses performed using employee exposure records shall be preserved and maintained until license termination, at which time the records shall be transferred to the USNRC.
- 5.9.3 Records of dose to members of the general public shall be maintained until license termination.
- 5.9.4 Records relating to the radiation protection program shall be maintained for no less than five (5) years after the record was generated.

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5.9.5 Records of surveillance activities shall be maintained for no less than five (5) years after the record was generated.

5.9.6 Records of waste disposal shall be maintained until license termination.

5.9.7 When the USNRC license is no longer in force, the RSO shall contact the USNRC for permission to dispose of radiation protection records other than personnel exposure records.

6 EXEMPTION PROVISIONS

Variances and exceptions to the requirements of this Radiation Safety Procedure shall be permitted pursuant to the written authorization of the RSO and the Vice President, and after consultation with AMS's legal counsel.

7 DOCUMENTATION

None

8 ATTACHMENTS

None