UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
GENERAL COUNSEL

February 23, 1996

Marshall E. Miller
Presiding Officer
512 Magnolia
Frederick, MD 21701

Dr. Harry Foreman
Special Assistant
1564 Burton Avenue
St. Paul, MN 55108

In the Matter of
ADVANCED MEDICAL SYSTEMS, INC.
Material License No. 34-19089-01
Docket No. 30-16055-ML-REN

Dear Administrative Judges:

Pursuant to 10 C.F.R. § 2.1231(c), attached please find the following documents to be included in the hearing file for this proceeding.

48. Letter to Kevin G. Null, Licensing Reviewer, United States Nuclear Regulatory Commission, Region 3 from David Cesar, Vice President and Treasurer, Advanced Medical Systems, Inc., re: Standby Trust Agreement, dated December 14, 1995, with attachment.

49. Letter to Kevin G. Null, Nuclear Materials Licensing Branch, United States Nuclear Regulatory Commission, from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: Radiation Safety Procedures for USNRC License No. 34-19089, dated December 28, 1995, with attachment.

50. Letter to Kevin G. Null, Nuclear Materials Licensing Branch, United States Nuclear Regulatory Commission, from Robert Meschter, RSO, Vice President and Treasurer, Advanced Medical Systems, Inc., re: Radiation Safety Procedures for USNRC License No. 34-19089, dated January 5, 1996, with attachment.

51. Letter to David Cesar, Vice President, Advanced Medical Systems, Inc., from Kevin G. Null, Nuclear Materials Licensing Branch, Nuclear Regulatory Commission, re: decommissioning financial assurance, dated January 8, 1996.

52. Letter to Mr. Hubert Miller, Regional Administrator, Region III, United States Nuclear Regulatory Commission, from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: Strategic Plan (USNRC License No. 34-19089-01), dated January 15, 1996, with attachment.

53. Letter to Robert Meschter, Radiation Safety Officer, Advanced Medial Systems, Inc. from Kevin Null, Nuclear Materials Licensing Branch, re: Amendment No. 40 to NRC Material License No. 343-19089-01, dated January 18, with attachment.

By letter dated April 12, 1995, the Staff estimated that it would complete its review of the renewal application within three to six months of the date of the letter. Please note that the Staff currently estimates that it will complete its review of the license renewal application within 4 to 5 months of the date of this letter.

Sincerely,

Marian L. Zobler
Counsel for NRC Staff

Enclosures: As stated

cc w/encl.: Service List

AMC medical group
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110
(216) 692-3270

December 14, 1995

Kevin G. Null, Licensing Reviewer
United States Nuclear Regulatory Commission
Region 3
801 Warrenville Road
Lisle, IL 60532-4351

Re: License No. 43-19089-01
Docket No. 030-16055

Dear Kevin:

In response to your December 5, 1995 letter requesting evidence that the treasurer is authorized to represent the company to sign the Standby Trust Agreement, enclosed is a Certified Resolution of Advanced Medical Systems, Inc. which indicates that the treasurer of the corporation is authorized on behalf of the corporation to execute the Standby Trust Agreement.

If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

DAVID CESAR
Vice President and Treasurer

DC:sb

Enclosure

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CERTIFIED RESOLUTION
OF
ADVANCED MEDICAL SYSTEMS, INC.

RESOLVED, that the Treasurer of the Corporation is hereby authorized, on behalf of the Corporation, to execute the Standby Trust Agreement (As Modified and Restated) between the Corporation and Bank One Ohio Trust Company N.A., as Trustee.

RESOLVED FURTHER, that a copy of the aforesaid Standby Trust Agreement (As Modified and Restated) of the 5th day of July, 1995 be kept in the corporate file.

CERTIFICATE OF SECRETARY

C. ANTHONY STAVOLE, Secretary of Advanced Medical Systems, Inc., hereby certifies that the foregoing is a true and accurate copy of Resolution duly adopted by the Board of Directors of the Corporation, as of the 5th day of July, 1995, in which all members consented; and that said Resolutions remain in effect, unchanged to the present date.

C. Anthony Stavole

C. ANTHONY STAVOLE, Secretary

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

December 28, 1995

Kevin G. Null
Nuclear Materials Licensing Branch
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Radiation Safety Procedures for USNRC License No. 34-19089

Dear Mr. Null:

Advanced Medical Systems, Inc. (AMS) is in receipt of your letter dated December 5, 1995 wherein you requested the opportunity to review the Radiation Safety Procedures (RSPs) that were referenced in our license renewal application dated October 30, 1995. In partial compliance with that request, enclosed are the following RSPs:[1]

- RSP-002, "Definitions"
- RSP-004, "Radiation Protection Records"
- RSP-005, "ALARA Program"
- RSP-007, Training in Radiation Protection"
- RSP-009, "Contamination Control"
- RSP-011, "Radiological Areas and Posting"
- RSP-012, "Control of Work"
- RSP-013, "Control of Radioactive Waste"
- RSP-016, "Emergency Response and Notifications"
- RSP-017, "Stop Work Authority"

These procedures are being submitted to the USNRC as supplemental information only to assist in your review of our application. They are not to be considered part of the application package or incorporated as license conditions. However, your comments on these RSPs, which have been reviewed and approved by the AMS Radiation Safety Committee, are welcome.

[1] RSP-001 and RSP-003 were sent to you previously as part of our October 30, 1995 license renewal application. RSP-006, RSP-008, RSP-010, RSP-014, and RSP-015 are currently undergoing technical and administrative review. As soon as the reviews are complete, the final versions of these RSPs will be immediately forwarded to the USNRC.

Because our renewal application was originally submitted more than thirty (30) days prior to the expiration date of License No. 34-19089-01, AMS assumes the license will remain in effect, under its existing provisions, until final action is taken on this revised application. Since AMS wishes to institute significant changes in our radiation protection program in order to improve its applicability and auditability, your prompt consideration of our revised application would be greatly appreciated. If you have any questions, please contact me at (216) 692-3270.

Sincerely

Robert Meschter, R.S.O.

cc (w/o attach): D. Cesar
D. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

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1 PURPOSE

This procedure provides definitions of terms used in the Advanced Medical Systems, Inc. (AMS) Radiation Protection Program Plan and in operating procedures. Its purpose is to ensure consistent implementation through a common understanding of applicable terms.

2 SCOPE

The definitions contained in this Operating procedure apply to activities and procedures performed in support of the AMS Radiation Protection Program Plan.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Radioactive Material License No. 34-19089-0

3.2 Advanced Medical Systems, Inc., Operating Procedure No. RSP-001, "Radiation Protection Program Plan"

4 DEFINITIONS

4.1 A_1 and A_2 Quantities - The maximum quantity of radioactive material permitted in a Type A package. The A_2 quantity is used when the physical form has not been certified as a special form by the DOT. These quantities are listed by individual isotopes in the DOT regulations, 49 CFR 173.435.

4.2 Activity - Disintegration rate of a radioactive material stated in dps, becquerels, μCi, nCi, pCi, or other acceptable units.

4.3 Airborne Radioactivity Area - A room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed materials, exist in concentrations in excess of the DAC specified in 10 CFR 20.1001-20.2401 or, to such a degree that an individual present in the area could incur an exposure of 12 DAC-hours in a week.

4.4 ALARA (acronym for "as low as is reasonably achievable") - Making every reasonable effort to maintain exposures to radiation as far below the regulatory dose limits as is practical consistent with the purpose for which the licensed activity is undertaken, and taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and in relation to the utilization of licensed materials in the public interest.

4.5 Alert - Events that occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect members of the general population.

4.6 Annual Limit on Intake (ALI) - The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5,000 millirems or a committed dose equivalent of 50,000 millirems to any individual organ or tissue. ALI values are given in Table 1, Columns 1 and 2 of Appendix B, 10 CFR 20.1001-2401.

4.7 Approval - An act of endorsing or adding positive authorization or both.

4.8 Authorized User - Employees who supervise the use of radioactive material and who supervise individuals who work with radioactive material. Authorized users are qualified, by training and experience, to assure radioactive material is used for its intended purpose in a manner that protects health and minimizes danger to life or property. Training and qualifications of authorized users is contained in RSP-006, "Training and Qualifications of Radiation Protection Personnel".

4.9 Bioassay - Measurement of amount or concentration of radioactivity in the body or in material excreted or removed from the body for purposes of estimating the quantity of radioactive material in the body.

4.10 Breathing Zone - That region adjacent to a worker's mouth and nostrils from which air is drawing into the lungs while performing his/her assigned work. Air sampled from this region represents the air the worker breaths while at work, whether standing, sitting, or moving.

4.11 Byproduct material - Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

4.12 Background Radiation - The ambient radiation field to which we are exposed daily, originating from cosmic rays, naturally-occurring radionuclides (^{40}K, etc.) and human endeavors (fallout, fuel cycle, etc.). This radiation field is variable, and causes a survey meter to respond in the absence of radioactive materials.

4.13 Calibration - Determining the response of an instrument relative to a series of reference values over the range of the instrument; or the strength of a source of radiation relative to a reference standard.

4.14 Calibration Source - A commercially-purchased standard consisting of either an aqueous-equivalent matrix or a soil-equivalent matrix, containing a known (e.g., traceable to the National Institute of Standards and Technology) of radioactivity, used to verify geometry efficiency.

4.15 Commercial Analytical Laboratory - An analytical laboratory, licensed by the USNRC or applicable agreement state to possess byproduct materials, that provides quality assurance pursuant to the requirements of ANSI/ASME NQA-1 and Regulatory Guide 4.15.

4.16 Committed Dose Equivalent - The time integral, over 50 years, of the dose equivalent rate in an organ or a tissue following intake of a radionuclide:

$$H_{50} = \int_{t=0}^{t=50} H(t)\ dt$$

where t = 0 is the time of intake and H(t) is the dose equivalent rate in an organ or a tissue at time t.

4.17 Committed Effective Dose Equivalent - The sum of the committed dose equivalents to individual tissues resulting from an intake of a radionuclide multiplied by the appropriate weighting factors (w_T):

$$CEDE = \sum w_T H_T \leq H_{wb}$$

where w_T = the weighting factor representing the ratio of the stochastic risk resulting from irradiation of tissue (T) to the total risk when the whole body is irradiated uniformly; and H_T is the dose equivalent received by tissue (T).

4.18 Contamination - The deposition of radioactive material on accessible surfaces structures, objects, equipment, or personnel. Contamination may be either "fixed" (e.g., not removable by rubbing with a dry smear) or "removable". Total Contamination refers to fixed plus removable contamination.

4.19 Contaminated Area - Any area which contains removable or total (fixed plus removable) activity in excess of site-specific release criteria.

4.20 Controlled Area - The area within the London Road site (property) boundaries.

4.21 Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

4.22 Critique - A meeting of management and involved/concerned personnel to analyze an event to determine what happened, why it happened, and how to minimize or prevent recurrence.

4.23 DAC-hours - A unit of internal radiation exposure. For purposes of workplace control, the secondary occupational dose limit is 2,000 DAC-hours.

4.24 Deep Dose Equivalent (H_D) - The dose equivalent from external whole body exposure at a tissue depth of one (1) centimeter.

4.25 Derived Air Concentration (DAC) - The concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work (inhalation rate of 1.2 m^3 per hour) results in an intake of one Annual Limit on Intake (ALI). DAC values are given in Table 1, Column 3 of Appendix B, 10CFR 20.1001-2401.

4.26 Direct Bioassay - In vivo measurements to estimate the quantity of radioactive material in the human body using instrumentation that detects radiation emitted from within the body.

4.27 Escorted personnel - Individuals (e.g., visitors, contractors) who have not received training in radiation protection. These individuals are under the direct supervision of a trained employee while they are within the controlled area.

4.28 Extremity - The arms below the elbow and the legs below the knee.

4.29 Eye Dose Equivalent (H_E) - The dose equivalent to the lens of the eye from external whole body exposure at a tissue depth of one (0.3) centimeter.

4.30 Field Service - Activities, performed by Authorized Users, at customer facilities on teletherapy equipment. Field service includes the service procedures specified in ISP-15, "Cobalt Service Procedures Mamnual", installation and dismantling of teletherapy equipment, packaging and transportation of radioactive material, the use of radiation detection intsrumentation, and the use of tools and equipment associated with field service work.

4.31 Flammable Liquids - Any liquid having a flash point below 100 degrees fahrenheit (°F) or 37.8 degrees centigrade (°C). This includes materials like, acetone, alcohols, hexane and ethers. Other flammable liquids are listed in the DOT regulations, 49 CFR 172.01.

4.32 Flammable solids - Any solid material, other than an explosive, which under conditions normally incident to transportation, is liable to cause fires through friction, retained heat and when ignited, burns vigorously as to create a serious transportation hazard. This

includes materials like, charcoal, phosphorous, lithium metal and magnesium metal. Other flammable solids are listed in DOT regulations, 49 CFR 172.101.

4.33 General Employee - Any employee, visitor, or contractor who is permitted unescorted access to the controlled area.

4.34 Geometry - The size and type of container used to hold a sample during counting.

4.35 Half-life, Biological (T_b) - The time in which half the quantity of a material in a compartment, in an organ, or in the whole body is eliminated by biological processes.

4.36 Half-life, Effective (T_e) - The time taken for the activity of a radioactive material in a compartment, in an organ or in the whole body to be reduced to half its value by a combination of biological elimination and radioactive decay:

$$\frac{1}{T_e} = \frac{1}{T_b} + \frac{1}{T_R}$$

where T_e = the effective half time; T_b = the biological half time; and T_R = the radiological or physical half time.

4.37 Half-life, Physical (T_R) - The time taken for the activity of a radionuclide to lose half its value by radioactive decay.

4.38 High Radiation Area - Any area, accessible to individuals, in which there exists radiation at levels that could expose a major portion of the body to more than 100 millirem in one hour measured at 30 cm from the source or surface that the radiation penetrates.

4.39 Incident/Event - Potential conditions or real occurrences which are described in appendices to this procedure. Incidents may include power failures, minor spills of radioactive materials, or radioactive contamination that present no significant hazard to personnel, etc. Emergency situations may include fires, acute illness or personnel injuries involving a contamination hazard, major spills, accidents resulting in personnel exposure to radioactive dusts, mists, fumes, organic vapors or gases.

4.40 Indirect Bioassay - Estimate of the amount of radioactive material in the human body based on measurements of radioactive material in excreta or in other biological materials from the body, and on a biological model for movement of the material in body tissues and organs.

4.41 Inner Container - A container or some other package that surrounds the compound being transported. The inner container provides the first level of containment in order to minimize the likelihood of a spill.

4.42 Intake - Amount of radioactive material entering the body through the nose, mouth, or skin.

4.43 Internal Dosimetry - Specification, analysis, and interpretation of bioassay measurements that result in an estimate of internal dose equivalent or dose commitment.

4.44 International Air Transport Association (IATA) - Association of commercial airline companies which publish regulations addressing the conveyance of goods and passengers via air.

4.45 Labels - Shipping labels prescribed by the DOT to provide a warning of the hazard of the material contained within the package and information about the safe segregation of shipping packages. Labels are affixed to the exterior of the package.

4.46 License - A radioactive materials license issued by the USNRC in accordance with the regulations adopted by the USNRC.

4.47 Limited Quantity - A maximum quantity of a hazardous material listed by the DOT, for which there are specific exceptions from marking, labeling and packaging. The quantity of radioactive material that is exempted from these requirements is listed in 49 CFR 173.421.

4.48 Low Specific Activity (LSA) - A concentration of radioactive material that is not likely to result in a significant radiation exposure if the integrity of the shipping package is breached. The following guidelines are used to establish the criteria.

4.48.1 Material in which the radioactivity is essentially uniformly distributed and in which the average concentration of the compound, excluding the weight of the shipping package, does not exceed:

4.48.1.1 0.0001 millicurie per gram (mCi/gm) for isotopes in which the A_2 quantity is not more than 0.05 Curies (Ci); or

4.48.1.2 0.005 mCi/gm for isotopes in which the A_2 quantity is not more than 1 Ci; or

4.48.1.3 0.3 mCi/gm for isotopes in which the A_2 quantity is not more than 1 Ci.

4.48.1.4 Uranium or thorium ores and their chemical concentrates.

4.48.1.5 Tritium Oxide in aqueous solutions in which the concentration does not exceed 5 mCi per milliliter (5 mCi/ml).

4.48.2 Objects of nonradioactive material externally contaminated with radioactive material that is not readily dispersed and the surface contamination, averaged over a square meter does not exceed:

4.48.2.1 0.01 mCi per 100 square centimeters (cm^2) (2.22×10^7 dpm/100 cm^2) for isotopes in which the A_2 quantity is not more than 0.05 Curies; or

4.48.2.2 0.1 mCi/100 cm^2 (2.22×10^7 dpm/100 cm^2) for isotopes in which the A_2 quantity is greater than 0.05 Ci.

4.49 Markings - Information printed or durably affixed to the exterior of the shipping package.

4.50 May - The word may is used to denote permission.

4.51 Milliroentgen per hour (mR/hr) - A unit of gamma exposure rate. One mR/hr shall be equivalent to 1000 μR/hr.

4.52 Minimum Detectable Activity (MDA) - The smallest amount of radioactivity that can be detected given the conditions of a specific sample. It is reported at the 95% confidence interval, meaning that there is a 5% chance that a false signal was reported as activity, and a 5% chance that true radioactivity went undetected.

4.53 Minor change - Refers to changes to RSPs. A minor change is one that does not substantively effect the actions required in the procedure. For example, typographical changes and formatting changes are considered to be minor changes.

4.54 Monitored Employee or Personnel - An individual who performs work within a restricted area and has the potential to receive greater than 500 millirem total effective dose equivalent in one calendar year.

4.55 Monitoring - The measurement of radioactivity in the whole body, in a region of the body, in material eliminated from the body or in the air for purposes of estimating the intake of radioactive material. The term monitoring also includes interpretation of the measurements. It may consist of the use of personnel dosimetry devices for measurement of deep dose equivalent from external sources, or bioassay services for measurement of committed effective dose equivalent.

4.55.1 Routine monitoring is monitoring carried out at regular intervals during normal operations.

4.55.2 Special monitoring is monitoring carried out in actual or suspected abnormal conditions.

4.55.3 Confirmatory monitoring is monitoring carried out in situations where workers are unlikely to be exposed to significant intakes, in order to demonstrate satisfactory work conditions.

4.56 Organ - A differentiated part of the body that performs a special function.

4.57 ORM E - Other Regulated Material (ORM) that may pose an unreasonable risk to health, safety or property when transported in commerce, and does not meet any of the definitions of the other hazard classes. This includes materials such as hazardous substances, n.o.s., polychlorinated biphenyls, mercaptans, or dinitrotoluene. Most shipments of hazardous waste as defined by the EPA and the RCRA regulations that do not satisfy the DOT hazard classes are defined as ORM-E.

4.58 Placard - A large diamond shaped sign indicating the hazard class of the materials being transported. The placard shall be affixed to four sides of the transport vehicle.

4.59 Qualified Technicians - See Radiation Protection Technicians.

4.60 Quality Assurance Record - A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

4.61 Radiation Area - Any area, accessible to individuals, in which there exists radiation at levels that could expose a major portion of the body to more than five (5) millirems in one hour measured at 30 cm from the source or surface that the radiation penetrates.

4.62 Radiation Protection Technicians - Personnel who perform work at the London Road site involving radioactive materials or radiation-producing machines, such as inventory/management, receiving activities, shipping/receiving activities, release surveys, area surveys, contamination surveys, leak tests, radiation survey records maintenance, and quality assurance activities as they pertain to radiation surveys. Training and qualifications of personnel performing radiation support activities is contained in RSP-006, "Training and Qualifications of Radiation Protection Personnel". Radiation Protection Technicians may also be referred to as "qualified technicians".

4.63 Radiation Safety Committee (RSC) - A standing committee of management, health/safety, quality assurance, and operations personnel that provides oversight for the radiation protection program. Members are appointed and empowered by the Vice President. The RSO is a permanent member of the RSC.

4.64 Radiation Safety Officer (RSO) - An individual who, by virtue of qualifications and experience, has been given the authority to implement the Radiation Protection Program Plan. The RSO is qualified to direct the use of radioactive material or radiation-producing machines for their intended purpose in a manner that protects health and minimizes

danger to life or property. The RSO is responsible for recognizing potential radiological hazards, developing a radiation safety program to protect against these hazards, training workers in safe work practices, and supervising day-to-day radiation safety operations.

4.65 Radiation Safety Procedure (RSP) - A document that specifies or describes how an activity is to be performed. It may include methods to be employed, equipment or materials to be used and sequence of operations.

4.66 Radiation Survey Instrument - A hand-held radiation survey instrument capable of detecting ionizing radiation.

4.67 Radiation Worker - An occupational worker who may enter radiological areas and/or who has the potential to receive greater than 100 millirem TEDE in a calendar year. Training and qualifications of radiation workers is contained in RSP-007, Training in Radiation Protection".

4.68 Radioactive Material - Any solid, liquid or gaseous substance which emits radiation spontaneously.

4.69 Radioactive Material Storage Area - A restricted area where radioactive materials are secured from unauthorized removal or access, or where constant surveillance over the materials is maintained.

4.70 Radioactive Shipping Labels - A label applied to two sides of a shipping package bearing the radiation symbol and the isotope and quantity contained in the package. The label shall be indicative of the external radiation levels measured on the surface of the package. Specifically:

4.70.1 White Bar I - gamma radiation levels on the surface of the package are less than 0.5 mR/hr.

4.70.2 Yellow Bar II - gamma radiation levels on the surface of the package are less than 50 mR/hr.

4.70.3 Yellow Bar III - gamma radiation levels on the surface of the package are less than 200 mR/hr.

4.71 Reference Man - A person with the anatomical and physiological characteristics defined in the report of the ICRP Task Group on Reference Man (ICRP Report No. 23).

4.72 Release Criteria - Minimum requirements for release or discharge of liquid effluent into the waters of the state or the sanitary sewer system. For the AMS facility, the release criteria are:

4.72.1 The material is readily soluble (or is readily dispersible biological material) in water pursuant to the requirements of NRC Information Notice 94-07;

4.72.2 The concentration of licensed material does not exceed 200 pCi/liter.

4.73 Representative - Faithfully showing the quality and characteristics of the entire volume from which a sample is drawn or a measurement is made.

4.74 Research and Development - Theoretical analysis, exploration, or experimentation; the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

4.75 Restricted Area - Any area at the London Road facility, accessible to humans, to which access is limited by AMS for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. At the London Road facility, a restricted area has an ambient exposure rate and/or contamination levels that may result in an individual receiving a total effective dose equivalent in excess of 100 millirem per year.

4.76 Restricted Use - Equipment, components, materials, land areas (property), and other items that, by virtue of their levels of fixed and/or removable radioactivity are maintained under the control of AMS or transferred to another licensee.

4.77 Retention Function - A mathematical expression for that fraction of the initial body content of radioactive material retained in the organ of reference at time t after intake. The retention function is represented by the expression R(t).

4.78 Root Cause - The most basic, fundamental cause, which, if corrected will prevent recurrence. There may be more than one root cause of an incident or event.

4.79 Sample - A representative portion of an atmosphere of interest, or one or more separated constituents from a representative portion of an atmosphere.

4.80 Sealed Source - Any device containing radioactive material that may be used as a source of radiation, and which has been constructed in such a manner as to prevent the escape of radioactive materials; or radioactivity fixed in inaccessible areas (e.g., inside surfaces) of equipment or containers.

4.81 Shall - The word shall is to be understood as a requirement.

4.82 Shallow Dose Equivalent (H_s) - The dose equivalent from external whole body exposure at a tissue depth of one (0.007) centimeter, averaged over an area of one (1) square centimeter.

4.83 Shipping Paper - A bill of lading, shipping order, manifest or other shipping document containing information about the materials being transported. The information to be included in this shipping document is prescribed by the DOT in 49 CFR 172.202 through 172.204.

4.84 Should - The word should is to be understood as a recommendation.

4.85 Site Area Emergency - Events may occur, are in progress, or have occurred that could le to a significant release of radioactive material and that could require a response by off-s response organizations to protect the general public.

4.86 Source Housing - Device designed to support, shield and contain a sealed radiation source capsule.

4.87 Strong, Tight Container - A package not likely to lose its contents under conditions normally incident to transportation.

4.88 Thermoluminescent Dosimeter - The thermoluminescence phosphor(s) used for determining external radiation exposure to beta, gamma, x-rays, and neutrons. The words TLD and dosimeter are used interchangeably throughout this procedure.

4.89 Total Dose Equivalent (TDE) - The sum of the deep dose equivalent (for exte exposures) and the committed dose equivalent (for internal exposures).

4.90 Total Effective Dose Equivalent (TEDE) - The sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

4.91 Transport Index - A number on the label of a package that indicates the degree of radiological control to be exercised by the carrier during transport. The transport index is the maximum radiation exposure rate, in units of "millirem per hour" measured at a distance of one (1) meter form the external surface of the package.

4.92 Type A Container - A shipping container designated by the Department of Transportation (DOT) to package radioactive materials. The configuration for each package is approved by the DOT and published in the Mound Laboratory Manual, MLM 3245 and supplements. The maximum quantity of radioactive materials is limited to the A_1 quantity for materials certified to be special form or limited to the A_2 quantity for other physical forms.

4.93 Type A Quantity - A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 49 CFR 173.435 or may be determined by procedures described in 49 CFR 173.433.

4.94 Uncontaminated Area - Any area which contains removable or total (fixed plus removable) activity below the site-specific release criteria.

4.95 Uniform Hazardous Waste Manifest - A shipping paper on which all hazardous waste is identified. A copy of the manifest shall accompany each shipment of hazardous waste from the point of pickup to the destination.

4.96 Unrestricted Area - Any area to which access is neither limited nor controlled.

4.97 Unrestricted Use - Equipment, components, materials, land areas (property), and other items that may be used, transferred, sold, or disposed of without regard for their radiological constituents.

4.98 USNRC - Acronym for "United States Nuclear Regulatory Commission," a federal regulatory agency.

4.99 Very High Radiation Area - Any area where an individual may receive an effective dose equivalent from external sources of 500 rads or greater in one hour measured at a distance of one (1) meter from the radiation source or from any surface through which the radiation penetrates.

4.100 Vice President - Designated senior manager or other responsible officer of AMS with the authority to commit AMS resources for health and safety purposes, and with administrative influence over all participants in radiation protection activities.

4.101 Visitor - A company individual who is not assigned to the London Road site or non-company personnel such as vendors, contractors, inspectors, auditors or observers.

5 PROCEDURE

None

6 EXEMPTION PROVISIONS

None

7 DOCUMENTATION

None

8 ATTACHMENTS

None

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.

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.

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, 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.

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;

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;

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

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

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

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 radioactivity 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.

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

Advanced Medical Systems, Inc.

ALARA PROGRAM	Procedure: RSP-005	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 Advanced Medical Systems, Inc. (AMS) ALARA (as low as reasonably achievable) program regarding exposures to ionizing radiation and radioactive material. This procedure is applicable to all operations, activities, and personnel at the London Road facility.

2 SCOPE

This procedure applies to all AMS employees, visitors, and contractors performing work for AMS at the London Road facility.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.2 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.3 U. S. Nuclear Regulatory Commission, Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable", 1982.

3.4 U. S. Nuclear Regulatory Commission, Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable", 1977.

3.5 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan"

3.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-004, "Radiation Protection Records".

3.7 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-010, "Exposure Control".

3.8 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-017, "Stop Work Authority"

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 shall:

5.1.1.1 Ensure that facility personnel are aware and supportive of management's commitment to keep occupational radiation exposures ALARA.

5.1.1.2 Ensure that revisions to operating and maintenance procedures, and modifications to equipment and facilities are made if they will substantially reduce exposures at a reasonable cost.

5.1.1.3 Appoint and empower members of the Radiation Safety Committee (RSC).

5.1.1.4 Ensure that the resources needed to achieve ALARA goals are made available to the RSO and the RSC.

5.1.2 The Radiation Safety Officer (RSO) shall:

5.1.2.1 Ensure performance of radiological surveys in order to provide comprehensive and current information on the radiological status of the London Road facility and its equipment.

5.1.2.2 Ensure that posting and labeling is appropriate and commensurate with the hazards.

5.1.2.3 Provide appropriate radiation protection information on Radiation Work Permits.

5.1.2.4 Ensure radiation monitoring and surveillance instruments are functional, calibrated, and available in adequate quantities to perform both routine and emergency tasks.

5.1.2.5 Serve as a permanent member of the RSC.

5.1.2.6 Determine the need for and provide a listing of ALARA goals to the RSC for consideration.

5.1.2.7 Participate in design reviews for facilities and equipment that may affect potential radiation exposures.

5.1.2.8 Identify locations, operations, and conditions that have the potential for causing significant exposures to radiation;

5.1.2.9 Initiate and implement an exposure control program

5.1.2.10 Develop plans, procedures and methods for keeping radiation exposures of AMS personnel ALARA;

5.1.2.11 Review, comment on, and recommend changes in job procedures to maintain exposures ALARA.

5.1.2.12 Maintain and exercise stop work authority as described in RSP-017.

5.1.3 The Radiation Safety Committee (RSC) shall

5.1.3.1 Ensure that a corporate program that integrates management philosophy and regulatory requirements is established, with specific goals and objectives for implementation included.

5.1.3.2 Ensure that measurement system results are reviewed on a periodic basis and that corrective actions are taken when attainment of specific objectives appears to be jeopardized.

5.1.3.3 Ensure that the authority for providing procedures and practices by which the specific goals and objectives will be achieved is delegated.

5.1.3.4 Review and approve ALARA goals at a frequency of not less than once per calendar quarter.

5.1.3.5 Support the RSO in formulating and implementing the program for maintaining radiation exposures ALARA.

5.1.4 AMS personnel shall:

5.1.4.1 Follow the basic radiation protection principles of "time", "distance", "shielding" and "contamination control" whenever possible.

5.1.4.2 Comply with instructions contained on Radiation Work Permits or given by the RSO.

5.1.4.3 Obtain special briefings pursuant to RSP-008 when advised by the RSO.

5.1.4.4 Comply with the listing of individual worker responsibilities for ALARA (Attachment 1)

5.2 ALARA Objectives at AMS

5.2.1 A program for maintaining occupational radiation doses ALARA shall be established.

5.2.2 Facilities and select equipment shall be designed with consideration for the ALARA concept;

5.2.3 Radiation controls shall be established in programs, plans, and procedures.

5.2.4 Supporting equipment, instrumentation, and facilities shall be made available.

5.3 Program for Maintaining Personnel Radiation Doses ALARA

5.3.1 A formal management policy and commitment to ALARA shall be established (See Attachment 2).

5.3.2 The policy should make clear that all personnel shall be responsible for ensuring that the work they perform is in accordance with the ALARA Policy.

5.3.3 Responsibility and authority for the programs shall be clearly delegated by the Vice President.

5.3.4 A training program in the fundamentals of radiation protection and ALARA procedures shall be established.

Note: **AMS has established an effective program which addresses these topics. The program is described in RSP-007.**

5.4 Designing Facilities and Selecting Equipment Using ALARA Concepts

5.4.1 Whenever applicable, the design of facilities and selection of equipment shall be based upon the concept of ALARA.

5.4.2 These reviews shall be conducted by the RSC.

5.4.3 Reviews shall be based upon the guidance of Regulatory Guide 8.8, Section 2.

5.5 Establishing Radiation Controls

5.5.1 Radiation controls shall be established for work operations to ensure radiation exposures are ALARA, and should be included in:

5.5.1.1 Work planning and preparation,

5.5.1.2 Actual work operations, and

5.5.1.3 Post operation reviews.

5.5.2 The specific requirements for implementing radiation controls shall be described in job-specific procedures and/or work plans.

5.6 Supporting Equipment, Instrumentation, and Facilities

5.6.1 Appropriate support equipment, instrumentation, and facilities shall be provided for all AMS work involving ionizing radiation.

5.6.2 Support may include:

5.6.2.1 A sample counting area

5.6.2.2 Radiation survey instrumentation (portable and non-portable)

5.6.2.3 Personnel monitoring devices

5.6.2.4 Protective clothing

5.6.2.5 Respiratory protection

5.6.2.6 Decontamination areas for personnel and equipment

5.6.2.7 Change rooms

5.6.2.8 Communication equipment

5.6.2.9 Office space and equipment

5.7 ALARA Goals

5.7.1 The RSC shall establish radiological goals to direct all levels of management and workers at AMS toward improvement in radiological performance.

5.7.2 ALARA goals, as necessary, shall be established, reviewed, and documented at least once per calendar quarter.

Note: Examples of alara goals are square footage of contaminated areas, maximum individual dose for employees, and maximum dose to a member of the general population.

5.7.3 The following steps for establishing an ALARA goal shall be included in the goal-setting process:

5.7.3.1 The RSC, with input from the RSO, shall determine which areas need improvement.

5.7.3.2 The RSC shall:

5.7.3.2.1 Evaluate the existing condition(s), root cause(s), and corrective action(s).

5.7.3.2.2 Determine the improvement needed and propose the goal.

5.7.3.2.3 Periodically review performance in achieving the goal and modify the action plan, if necessary.

5.7.3.3 The RSO shall document radiological goals, their status, and performance, and shall present them to the RSC at planned and periodic meetings.

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.

7 DOCUMENTATION

7.1 All records pertinent to this procedure shall be maintained pursuant to RSP-004.

7.2 A listing of annual radiological goals, and method/date of closure shall be maintained.

7.3 The minutes of the RSC meetings shall reflect RSC action in establishing and monitoring ALARA goals.

8 ATTACHMENTS

8.1 Attachment 1 - Individual Worker's Responsibilities for ALARA

8.2 Attachment 2 - Management Policy Statement on Radiation Protection

ATTACHMENT 1
INDIVIDUAL WORKER'S RESPONSIBILITIES FOR ALARA

1. Obey promptly "stop work" and "evacuate" instructions issued by RSO.
2. Follow all procedures and instructions.
3. Wear monitoring devices as required by procedures and instructions, signs, or the RSO.
4. Keep track of your own radiation dose status.
5. Remain in as low a radiation area as practical to accomplish work.
6. Leave radiation areas or airborne radioactivity areas when not working, and use "wait areas" when designat
7. **DO NOT** smoke, eat, or drink in restricted areas, or bring smoking, eating, or drinking materials into such areas.
8. Wear protective clothing and respirators properly and whenever required by signs, RWPs, the RSO, procedures and instructions.
9. Remove protective clothing and respirators properly to minimize spread of contamination.
10. Frisk yourself or be frisked for contamination when leaving contamination areas.
11. Minimize the spread of a known or possible radioactivity spill and notify the RSO promptly.
12. Avoid unnecessary contact with contaminated surfaces, including your clothing (if contaminated), tools and other equipment.
13. If directed by the RSO, place contaminated tools, equipment, and solid waste on disposable surfaces (e sheet plastic) when not in use, and inside plastic bags when work is finished.
14. Minimize the amount of materials brought into contaminated areas.
15. Report the presence of treated or open wounds to the RSO before working in areas where radioactive contamination exists. Exit the area promptly if a wound occurs while in such an area.
16. Report promptly unsafe or noncompliance situations to the RSO.
17. Report prior or concurrent occupational radiation exposure to the RSO.
18. Report pregnancy in accordance with AMS procedures and instructions.

ATTACHMENT 2
MANAGEMENT POLICY STATEMENT ON RADIATION PROTECTION

Advanced Medical Systems, Inc. (AMS) has the responsibility for providing a work-place environment in which employees, visitors and contractors are adequately protected from hazards, including the hazards associated with exposure to radiation and radioactive material. At AMS, some individuals, by nature of their work, will be exposed to these hazards to varying degrees.

While the majority of occupational radiation exposures are low, all exposures are assumed to entail some risk to the employee. Therefore, AMS has adopted the following three principles to govern all work activities with the potential for exposure to radiation or radioactive materials:

1. No activity or operation will be conducted unless its performance will produce a net positive benefit.

2. All radiation exposures will be kept as low as reasonably achievable (ALARA) considering economic and societal costs.

3. No individual will receive radiation doses in excess of federal limits.

The first principle is self-explanatory. AMS personnel will not be exposed to radiological hazards unless there is some benefit to be gained from the activity involving the exposure. The third principle is also self-explanatory. Federal authorities and AMS management have identified an upper limit on radiation doses to which workers may be exposed without incurring unacceptable risks. The second principle, ALARA, is the basis for much of our radiation protection program, other than demonstrating compliance with regulations. ALARA is an operating policy that is integrated into each of our Radiation Safety Procedures.

Incorporated into the AMS radiation protection program plan are the following goals:

1. Individual exposures will be ALARA.

2. Collective exposures will be ALARA.

3. Measures to keep radiation exposures ALARA will not result in an increased total risk to workers from other hazards.

The objective of these goals is to minimize the <u>total</u> risk to our employees. Working at AMS should not expose our workers to greater risk than is incurred by workers in other "safe" industries of occupations. These risks should also be no greater than those commonly accepted by each of us in our daily lives.

The AMS radiation protection policy can only be effective through the concern and commitment of employees and management and must be integrated into each aspect of our operations. As individuals, each of us must assume the responsibility to maintain our radiation exposures ALARA. Each supervisor must also

assume additional responsibilities. They shall ensure that potential radiation hazards are assessed before workers are exposed to them, that measures to address these hazards are documented in appropriate health and safety plans, and that workers have adequate training to understand the hazards and protective measures. Supervisors shall maintain continual oversight and evaluate means by which radiation exposures to their employees can be minimized. They shall institute programs of exposure control, and encourage employee participation in ALARA activities.

In support of the employees and supervisors, AMS will maintain an effective radiation protection program designed to comply with our three principles, and a radiation protection staff of qualified personnel. Each AMS employee should become familiar with the procedures for radiation safety. This will ensure that all of our workday activities are conducted according to our three radiation protection principles and that we will meet our ALARA goals.

David Cesar
Vice President and Treasurer

Advanced Medical Systems, Inc.

TRAINING IN RADIATION PROTECTION	Procedure: RSP-007	Revision No.: 000
	Page: 1 of 10	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

In compliance with 10 CFR 19, this procedure describes the training program designed to instruct Advanced Medical Systems, Inc. (AMS) employees, contractors and visitors in the radiological hazards to which they may be exposed.

2 SCOPE

The contents of this procedure applies to all AMS employees, visitors and contractors who require unescorted access to the Controlled Area at AMS. Escorted personnel are exempt from the provisions of this procedure.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.2 Title 10, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports for Workers: Inspection and Investigations".

3.3 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation"

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan".

4 DEFINITIONS

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

5 PROCEDURE

5.1 Responsibilities

5.1.1 The Vice President shall be responsible for ensuring implementation of this program.

5.1.2 The RSO shall be responsible for ensuring delivery, oversight and technical content of the training programs.

5.1.3 Supervisors and Authorized Users shall be responsible for ensuring that workers and visitors are trained prior to exposure to radiological hazards.

5.2 Requirements

5.2.1 All AMS employees, contractors, and visitors with unescorted access to the controlled area shall be trained in regard to radiological hazards they might encounter.

5.2.2 Employees, contractors, and visitors who are escorted are exempt from the training requirements of this RSP.

5.2.3 The level of training shall be commensurate with the level of radiological hazard to which they may be exposed.

5.3 Radiation Protection Training Programs

5.3.1 The AMS training program is designed to accommodate three groups of personnel:

5.3.1.1 Visitors

5.3.1.2 General Employees (non-radiation workers)

5.3.1.3 Radiation workers

5.3.2 Visitors shall be trained by reading and signing a briefing form (Attachment 1).

5.3.3 General employees shall receive a General Employees Training in Radiation Protection (GET) program.

5.3.3.1 This program shall address the topics outlined in Attachment 2

5.3.3.2 The duration of GET should be approximately one (1) hour.

5.3.3.3 GET may be delivered as part of Hazard Communication Training provided to new employees.

5.3.4 Radiation workers shall receive the Radiation Worker Training in Radiation Protection (RWT) program.

5.3.4.1 This program shall address the topics outlined in Attachment 3

5.3.4.2 The duration of RWT should be approximately eight (8) hours.

5.3.5 Special Briefings shall be made available on a case-by-case basis

5.3.5.1 Special briefings shall provide comprehensive and in-depth knowledge of certain radiation protection topics (e.g., remote handling, containments, engineering controls).

5.3.5.2 The need for Special Briefings shall be determined and arranged by the RSO.

5.4 When Training is Required

5.4.1 Visitors shall sign a "Visitor Radiation Protection Briefing" form at the start of each month that they have unescorted access to the controlled area.

5.4.2 General employees:

5.4.2.1 Shall receive GET within one week of assignment at AMS.

5.4.2.2 Shall be retrained at least annually thereafter by the end of the same quarter in which training was originally completed if the employee is at or has potential to work at the location covered by this RSP.

5.4.3 Radiation workers:

5.4.3.1 Shall receive RWT Training prior to entering any restricted area.

5.4.3.2 Shall be retrained annually thereafter by the end of the same qua in which training was originally completed in order to maintain ac radiation worker status.

5.5 Conduct of Training

5.5.1 Visitors may be briefed by any individual who has received GET or RWT.

5.5.2 GET and RWT shall be conducted by individuals who are trained and qualified to provide such training, and who have been approved, in advance, by the RSO.

5.6 Testing

5.6.1 Testing to demonstrate proficiency in RWT should be required for Radiation Workers and may be required for General Employees.

5.6.2 The self-graded written test should address all of the required topics shown in Attachments 2 and 3.

5.7 Credit for Non-AMS Training Courses

5.7.1 Credit for previous training shall require the following:

5.7.1.1 Evidence of satisfactory completion of training (i.e., certificate, test results).

5.7.1.2 List of subjects covered in the training.

5.7.1.3 Test score, if available.

5.7.2 The RSO shall review the training documentation and make a determination of equivalency.

5.7.3 The basis for RSO's decision shall be documented.

6 EXEMPTION PROVISIONS

6.1 A waiver of GET shall require the approval of the RSO.

6.2 A waiver of RWT shall require the approval of the RSO and the Vice President.

6.3 Waivers shall be documented on the "Waiver of Training" form (Attachment 4).

6.4 All individuals who have training waived should be escorted by individuals who are currently trained.

6.5 Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the Vice President.

7 DOCUMENTATION

7.1 All records pertinent to this procedure shall be maintained pursuant to RSP-004, "Radiation Protection Records".

7.2 The following training records shall be maintained, as applicable:

7.2.1 Instructor Qualifications

7.2.2 Course lesson plans.

7.2.3 Test results.

7.2.4 Copies of tests.

7.2.5 Training attendance rosters.

7.2.6 Equivalency determinations.

7.2.7 Course critiques or critique summaries.

7.2.8 Certificates of completion.

7.2.9 Waivers of Training (Attachment 4).

7.3 Individual employee records shall be maintained by the Vice President.

8 ATTACHMENTS

8.1 Attachment 1: Visitor Radiation Protection Briefing

8.2 Attachment 2 - General Employee Training in Radiation Protection

8.3 Attachment 3 - Radiation Worker Training in Radiation Protection

8.4 Attachment 4 - Waiver of Training

ATTACHMENT 1

VISITOR RADIATION PROTECTION BRIEFING

The following guidelines shall be read and acknowledged by signing the bottom of this form.

1. Visitors shall not enter any Restricted Area or any area posted with radiological warnings or cautions unless a Waiver of Training form has been completed and the visitor is properly escorted.

2. Visitors who do enter Restricted Areas shall have their dose estimated by the RSO or be issued a monitoring device.

3. During emergencies the visitor shall remain in the custody of their escort and follow the escort's instructions.

Visitor's signature: _____ Date: _____

Visitor's printed name: _____

Escort agreement: I understand that as the escort for the above mentioned visitor, I am responsible for their radiation protection while they are within the AMS controlled area. The visitor has been shown an example of a radiation symbol and a radiological caution sign.

Escort's signature: _____ Date: _____

Individual administering briefing:

Signature: _____ Date: _____

Distribution: RSO (original)
Visitor
Escort

ATTACHMENT 2

GENERAL EMPLOYEE TRAINING IN RADIATION PROTECTION

1. General Employee Training in Radiation Protection (GET) is administered to all employees permitted unescorted access to the London Road Facility of AMS.

2. GET addresses the following topics:

   a. The type and form of radioactive material present at the facility.
   b. The location of USNRC and AMS radiation protection policies and procedures.
   c. Employee and management responsibilities for radiation safety.
   d. Identification of radiation postings and barriers.
   e. Emergency procedures.
   f. Industrial safety.

3. GET consists of classroom lecture and a question/answer period.

4. Although not required, AMS may test individuals in GET to ensure proficiency. If a written test is administered, a score of 80% is required to successfully complete the course. Employees failing an exam shall review the incorrectly answered questions with the RSO. Following the review a second test may be administered. If so, a score of 80% is required for passing. Any employee failing the second test shall be required to attend another GET session.

ATTACHMENT 3

RADIATION WORKER TRAINING IN RADIATION PROTECTION

1. Radiation Worker Training in Radiation Protection (RWT) is administered to any employee, visitor or contractor with the potential to receive in excess of 100 millirem TEDE within one calendar year at the London Road facility of AMS.

2. RWT shall address the following topics:
   a. Radioactivity and radioactive decay.
   b. Characteristics of ionizing radiation.
   c. Man-made radiation sources.
   d. Acute effects of exposure to radiation.
   e. Risks associated with occupational radiation exposures.
   f. Special considerations in the exposure of women of reproductive age.
   g. Dose-equivalent limits.
   h. Modes of exposure - internal and external.
   i. Dose-equivalent determinations.
   j. Basic protective measures - time, distance, shielding.
   k. Specific procedures for maintaining exposures as low as reasonably achievable.
   l. Radiation survey instrumentation - calibration, use and limitations.
   m. Radiation monitoring programs and procedures.
   n. Contamination control, including protective clothing, equipment and work place design.
   o. Personnel decontamination.
   p. Emergency procedures.
   q. Warning signs, labels, and alarms.
   r. Responsibilities of employees and management.
   s. Interaction with radiation safety staff.
   t. The location of operational procedures associated with specific job assignments (e.g., handling radioactive material, HEPA filter changes).

3. RWT consists of classroom lecture and a demonstration of practical abilities.

4. RWT requires demonstration of proficiency by testing. Each part of the training will be evaluated and a passing score of 80% is required for each part.

5. Review of incorrectly answered questions with the trainer, followed by retesting or repeating the course, are options available to "failed" employees.

6. Workers will be given the opportunity to review their tests and have incorrect responses reviewed for the correct response.

7. Workers with appropriate training and experience may elect to take examinations without benefit of the instruction if arranged in advance with the RSO.

ATTACHMENT 4

WAIVER OF TRAINING

Individual's Name (Print): _____

Individual's Signature: _____

Training course being waived:

___ General Employee Training in Radiation Protection

___ Radiation Worker Training in Radiation Protection

___ Classroom Training

___ Practical Demonstrations

Reason: _____

Escort's Name (Print): _____

Escort's Signature: _____

APPROVALS:

RSO: _____
Signature Date

Vice President: _____
Signature Date

Distribution: RSO (original)
Individual
Escort

Advanced Medical Systems, Inc.

CONTAMINATION CONTROL	Procedure: RSP-009	Revision No.: 000
	Page: 1 of 5	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

TABLE OF CONTENTS

CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure provides requirements and guidelines for controlling radioactive contamination at Advanced Medical Systems, Inc.'s (AMS's) London Road facility.

2 SCOPE

This procedure applies to the controlled area at AMS, and to all AMS employees, contractors and visitors that perform work in the controlled area of the London Road facility.

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-004, "Radiation Protection Records".

3.4 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-005, "ALARA Program".

3.5 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-008, "Instrumentation and Surveillance".

3.6 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-011, "Radiological Areas and Posting"

3.7 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-012, "Control of Work"

3.8 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-016, "Emergency Response and Notifications".

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 shall supply adequate resources to ensure compliance with this procedure.

5.1.2 The Radiation Safety Officer (RSO) shall:

5.1.2.1 Assure that the requirements of this procedure are met.

5.1.2.2 Assure that all Radiation Protection Technicians are trained in the provisions of this procedure.

5.1.2.3 Verify compliance with this procedure during planned and periodic audits of the Radiation Protection Program.

5.1.3 The Radiation Safety Committee (RSC) shall review unusual incidents involving contamination pursuant to RSP-016.

5.1.4 Radiation Protection Technicians, Authorized Users and contractors shall

5.1.4.1 Comply with applicable requirements of this procedure.

5.1.4.2 Report any unusual findings to the RSO.

5.2 Contamination Limits

5.2.1 Personnel and equipment are considered to be contaminated if the surface being surveyed exceeds the following release criteria:

5.2.1.1 Loose contamination limits for uncontaminated areas are as shown in Attachment 1.

Note: Loose contamination in Contamination Areas within Restricted Areas may exceed these criteria.

5.2.1.2 Total (fixed plus removable) contamination limits for uncontaminated areas are as shown in Attachment 1.

Note: Total contamination in Contamination Areas within Restricted Areas may exceed these criteria.

5.2.2 Screening levels, as shown in Attachment 1 and following the measurement methodology described in RSP-008 may be used to demonstrate compliance with the release criteria.

5.3 Tagging and Posting

5.3.1 Contamination Areas shall be posted/labeled in accordance with RSP-011.

5.3.2 All contaminated items that are not secured within a restricted area shall be tagged with information on extent and type of contamination.

5.4 Protection of Personnel

5.4.1 All unescorted personnel should wear personal protective clothing (PCs) in contaminated areas.

Note: PC may include shoe covers, coveralls, hood, gloves, face shields, other items, or any combination thereof.

5.4.2 The level of PC shall be specified in a Radiation Work Permit (RSP-012) or by the RSO.

5.4.3 Whole body frisks upon exiting Contamination Areas shall be required.

5.5 Measurement Methodologies

5.5.1 Removable contamination on surfaces shall be measured pursuant to RSP-008.

5.5.2 Total (fixed plus removable) contamination on surfaces shall be measured pursuant to RSP-008.

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.

7 DOCUMENTATION

All records pertinent to this procedure shall be maintained pursuant to RSP-004.

8 ATTACHMENTS

Attachment 1: Release Criteria

ATTACHMENT 1
RELEASE CRITERIA

NUCLIDE[1]	REMOVABLE[2,4]	TOTAL[2,3] (FIXED PLUS REMOVABLE)	SCREENING LEVEL[5]
U-nat, U-235, U-238 and associated decay products	1,000 dpm α/100 cm^2	5,000 dpm α/100 cm^2	--
Cobalt-60 and Cesium-137	1,000 dpm β/γ per 100 cm^2	5,000 dpm β/γ per100 cm^2	60 cpm above background

---

1 Where surface contamination by both α and β-gamma-emitting radionuclides exists, the limits established for α and β-gamma-emitting radionuclides should apply independently.

2 As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

3 The levels may be averaged over 1 m^2, provided the maximum surface activity in any area of 100 cm^2 is less than three times the guide values. For purposes of averaging, any square meter of surface shall be considered to be above the activity guide G if: (1) from measurements of a representative number (n) of sections it is determined that $1/n \, \Sigma_n \, S_i \geq G$, where S_i is the dis/min-100 cm^2 determined from measurement of section I; or (2) it is determined that the sum of the activity of all isolated spots or particles in any 100 cm^2 area exceeds 3G.

4 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area less than 100 cm^2 is determined, the activity per unit area should be based on the actual area and the entire surface should be wiped. It is not necessary to use wiping techniques to measure removable contamination levels if direct scan surveys indicate that the total residual surface contamination levels are within the limits for removable contamination.

X This screening level is based upon the assumptions that a pancake GM detector with a 60 cm^2 active area is used as described in RSP-008, that the detector efficiency is 10% for β/γ activity, and that the removable activity is the limiting value.

Advanced Medical Systems, Inc.

RADIOLOGICAL AREAS AND POSTING	Procedure: RSP-011	Revision No.: 000
	Page: 1 of 5	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

TABLE OF CONTENTS

CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure describes the radiological areas and posting requirements for the Advanced Medical Systems, Inc. (AMS) facility on London Road.

2 SCOPE

This procedure applies to all controlled and restricted areas at the London Road facility.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports for Workers; Inspection and Investigations"

3.2 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.3 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-001, "Radiation Protection Records".

3.5 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-007, "Training in Radiation Protection".

4 DEFINITIONS

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

5 PROCEDURE

5.1 Responsibilities

5.1.1 The Radiation Safety Officer (RSO) shall:

5.1.1.1 Ensure radiological areas are established based upon radiological conditions.

5.1.1.2 Approve all work in restricted areas prior to the beginning of work.

5.1.1.3 Ensure that all employees understand the appropriate labeling of radiological areas.

5.1.1.4 Ensure removal of radiation hazard identification postings when the conditions requiring their use no longer exist.

5.1.2 Radiation Protection Technicians shall periodically observe radiological areas to ensure that the requirements of this procedure are being met.

5.1.3 AMS personnel shall:

5.1.3.1 Observe and obey radiological areas and postings.

5.1.3.2 Periodically review this procedure.

5.2 Areas to be Posted

5.2.1 Radiological area posting/labeling requirements throughout AMS shall be as described in 10 CFR 20, Subpart J.

5.2.2 The following radiological areas may be established by the RSO:

5.2.2.1 Restricted Areas

5.2.2.2 Radiation Areas

5.2.2.3 High Radiation Areas

5.2.2.4 Very High Radiation Areas

5.2.2.5 Airborne Radioactivity Areas

5.2.2.6 Contaminated Areas

5.2.3 Each area, building, or room in which licensed radioactive materials are stored in quantities that exceed 10 times the quantity of such materials shown in 10 CFR Appendix C of 20.1001-2401 shall be posted with the magenta and yellow symbol and the words "CAUTION - RADIOACTIVE MATERIAL(S)" at each entrance point.

Note: For ^{60}Co and depleted uranium, the Appendix C quantities are one (1) microcurie and 100 microcuries, respectively. If a combination of materials is present (i.e., a combination of uranium and ^{60}Co), the following relationship must be true:

$$\frac{\mu Ci_{Co}}{1} + \frac{\mu Ci_{U}}{100} \geq 1$$

5.2.4 Caution signs may not be necessary in areas/rooms containing radioactive materials for a period of less than eight (8) hours, provided that the materials are attended throughout the temporary storage period by an individual who has been trained in the precautions for radiation exposure of personnel.

5.3 Posting Requirements

5.3.1 The yellow and magenta trefoil (three-blade) radiation symbol shall be used to signify the actual or potential presence of ionizing radiation and to identify objects, devices, materials, or combinations of materials which emit ionizing radiation.

5.3.2 The symbols and color combination of yellow and magenta are not to be used for purposes other than to warn of the actual or potential presence of a radiation contamination hazard.

5.3.3 Each sign, tag, or label shall be displayed prominently and must be recognizable from a safe distance.

Note: The signs and symbols shall conform to 10 CFR 20.1901.

5.3.4 Each posted area shall be defined and clearly marked with appropriate signs and may include a portion or all of a room, building, area, or vehicle.

Note: Areas without clearly defined existing boundaries (e.g., walls or fences) should be defined by the use of magenta/yellow tape, ribbon, or rope.

5.3.5 Supplementary notices specifying the requirements for entry to and exit from a and other special precautions that are to be exercised should be posted in conjunction with radiation warning signs and tags to provide personnel with any required additional instructions or information not given by the signs and tags.

5.3.6 Information signs, tags, labels, and notices shall be kept current, reflecting any changes in radiological conditions.

5.3.7 Warning signs, tags, labels, notices and other radiation hazard identification markings shall be removed only by the RSO when conditions requiring their use no longer exist.

5.3.8 Form USNRC-3, "Notice to Employees" shall be posted in prominent locations within the AMS controlled area, such as employee break rooms and bulletin boards.

5.4 Training

General employees and other personnel permitted unescorted access to the AMS Controlled Area shall be trained in recognition of posting/labeling pursuant to RSP-007.

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.

7 DOCUMENTATION

All records pertinent to this procedure shall be maintained pursuant to RSP-004.

8 ATTACHMENTS

None

Advanced Medical Systems, Inc.

CONTROL OF WORK	Procedure: RSP-012	Revision No.: 000
	Page: 1 of 9	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

TABLE OF CONTENTS

CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure establishes the methods for controlling work involving radioactive materials and radiation producing machines, and for obtaining a Radiation Work Permit (RWP).

2 SCOPE

This procedure applies to all work within a restricted area at Advanced Medical Systems, Inc. (AMS) that is not covered by Radiation Safety Procedures, or for work in controlled areas at AMS or field service sites for which a RWP is deemed necessary by the RSO.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports for Workers; Inspection and Investigations"

3.2 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.3 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.4 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-003, "Radiation Protection Records".

3.5 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-007, "Training in Radiation Protection".

3.6 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-009, "Contamination Control".

3.7 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-010, "Exposure Control".

3.8 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-016, "Emergency Response and Notification".

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 Radiation Safety Officer (RSO) shall:

5.1.1.1 Maintain a supply of Radiation Work Permit (RWP) forms (Attachment 1)

5.1.1.2 Insure that all work performed inside an AMS restricted area is covered by a RSP or a current RWP.

5.1.1.3 Perform periodic surveillance to determine compliance with this procedure.

5.1.1.4 Maintain copies of completed RWP's as part of the radiation protection records.

5.1.1.5 Ensure that RWP requirements are followed by all personnel that enter the area.

5.1.2 AMS personnel performing work under an RWP shall:

5.1.2.1 Review completed RWP's with the RSO who shall provide additional instructions if required.

5.1.2.2 Read the RWP and sign page two (2) of the RWP to indicat knowledge of its requirements.

5.1.2.3 Perform the work in accordance with the requirements specified in the RWP.

5.2 Equipment and Materials that May be Necessary for Work under an RWP

5.2.1 Portable radiation survey meter capable of detecting the radiation likely to be emitted from the samples being analyzed.

5.2.2 Container suitable for collecting contaminated waste and trash.

5.2.3 Warning signs and banners capable of restricting access to area.

5.3 Initiating the RWP

5.3.1 Upon determination that non-routine operations are necessary within a restricted area, the RSO shall initiate the RWP process.

5.3.2 The RSO shall complete the RWP form by providing the following:

5.3.2.1 RWP number.

5.3.2.1.1 The RWP number shall be the year that the RWP is issued, plus a sequential number at the end (ex., 95-01).

5.3.2.1.2 The RWP number shall be entered into a log maintained by the RSO (see Attachment 2).

5.3.2.2 Current and expected radiological conditions.

5.3.2.3 Protective requirements.

5.3.2.4 Special instructions.

5.3.2.5 Approval signature.

5.4 General Requirements

5.4.1 The RWP shall be maintained by the RSO in a location that is readily accessible to the worker.

5.4.1.1 All employees performing the job shall sign and date page two (2) of the RWP for each day that they work under that RWP.

5.4.1.2 Workers shall not be logged under more than one RWP at a time.

5.4.1.3 This signature shall demonstrate the employee's understanding of all requirements.

5.4.1.4 The RSO shall confirm, and initial on page two (2) of the RWP, that the specified dosimetry (TLD, pocket ionization chamber, etc) is being worn.

5.4.2 If job requirements on a RWP change or any unusual/unexpected events occur:

5.4.2.1 The RSO shall be notified as soon as possible

5.4.2.2 A new RWP shall be issued or changes shall be made to the existing RWP.

5.4.3 The RSO shall investigate any suspected personnel contamination incidents pursuant to RSP-016.

5.5 Personnel Requirements

5.5.1 Personnel working inside the restricted area shall:

5.5.1.1 Complete the radiation safety training courses required by RSP-007.

5.5.1.2 Participate in the internal and/or external monitoring program required in RSP-010.

5.5.2 Personnel who have not completed the requirements specified above, may enter the work area if approved by the RSO and escorted by a person designated by the RSO.

5.5.2.1 The visitors shall comply with all elements of the RWP.

5.5.2.2 The escort shall confirm that all visitors have properly surveyed their personal clothing before leaving the zone.

5.5.3 Persons exiting contaminated areas shall perform a whole body frisk before leaving as required in RSP-009.

5.6 Terminating the RWP

5.6.1 A RWP shall be valid for the specified duration or the last day of the current calendar year.

5.6.2 If an activity covered by a RWP exceeds the specified duration, an extension may be granted by the RSO.

5.6.3 The Authorized User shall notify the RSO when the work with the radioactive material is completed.

5.6.4 The RSO shall:

5.6.4.1 Ensure that all materials requiring a RWP have been removed from the area or transferred to a different restricted area.

5.6.4.2 Ensure that all waste and contaminated trash has been removed from the area and is properly stored.

5.6.4.3 Ensure performance of a direct survey of the floors and surfaces that came in contact with the radioactive material.

5.6.4.4 Ensure performance of a wipe test survey of the floors and surfaces that came in contact with the radioactive material.

5.6.5 The RSO shall remove the RWP and other restrictions from the area after the results of the surveys are complete.

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.

7 DOCUMENTATION

All Records pertinent to this procedure shall be maintained pursuant to RSP-003.

8 ATTACHMENTS

8.1 Attachment 1 - Radiation Work Permit

8.2 Attachment 2 - RWP Log

ATTACHMENT 1
RADIATION WORK PERMIT

Permit No:	Type: ☐ Job Specific ☐ Extended
Expiration Date:	

Description and Location of Work:

SURVEY INFORMATION

General Area Dose Rates (mR/hr):
Maximum Accessible Dose Rates (mR/hr):
Removable Contamination (dpm/100 cm^2):

ALARA REVIEW

Estimated Total Dose:	Actual Total Dose:
Pre-Job Briefing by:	Post-Job Briefing by:
Dose Reduction Techniques to be Employed:	

DOSIMETRY REQUIREMENTS

☐ TLD/Film Badge	☐ Finger Ring	☐ SRPD (200mR)	☐ SRPD (1R)	☐ SRPD(5R)
☐ Other (Specify):				

PROTECTIVE EQUIPMENT

☐ Coveralls	☐ Lab Coat	☐ Hood	☐ Rubber Gloves	☐ Booties
☐ Rubbers	☐ Respirator	☐ Taped Seams	☐ HP Coverage	☐ Air Sampling
Other Precautions and Special Instructions:				

Authorized by:
Terminated by:

ATTACHMENT 1 (continued)
ACKNOWLEDGMENT OF RWP REQUIREMENTS

Permit No.____________________

Printed Name	Signature	Date that RWP was Reviewed	RSO Confirmation of Dosimetry Requirements

ATTACHMENT 2
RWP LOG

Permit No.	Preparer	Authorization Date	Termination Date	Description of Work

Advanced Medical Systems, Inc.

CONTROL OF RADIOACTIVE WASTE	Procedure: RSP-013	Revision No.: 000
	Page: 1 of 7	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure describes the methods for the control, segregation, analysis, and disposal of radioactive waste generated at Advanced Medical Systems, Inc. (AMS).

2 SCOPE

This procedure applies to waste materials that have the potential to be contaminated with licensable radioactive material. This procedure is applicable to all work performed by AMS employees, visitors and contractors.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.2 Title 10, Code of Federal Regulations, Part 71, "Packaging and Transportation of Radioactive Material".

3.3 Title 49, Code of Federal Regulations, Subpart C, Parts 171 through 177, "Hazardous Materials Regulations".

3.4 Environmental Protection Agency, Title 40, Code of Federal Regulations, Part 240 through 281, "Resource Conservation and Recovery Act".

3.5 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.6 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-015, "Packaging and Transportation of Radioactive Materials".

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 shall supply adequate resources to ensure compliance with this procedure.

5.1.2 The Radiation Safety Officer (RSO) shall:

5.1.2.1 Train Radiation Protection Technicians on the requirements of this procedure, as applicable.

5.1.2.2 Identify waste collection points and supervise the storage of radioactive wastes at these locations.

5.1.2.3 Make final waste disposal arrangements with vendors as necessary.

5.1.2.4 Maintain a records of packaged waste.

5.1.2.5 Confirm that the requirements of this procedure are met during planned and periodic audits of the Radiation Protection Program.

5.1.3 Radiation Protection Technicians shall be responsible for:

5.1.3.1 Ensuring that only plastic bags are used for collection of contaminated waste.

Note: Normally these are equivalent to 55-gallon drum liners.

5.1.3.2 Sealing and transporting contaminated waste bags.

5.1.3.3 Handling radioactive waste in a manner that prevents the spread of contamination.

5.1.3.4 Segregating wastes in appropriately-marked containers.

5.1.3.5 Complying with the applicable requirements of this procedure.

5.1.3.6 Periodically reviewing the requirements of this procedure.

5.2 Control of Waste

5.2.1 Control of radioactive waste materials should be accomplished by the following:

5.2.1.1 Preventing materials from becoming unnecessarily and/or excessively contaminated;

5.2.1.2 Decontaminating and reusing radioactive materials such as tools and equipment;

5.2.1.3 Re-cycling;

5.2.1.4 Using waste volume reduction techniques when practical; and

5.2.1.5 Monitoring materials for radioactivity and removing non-radioactive materials prior to disposal.

5.2.2 Radioactive waste streams generated at AMS may include dry solid waste, dry combustible waste and liquid waste.

5.3 Collection of Waste

5.3.1 Each restricted area that generates radioactive waste shall have designated waste collection locations.

5.3.2 Precautions to prevent mixing of various hazardous substances when organizing the waste disposal area should be instituted.

5.3.3 If a bag tears during collection, the waste shall be re-packaged.

5.4 Screening Drummed Waste

5.4.1 Radiological screening shall be performed on all packaged waste.

5.4.2 The following steps shall be taken to screen drummed waste:

5.4.2.1 Don lab coat (or coveralls), safety glasses and gloves prior to the start of work.

5.4.2.2 Assign a unique identification number to the drum and record the number on the Waste Screening Form (Attachment 1)

5.4.2.3 Inspect the drum.

Note: If the drum is leaking, off-gassing, or bulging, do not open the drum, and notify the RSO immediately.

5.4.2.4 Perform ambient and contact exposure rate surveys as described in RSP-008 and record results on Waste Screening Form.

5.4.3 A label containing the curie content of the drum should be affixed to the drum.

5.5 Waste Disposal

5.5.1 Radioactive waste generated by AMS shall be stored on site in a restricted area.

5.5.2 Alternative means of disposal, such as the following, may be implemented:

5.5.2.1 Transfer to a waste disposal service which is licensed to receive such waste in accordance with 10 CFR 20.2001;

5.5.2.2 Transfer to the original supplier which is properly licensed to receive radioactive materials;

5.5.2.3 Transfer to an authorized recipient as provided for in 10 CFR 20.2001;

5.5.2.4 Release into the sanitary sewer in conformance with USNRC 10 CFR 20.2003;

5.5.2.5 Recycled; or

5.5.2.6 Other means specifically approved in advance by the USNRC pursuant to 10 CFR 20, Subpart K.

5.5.3 For off-site disposal, the RSO should perform the following:

5.5.3.1 Contract an independent licensed vendor to seal, survey, pick up and transport filled drums to a final disposal facility, or

5.5.3.2 Arrange transfer and disposal of sealed, surveyed, and manifested drums to a disposal facility.

5.5.4 The RSO, in conjunction with the disposal vendor, shall confirm that each container is sealed and surveyed for radioactive contamination before the containers leave the waste area.

5.5.5 The RSO shall provide the disposal vendor with the inventory of radioactive materials contained in the waste drums.

5.5.6 The RSO shall determine when the capacity of a radioactive waste collection area dictates a radioactive waste shipment to a commercial disposal facility or waste broker.

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.

7 DOCUMENTATION

All Records pertinent to this procedure shall be maintained pursuant to RSP-003.

8 ATTACHMENTS

Attachment 1: Waste Screening Form

ATTACHMENT 1
WASTE SCREENING FORM

Waste Drum Number:	Drum Weight:
Description of Contents:	Drum Location:

EXPOSURE RATE SURVEY RESULTS (mr/hr)	
Instrument Serial No:	Calibration Due:
Contact Exposure Rate - Top:	Contact Exposure Rate - Bottom:
Contact Exposure Rate - Side (min):	Contact Exposure Rate - Side (max):
Ambient Exposure Rate (Quadrant 1):	Ambient Exposure Rate (Quadrant 3):
Ambient Exposure Rate (Quadrant 2):	Ambient Exposure Rate (Quadrant 4):
Transport Index:	Curie Content:

CONTAMINATION SURVEY RESULTS (dpm/100 cm^2)	
Total (fixed plus removable) - Top:	Total - Bottom
Total - Side (min):	Total - Side (max)
Removable (max):	

Survey Performed By:	Signature:
Date of Survey:	Time of Survey:
Approved by:	Signature

Advanced Medical Systems, Inc.

EMERGENCY RESPONSE AND NOTIFICATIONS	Procedure: RSP-016	Revision No.: 000
	Page: 1 of 23	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure contains the general policies and actions to be implemented during incidents or emergencies where radioactive materials or radiation sources are handled or stored at Advanced Medical Systems, Inc. (AMS). It establishes the responsibilities and methods by which incident/events are to be reported, documented, reviewed, distributed, and the root cause(s) determined in order to develop corrective action to minimize or prevent the same or similar occurrences.

2 SCOPE

This procedure applies to all AMS and contractor personnel working with or in the vicinity of radioactive material or radiation sources at AMS.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation"

3.2 U. S. Nuclear Regulatory Commission Regulatory Guide 3.67, "Standard Format and content for Emergency Plans for Fuel Cycle and Materials Facilities".

3.3 U. S. Nuclear Regulatory Commission Radioactive Material License No. 34-19089-01.

3.4 Advanced Medical Systems, Inc.,"Emergency Plan for the London Road Facility", Revision 0, 1995.

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 shall:

5.1.1.1 Review and approve the requirements of this procedure.

5.1.1.2 Supply adequate resources to ensure compliance with this procedure.

5.1.1.3 Designate a corporate official to serve as a spokesperson (public information manager).

5.1.1.4 Respond in the event of an alert or site area emergency.

5.1.2 The Radiation Safety Officer (RSO) shall:

5.1.2.1 Assure that all personnel working in a radiologically-controlled area are instructed in the procedures for responding to an incident or emergency involving radioactive material.

5.1.2.2 Check the status of emergency equipment on a planned and periodic basis.

5.1.2.3 Notify the USNRC of any incident involving licensed material pursuant to the reporting requirements contained in 10 CFR 20.

5.1.2.4 In the event of an emergency:

5.1.2.4.1 Act as the Emergency Manager

5.1.2.4.2 Classify, upgrade and downgrade the emergency

5.1.2.4.3 Activate the "Emergency Plan for the London Road Facility"

5.1.2.4.4 Exchange information with authorities responsible for off-site emergency response;

5.1.2.4.5 Initiate and direct restoration;

5.1.2.4.6 Participate in critiques

5.1.2.4.7 Recommend revisions to the "Emergency Plan for the London Road Facility".

5.1.3 The Isotope Committee shall review unusual incidents involving radioactivity or radiation-producing machines and provide recommendations to the Vice President on how their reoccurrence should be prevented.

5.1.4 AMS personnel shall

5.1.4.1 Comply with the requirements of this procedure.

5.1.4.2 Participate in emergencies as described in the "Emergency Plan for the London Road Facility".

5.1.4.3 Be aware of the location of emergency exits, first-aid supplies, eyewash stations, safety showers, emergency supplies, fire alarms, and communications equipment.

5.1.4.4 Immediately notify the RSO of any known or suspected incident or emergency.

5.1.4.5 Periodically review this procedure.

5.2 General Requirements

5.2.1 The basic initiatives and actions for responding to incidents or emergencies at AMS are contained in the AMS "Emergency Plan for the London Road Facility".

5.2.2 All applicable safety and compliance guidelines set forth by AMS and federal, state, and local regulations shall be followed during an emergency.

5.2.3 Work shall be stopped in the event of a known or potential compromise to the health or safety of any AMS or contractor personnel and shall be reported immediately to the RSO.

5.2.4 Following a radiological incident or emergency, the RSO shall determine the need to collect personnel dosimeters for immediate processing.

5.2.5 If it is known or suspected that radioactive material has been taken into the body, the RSO shall evaluate the amount of material ingested/inhaled and the resulting exposure.

Note: This investigation may include air sampling and analysis, bioassays, or whole body counting, as needed.

5.3 Emergency Response

5.3.1 When an individual identifies an incident/event (I/E) that meets (or may potentially meet) the criteria shown in Attachment 1, the following shall be performed:

5.3.1.1 Ensure the situation is in a stable, safe condition, taking all required immediate corrective action;

5.3.1.2 Notify the RSO.

5.3.2 After notification, the RSO shall perform the following:

5.3.2.1 Make a determination if an I/E as described in Attachment 1 has occurred or may have occurred.

5.3.2.2 Ensure the notifications shown in Attachments 1 and 2 are made.

5.3.2.3 Ensure an I/E Report (Attachment 3) is initiated and recorded in the Incident/Event Report Log (Attachment 4) for tracking purposes.

5.3.2.4 Ensure that a critique is conducted and the critique package (Attachments 5-7) is assembled and attached to the I/E Report.

5.3.3 Upon completion of the critique and other initial review activities, the RSO sha determine whether the I/E should be reviewed or completed by other organizations such as independent, third-parties.

Note: If deemed appropriate, this course of action should be entered as immediate corrective action on Attachment 3.

5.3.4 The remainder of the report shall then be completed and all accompanying information shall be attached.

5.3.4.1 Root cause analysis may be required for certain events.

5.3.4.1.1 If the RSO determines root cause analysis is required, he/she shall assign an individual who has been formally trained or h previous experience in completing this action.

5.3.4.1.2 The analysis shall be attached to the I/E Report.

5.3.4.2 Long-term corrective action shall be specified, assigned, and a response due date entered.

Note: If more than two items are required, add another page 2 of the report and denote accordingly.

5.3.4.3 Each organization/individual assigned long-term corrective action shall indicate their concurrence with these assignments by signature.

5.3.4.4 The I/E Report shall be approved by the Vice President.

5.3.5 Verification of corrective action completion shall be periodically conducted by the RSO.

5.3.6 Closure of outstanding items shall be confirmed by the Isotope Committee.

5.4 Loss or Theft of Radioactive Material

5.4.1 The RSO shall determine whether a radiological hazard exists.

5.4.2 Notifications as described in Attachment 1 shall be made.

5.4.3 Personnel shall be questioned and attempts to locate the missing material through the use of survey instruments may be initiated.

5.5 Unauthorized or Accidental Entry to Restricted Area

5.5.1 The RSO shall determine whether a radiological hazard existed.

5.5.2 The RSO shall garner the facts and prepare a report that contains the following:

5.5.2.1 Name, address, employer, telephone number and social security number of individual.

5.5.2.2 Description of the radiation source/field.

5.5.2.3 Distance, time and portion of body that was exposed.

5.5.3 Notifications pursuant to Attachment 1 shall be made.

5.6 Electrical Power Failure

5.6.1 The RSO shall determine whether a radiological hazard exists and take appropriate action to control or contain the hazard.

5.6.2 The RSO and local utility shall determine the cause of a local power failure and, if possible, take corrective action to restore electrical power.

5.6.3 In the event of a general power failure, radiological activities shall cease until power is restored and the RSO has determined that operations can resume safely.

5.6.4 Notifications pursuant to Attachment 1 shall be made.

5.7 Minor Spills or Releases

5.7.1 All other persons in the area of the spill shall be notified at once.

5.7.2 The spill should be confined immediately.

5.7.3 The RSO shall be notified as soon as possible.

5.7.4 The RSO shall establish a contamination zone in the area of the spill by erecting barriers and or posting signs, as necessary.

5.7.5 The RSO shall restrict access of unnecessary personnel to the spill area.

5.7.6 The RSO shall supervise decontamination efforts.

5.7.7 For liquid spills

5.7.7.1 Don protective gloves

5.7.7.2 Drop absorbent paper on spill

5.7.7.3 Notify the RSO.

5.7.8 For dry spills:

5.7.8.1 Don protective gloves

5.7.8.2 Dampen the material thoroughly, taking care not to spread the contamination.

5.7.8.3 Notify the RSO.

5.7.9 Work in the area may resume after radiation surveys confirm that levels of radioactive contamination are below the action levels established in ISP-2, "Area Survey Procedure".

5.7.10 Notifications pursuant to Attachment 2 shall be made.

5.7.11 Injuries to personnel involving contamination shall be handled as described in "Emergency Plan for the London Road Facility"

5.7.12 Bioassay samples may be collected and analyzed pursuant to ISP-36.

5.8 Major Spills or Releases

5.8.1 All persons in the area shall be alerted and the area shall be cleared of unnecessary personnel.

5.8.2 Individuals shall be surveyed for radioactive contamination upon leaving radiological hazard areas by radiation protection personnel.

5.8.3 The RSO shall be notified as soon as possible.

5.8.4 The RSO shall restrict access to the area and post conspicuous warnings or guards to prevent accidental entry.

5.8.5 If the spill is liquid, and the hands are protected, the container shall be placed in an upright position.

5.8.6 If the spill is on the clothing, outer or protective clothing shall be removed at once, segregating it from other personal articles of clothing.

5.8.7 The RSO shall secure the area upon exit after confirming that the area has been evacuated.

5.8.8 The individual(s) involved in the incident should remain as close to the area as possible while awaiting the arrival of the RSO in order to minimize the spread of contamination.

5.8.9 All persons who evacuated the area shall be monitored (frisked) by a radiation surveyor.

5.8.10 Notifications pursuant to Attachment 1 shall be made.

5.9 Minor Fires

5.9.1 Employees shall only attempt to put out fires if a radiological hazard is not immediately apparent and if the fire is small enough to be completely smothered with an available fire extinguisher.

5.9.2 Firefighting and other emergency activities shall be restricted by the RSO to avoid tracking of contamination or passing of contaminated equipment into clean areas.

5.9.3 All persons involved in combating the fire shall be frisked and decontaminated, as necessary.

5.9.4 Following the emergency and prior to decontamination, the radiological status of the area shall be determined.

5.10 Emergencies Involving Significant (greater than 50 rad) Personnel Exposure (External)

5.10.1 The individual involved in the operation shall be removed from the area immediately and frisked.

5.10.2 The individual shall be examined by a physician as soon as possible

5.10.3 All details of the incident shall be recorded.

5.10.4 Personnel dosimeters shall be processed on a rapid turn-around basis.

5.10.5 The individual shall not be permitted to return to the work area until authorized to do so by the RSO.

5.11 Fires, Explosions or Other Major Emergencies

5.11.1 All other persons in the area shall be alerted and the building shall be evacuated.

5.11.2 All personnel not involved with the emergency shall walk to the nearest unencumbered exit and proceed to an established assembly point.

5.11.3 Notifications pursuant to Attachment 1 shall be made.

5.11.4 Employees shall only attempt to put out fires if a radiological hazard is not immediately apparent and if the fire is small enough to be completely smothered with an available fire extinguisher.

5.11.5 If ingestion or inhalation of radioactivity is possible, sand should be used instead of fire extinguisher to smother the fire.

5.11.6 Upon arrival, firemen shall be cautioned as to where radioactive materials are stored.

Note: Firemen should be advised of the best entrance route to the fire and any precautions necessary to avoid exposure or risk of creating contamination. Additional facility layout maps should also be made available.

5.11.7 Firemen shall not be permitted to enter a radiation area after the fire has been extinguished until the RSO evaluates the extent of damage and radiological conditions.

5.11.8 A thorough survey of firemen and their equipment shall be performed prior to their departure from the controlled area.

Note: Personnel and equipment should be decontaminated, as necessary.

5.12 Notifications

5.12.1 Depending upon the type/magnitude of the I/E, notifications as shown in Attachment 1 shall be made.

Note: The telephone numbers and designated representative of those individuals in the emergency response organization are shown in Attachment 2.

5.12.2 Pursuant to Attachment 1, the RSO shall submit an I/E Report (Attachment 3) to the Vice President and Isotope Committee within four working days detailing the circumstances, corrective actions, materials involved, exposures, and other applicable items for each I/E involving a radiological hazard.

5.12.3 The following telephone reports shall be provided to the USNRC Operations Center:

5.12.3.1 Immediate report (within four hours) of events that may result in exposures or releases of licensed material in excess of regulatory limits.

5.12.3.2 Twenty-four hour report of unplanned contamination events as described in 10 CFR 30.50 (b) (1), equipment failure as described in 10 CFR 30 (b) (2), unplanned medical treatment of a contaminated victim, or unplanned fire or explosion involving greater than 150 microcuries of ^{60}Co.

5.12.4 A written follow-up report to the USNRC Document Control Desk, Washington, D.C., and to Region III shall be provided within 30 days of the initial report and shall contain:

5.12.4.1 A description of the event, including location, date and time.

5.12.4.2 The radionuclides, quantities and chemical form of the licensed material involved.

5.12.4.3 Extent of personnel exposures.

5.12.4.4 Summary of corrective actions taken/planned.

5.13 Public Information

5.13.1 Information to the public and media shall be provided in the event of a Site Area Emergency.

5.13.2 Public information shall be relayed by a single corporate spokesperson designated by the Vice President.

5.13.3 In the absence of a spokesperson, the RSO shall provide public information.

5.14 Critiques

5.14.1 Pursuant to Attachment 1, the RSO shall initiate the critique activities when required.

5.14.2 The RSO shall be designated as the critique chairman unless a third party chairman is deemed appropriate by the Isotope Committee.

5.14.3 The chairman shall gather all involved or concerned personnel.

Note: Attendance at critiques is mandatory.

5.14.4 Attendance at critiques shall be documented on the Critique Attendance Form (Attachment 5).

5.14.5 Statements of all appropriate personnel shall be obtained and documented on the Statements by Involved Personnel form (Attachment 6).

Note: Consideration should be given to obtaining statements and conducting individual interviews prior to the critique.

5.14.6 The chairman shall ensure that minutes are taken at the critique and documented on the Critique Report form (Attachment 7).

5.14.7 The critique should attempt to determine the following, as appropriate;

5.14.7.1 An accurate chronology of events

5.14.7.2 Actual and expected responses of personnel and equipment

5.14.7.3 Adequacy of procedures

5.14.7.4 Factors affecting personnel performance (e.g., training, qualifications, mental/physical state)

5.14.7.5 Adequacy of immediate corrective action

5.14.7.6 Comparison with other similar events

5.14.8 After the critique, the critique package (i.e., Critique Attendance forms, Statements by Involved Personnel forms, and Critique Report forms) shall be assembled and incorporated as part of the Incident/Event Report.

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 approval by the USNRC.

7 DOCUMENTATION

7.1 All Records pertinent to this procedure shall be maintained pursuant to the AMS records retention policy.

7.2 The following documents shall be retained by the RSO:

7.2.1 Letters of agreement with local response organizations.

7.2.2 Training records, including lesson plans and test questions.

7.2.3 Drills, exercises, and related critiques.

7.2.4 Inventory of emergency equipment and supplies.

7.2.5 Revisions of "Emergency Plan for the London Road Facility"

7.2.6 Personnel Decontamination Records;

7.2.7 Area/Equipment Decontamination Records;

7.2.8 RSO contingency or emergency reports.

7.2.9 Incident/Event Reports

7.2.10 Incident/Event Logs

7.2.11 Critique Attendance Forms

7.2.12 Statements by Involved Personnel

7.2.13 Critique Reports

8 ATTACHMENTS

8.1 Attachment 1 - Radiological Incidents/Events Classification

8.2 Attachment 2 - Emergency Response Organization

8.2 Attachment 3 - Incident/Event Report Form

8.3 Attachment 4 - Incident/Event Report Log Sheet

8.5 Attachment 5 - Critique Attendance Form

8.6 Attachment 6 - Statement by Involved Personnel Form

8.7 Attachment 7 - Critique Report Form

ATTACHMENT 1
RADIOLOGICAL INCIDENTS/EVENTS CLASSIFICATION

F = Fire; X = Explosion; IJ = Injury; P - Personnel Exposure; SP = Spill; L = Loss/Theft; T = Transportation; ND = Natural Disaster; O = Other

Event Type	Mechanism	Action Levels	Classification	Notifications	Actions	I/E Report	Critique
Loss or Theft	L, IJ, P	Potential for exposure rates of <20 mR/hr	Unusual Event	USNRC Region III	Operating staff to a state of readiness	yes	no
	L, IJ, P	Potential for exposure rates >20 mR/hr	Alert	USNRC Region III City of Cleveland Police Department	Operating staff to a state of readiness; provide off-site authorities with sequence of events	yes	no
	L, IJ, P	Potential for exposure rates >100 mR/hr	Site Area Emergency	USNRC Command Center City of Cleveland Police Department	Operating staff to a state of readiness; provide off-site authorities with sequence of events	yes	yes
Loss of Electrical Power	P	Personnel exposure in excess of 250 mrad	Incident	Cleveland Electric Illuminating	RSO secures condition	no	no
	P	Personnel exposure in excess of 5000 mrad	Alert	Cleveland Electric Illuminating USNRC Region III	RSO secures condition; operating staff to a state of readiness	yes	no
	P	Personnel exposure in excess of 50 rad	Alert	Cleveland Electric Illuminating USNRC Region III University Hospital of Cleveland Cleveland Emergency Medical Services	RSO secures condition; emergency personnel to a state of readiness	yes	yes

Event Type	Mechanism	Action Levels	Classification	Notifications	Actions	I/E Report	Critique
Minor spill	SP, IJ, T	Unexpected Airborne activity in the building <10 DAC over 24 hours	Incident	None	RSO secures condition	no	no
	SP, P, T	Unexpected exposure rates in the building <20 mR/hr	Incident	None	RSO secures condition	no	no
Major Spill	SP, IJ, P, T, F	Unexpected Airborne activity in the building >10 DAC over 24 hours or exposure rates in the building > 20 mR/hr	Unusual Event	USNRC Region III	Operating staff to state of readiness	yes	no
Minor Release	F,X,L, IJ, P	Actual or projected effluents >10 DAC over 24 hours	Unusual Event	None	Operating staff to state of readiness	yes	no
	F,X,L, IJ, P	Actual or projected effluents >50 DAC over 24 hours	Alert	USNRC Region III	Operating staff to a state of readiness; provide off-site authorities with status reports	yes	yes
	F,X,L, IJ, P	Actual or projected site boundary exposure rates >20 mR/hr	Alert	USNRC Region III	Operating staff to a state of readiness; off-site emergency response agencies to a state of readiness; provide off-site authorities with status reports	yes	yes

Event Type	Mechanism	Action Levels	Classification	Notifications	Actions	I/E Report	Critique
Major Release	F,X,L, ND, IJ, P	Actual or projected effluents >250 DAC over 24 hours	Site Area Emergency	USNRC Operations Center Ohio Emergency Management Agency Ohio Department of Health Ohio Environmental Protection Agency	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; provide public information; provide off-site authorities with status reports	yes	yes
	F,X,L, ND, IJ, P	Actual or projected site boundary exposure rates >100 mrem/hr	Site Area Emergency	USNRC Operations Center Ohio Emergency Management Agency Ohio Department of Health Ohio Environmental Protection Agency	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; provide public information; provide off-site authorities with status reports	yes	yes

ATTACHMENT 2
EMERGENCY RESPONSE ORGANIZATION

Corporate Personnel
David Cesar - Vice President 216-466-4671 216-731-5235 (Home)

Facility Personnel
Robert Meschter, R.S.O. 216-692-3270 216-298-1462 (home)
Stephen Haddock 216-692-3269 216-953-3966 (home)
Christopher Reed 216-692-3269 216-205-1300 (home)
IEM, Inc. 301-762-0502 423-531-9140
ADT Security Services 216-526-9539

Off-site Personnel First Responders
Ohio Emergency Management Agency Larry Grove 614-889-7150
USNRC Operations Center 301-816-5100
City of Cleveland Fire Department Lloyd T. Root 911 or 216-621-1212
City of Cleveland Police Department Commander Robert Cermak 911 or 216-621-1234
Cleveland Emergency Medical Services 911 or 216-623-4545
University Hospital of Cleveland 216-844-3835
Ohio Department of Health Robert Owens, Chief 614-644-2727
Ohio Environmental Protection Agency Jane Hart, Chairperson 614-644-2776

Secondary Responders
USNRC Region III James Caldwell 708-829-9500
Ohio State Highway Patrol 216-587-4305
City of Cleveland Division of Water 216-644-2444 or 216-552-7899
Cuyahoga County LEPC 216-443-7597
Cleveland Electric Illuminating Co 216-479-1234
Northeast Ohio Regional Sewer District 216-881-6600

ATTACHMENT 3

ADVANCED MEDICAL SYSTEMS, INC.

INCIDENT/EVENT REPORT

I/E Number _____ Page ___ of ___

I/E Date:	I/E Location:
I/E Time:	Areas/Equipment Effected:

I/E CLASSIFICATION	EVENT TYPE	
☐ Site Area Emergency	☐ Electrical Failure	☐ Injury to Personnel Involving Contamination
☐ Alert	☐ Water/Sewer Failure	☐ Natural Disaster
☐ Unusual Event	☐ Security	☐ Fire
☐ Incident	☐ Minor Spill or Release (on-site)	☐ Minor Release (off site)
☐ Transportation Event	☐ Major Spill or Release (on-site)	☐ Major Release (off site)
☐ Information Only	☐ Other (Describe)	
☐ Other		

EVENT DESCRIPTION

NOTIFICATIONS			
☐ USNRC Region III	☐ University Hospital of Cleveland	☐ ADT Security Services	☐ Other
☐ USNRC Operations Center	☐ Ohio Emergency Management Agency	☐ IEM	☐ Other
☐ Cleveland Fire Department	☐ Cleveland Emergency Medical Services	☐ Ohio Department of Health	☐ Other
☐ Cleveland Police Department	☐ Ohio State Highway Patrol	☐ Ohio Environmental Protection Agency	☐ Other

☐ CRITIQUE HELD	IF YES, DATE/TIME:	☐ ROOT CAUSE ANALYSIS REQUIRED

APPARENT CAUSE:	IMMEDIATE CORRECTIVE ACTIONS:

ATTACHMENT 3 (CONTINUED)

ADVANCED MEDICAL SYSTEMS, INC.

INCIDENT/EVENT REPORT
(Continued)

Page ___ of ___

ADDITIONAL INFORMATION/CORRECTIVE ACTIONS/COMMITMENTS

SIGNATURES	
Prepared by:	Approved by (Vice President):
Approved by (RSO)	Approved by (Other, specify):
Long-term Corrective Action Plan Approved by:	

ATTACHMENT 4
INCIDENT/EVENT REPORT LOG SHEET

ADVANCED MEDICAL SYSTEMS, INC.

INCIDENT/EVENT REPORT LOG

Page ___ of ___

I/E NUMBER YY-XXX	DESCRIPTION	DATE OF OCCURRENCE	DATE REPORT INITIATED	DATE REPORT COMPLETED

ATTACHMENT 5
CRITIQUE ATTENDANCE FORM

ADVANCED MEDICAL SYSTEMS, INC.

CRITIQUE ATTENDANCE FORM

Page ___ of ___

INCIDENT/EVENT REPORT NUMBER: ______________________________

NAME	TITLE/DEPARTMENT	TELEPHONE NUMBER/EXT.

ATTACHMENT 6

ADVANCED MEDICAL SYSTEMS, INC.

STATEMENTS BY INVOLVED PERSONNEL

Page ___ of ___

INCIDENT/EVENT REPORT NUMBER: _____

Describe the event from your perspective. Include all pertinent information such as times, dates, job conditions, sequence of events, action taken, and any other related information.

Name:

_____ _____ _____

PRINT SIGNATURE DATE

ATTACHMENT 7

ADVANCED MEDICAL SYSTEMS, INC.

CRITIQUE REPORT

Page ___ of ___

INCIDENT/EVENT REPORT NUMBER: _____

Critique Minutes:

Recorded by: _____ _____
SIGNATURE DATE

Advanced Medical Systems, Inc.

STOP WORK AUTHORITY	Procedure: RSP-017	Revision No.: 000
	Page: 1 of 6	Date: December 28, 1995
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

This procedure describes situations that may require a Stop-Work order to be initiated at the London Road facility of Advanced Medical Systems, Inc. (AMS) and assigns responsibilities associated with the Stop-Work order.

2 SCOPE

This procedure applies to work situations that do or may violate regulatory or AMS requirements for radiological protection, and pertains to all AMS employees and contractors.

3 REFERENCES

3.1 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.2 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.3 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan"

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-006, "Training and Qualifications of Radiation Protection Personnel"

3.5 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-003,"Radiation Protection Records"

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 Radiation Safety Officer (RSO) shall:

5.1.1.1 Delegate authority to stop work to Radiation Protection Technicians and Authorized Users who have been trained in the proper use of their stop-work authority.

5.1.1.2 Shut-down or prevent job from starting if the job may violate regulatory or AMS requirements for radiological protection.

5.1.1.3 Specify the actions that are necessary to continue work and lift the Stop-Work order.

5.1.1.4 Assure that safe work conditions are in place before lifting the Stop-Work order.

5.1.1.5 Maintain the corrective actions implemented after a stop-work order on file upon completion.

5.1.1.6 Assure that the requirements of this procedure are met.

5.1.2 Radiation Protection Technicians and Authorized Users shall:

5.1.2.1 Shut-down or prevent job from starting if the job may violate regulatory or AMS requirements for radiological protection.

5.1.2.2 Specify the actions that are necessary to continue work and lift the Stop-Work order.

5.1.2.3 Assure that the requirements of this procedure are met.

5.1.3 AMS employees, visitors and contractors shall notify the RSO, a Radiation Protection Technician, an Authorized User, or any work supervisor of known or suspected unsafe work conditions.

5.2 Notifications

5.2.1 Once aware of known or suspected unsafe work conditions, the individual shall assesses the situation and shall issue a Stop-Work order if unsafe working conditions are evident.

5.2.2 If a Stop-Work order is issued by a Radiation Protection Technician or an Authorized User, the RSO shall be notified immediately.

5.3 Issuance of a Stop-Work Order

5.3.1 All Radiation Protection Technicians and Authorized Users have the responsibility and authority to initiate a Stop-Work order if they have been trained in this action pursuant to RSP-006.

5.3.2 The following example unplanned situations may require a Stop-Work order to be initiated.

5.3.2.1 Personnel may be exposed to greater than 40 DAC-hours without engineered controls, protective equipment, or monitoring.

5.3.2.2 Personnel may receive greater than 1 rem deep dose equivalent, 2 rem skin dose equivalent, or 6 rem extremity dose equivalent while performing a task.

Note: This list is not all inclusive.

5.3.3 Specific work activities shall be permitted to proceed to a safe condition after issuance of the Stop-Work order.

5.3.4 The RSO should supervise specific work activities as they proceed to a safe shut down.

5.4 Stop Work Record

5.4.1 The Stop Work Record (see Attachment 1) shall specify the corrective actions necessary to remove the Stop-Work order and for work to proceed past one or more specific hold points.

5.4.2 Radiological protection hold points may be developed by the RSO or the individual who initiated the Stop-Work order, after consultation with the appropriate work supervisor.

5.4.3 The RSO shall signify the completion of the individual actions by initialing Attachment 1.

5.4.4 The completed Stop Work Record shall be reviewed by the RSO.

5.5 Removal of a Stop-Work Order

5.5.1 Stop-Work orders shall be lifted by the RSO only after initiating conditions have been alleviated.

5.5.2 The RSO shall monitor operations after removing the Stop-Work order to ensure safe conditions are present.

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.

7 DOCUMENTATION

7.1 Stop work actions and radiological protection hold points shall be documented and maintained by the RSO.

7.2 All other records that are pertinent to this procedures shall be maintained as described in RSP-004.

ATTACHMENTS

Attachment 1 - Stop Work Record

ATTACHMENT 1
STOP WORK RECORD

Date/Time	Building/Location:	Description of Conditions which Triggered Stop-work Order:		
Item No.	**Corrective Actions and Radiological Hold Points**	**Responsible Individual**	**Date/Time Hold Point Released**	**RSO Initials**
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
Stop Work Order Lifted on (date/time):				
RSO (Signature):				

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

January 5, 1996

Kevin G. Null
Nuclear Materials Licensing Branch
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Radiation Safety Procedures for USNRC License No. 34-19089

Dear Mr. Null:

In response to your letter dated December 5, 1995 wherein you requested the opportunity to review the Radiation Safety Procedures (RSPs) that were referenced in our license renewal application dated October 30, 1995, enclosed are the following two additional RSPs:[1]

- RSP-014, "Receipt, Handing and Identification of Radioactive Materials"
- RSP-015, "Packaging and Transportation of Radioactive Materials"

These procedures are being submitted to the USNRC as supplemental information only to assist in your review of our application. They are not to be considered part of the application package or incorporated as license conditions. However, your comments on these RSPs, which have been reviewed and approved by the AMS Radiation Safety Committee, are welcome.

Because our renewal application was originally submitted more than thirty (30) days prior to the expiration date of License No. 34-19089-01, AMS assumes the license will remain in effect, under its existing provisions, until final action is taken on this revised application. Since AMS wishes to institute significant changes in our radiation protection program in order to improve its applicability and auditability, your prompt consideration of our revised application would be greatly appreciated. If you have any questions, please contact me at (216) 692-3270.

Sincerely

Robert Meschter, R.S.O.

cc (w/o attach): D. Cesar
D. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

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[1] RSP-001 and RSP-003 were sent to you previously as part of our October 30, 1995 license renewal application, and RSP-002, RSP-003, RSP-005, RSP-007, RSP-009, RSP-011, RSP-012, RSP-013, RSP-016, and RSP-017 were forwarded to you under separate cover. RSP-006, RSP-008 and RSP-010 are currently undergoing technical and administrative review. As soon as the reviews are complete, the final versions of these RSPs will be immediately forwarded to the USNRC.

Advanced Medical Systems, Inc.

RECEIPT, HANDLING AND IDENTIFICATION OF RADIOACTIVE MATERIALS	Procedure: RSP-014	Revision No.: 000
	Page: 1 of 9	Date: January 3, 1996
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure contains the methodology for receiving, handling, and identifying incoming shipments at Advanced Medical Systems, Inc. (AMS) that are known or suspected to be radioactive or to contain radioactive material.

2 SCOPE

This procedure applies to all functions pertaining to receipt, handling, and identification of incoming shipments known or suspected to be radioactive or to contain radioactive material. Shipments that are known or suspected to contain only radiologically stable (inert) materials are exempt from the provisions of this procedure.

REFERENCES

3.1 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.2 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".

3.3 Title 10, Code of Federal Regulations, Part 71, "Packing and Transportation of Radioactive Material".

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan".

3.5 Advanced Medical Systems, Inc. Standard Operating Procedure No. RSP-008, "Instrumentation and Surveillance".

3.6 Advanced Medical Systems, Inc. Standard Operating Procedure No. RSP-009, "Contamination Control".

3.7 Advanced Medical Systems, Inc. Standard Operating Procedure No. RSP-010, "Exposure Control".

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 shall supply adequate resources to ensure compliance with this procedure.

5.1.2 The Radiation Safety Officer (RSO) shall:

5.1.2.1 Verify that only Radiation Protection Technicians conduct receiving surveys.

5.1.2.2 Verify that radiation surveys are completed on incoming shipments known or suspected to be radioactive.

5.1.2.3 Evaluate radiation survey results from incoming shipments.

5.1.2.4 Assure that all Radiation Protection Technicians are trained in the provisions of this procedure.

5.1.2.5 Provide direction in any remediation of receiving incidents involving radioactive materials.

5.1.2.6 Assure that the requirements of this procedure are met.

5.1.3 Radiation Protection Technicians shall:

5.1.3.1 Comply with all applicable requirements of this procedure when receiving radioactive materials.

5.1.3.2 Periodically review the contents of this procedure.

5.2 General Information

5.2.1 While it is anticipated that all shipments will be clearly marked concerning the type and quantities of radioactive material, it is possible for packages containing radioactivity to arrive unmarked and unannounced.

5.2.2 Prior to handling radioactive material, all personnel shall be familiar with accompanying paperwork.

Note: This information can be critical to planning the safe handling of contaminated material.

5.2.3 If the information on these forms is unclear or incomplete:

5.2.3.1 Work shall be stopped.

5.2.3.2 Clarification shall be obtained from the RSO.

5.2.3.3 The RSO shall authorize work to proceed.

5.2.4 Incoming packages shall be inspected for visible defects, and all package defects shall be noted on the receiving papers.

5.2.5 Radiological survey instruments shall be selected and operationally checked in accordance with RSP-008 prior to use.

5.2.6 This survey procedure shall be considered useful only for detecting ionizing radiation that can penetrate packages (i.e., gamma radiation) or radioactive contamination (i.e., alpha, beta, and/or gamma radiation) on the outside of the shipment.

5.3 Purchase of Radioactive Materials or Radiation-Producing Machines

5.3.1 The RSO shall maintain a record of acquisitions pending their addition to the radioactive materials inventory log.

5.3.2 When the materials are received, they shall be added to the radioactive materials inventory log.

5.4 Scheduling

5.4.1 Shipments shall be surveyed for exposure rate and removable contamination within three (3) hours of arrival.

5.4.2 The documentation accompanying the shipment and radioactive shipping labels shall be reviewed in order to obtain information regarding the activity of its contents.

5.4.3 The shipment shall be marked and labeled as containing radioactive material and that it has no physical evidence of possible contamination (e.g., crushed, wet, or damaged).

5.5 Initial Survey of Items Known or Suspected to Contain Radioactive Materials

5.5.1 Upon receipt, packages containing radioactive material shall surveyed if there is evidence of degradation of the package integrity.

5.5.2 Exposure rate surveys shall be performed on contact and at a distance of approximately 1 meter from accessible surfaces of the shipment pursuant to RSP-008, "Instrumentation and Surveillance".

5.5.2.1 A gamma dose rate instrument shall be used to perform the surveys.

5.5.2.2 If the contact exposure rate exceeds 200 mR/hr:

5.5.2.2.1 The item shall be secured within the vehicle;

5.5.2.2.2 The RSO shall be notified;

5.5.2.2.3 The RSO shall inform the driver, prevent the vehicle from leaving, and contact the USNRC (Region III) for additional instructions.

Note: For "exclusive use" shipments, the contact exposure rate cannot exceed 1000 mR per hour.

5.5.2.3 If the one (1) meter exposure rate exceeds the Transport Index marked on the Radioactive Shipping Label:

5.5.2.3.1 The item shall be secured within the vehicle;

5.5.2.3.2 The RSO shall be notified;

5.5.2.3.3 The RSO shall inform the driver, prevent the vehicle from leaving, and contact the USNRC (Region III) for additional instructions.

5.5.3 A removable contamination survey shall be performed pursuant to RSP-008, "Instrumentation and Surveillance".

Note: A removable contamination survey is not required for special form materials pursuant to 10 CFR 20.1906(b)(1).

5.5.3.1 Dry disk smears shall be used to perform the survey, with smears analyzed using a smear counter.

5.5.3.2 If removable activity in excess of 1,000 dpm β/γ per 100 cm^2 is identified:

5.5.3.2.1 The item shall be secured within the vehicle;

5.5.3.2.2 The RSO shall be notified;

5.5.3.2.3 The RSO shall inform the driver, prevent the vehicle from leaving, and contact the USNRC (Region III) for additional instructions.

5.5.4 At the completion of receiving surveys:

5.5.4.1 The package shall be removed from the truck to the loading dock

5.5.4.2 The Transport Index for previously unaccessible surfaces shall be confirmed.

Note: Unaccessible surfaces means the bottom of heavy packages that require a forklift to raise.

5.5.4.3 The bill of lading shall be signed.

5.5.4.4 The vehicle may be released.

5.5.4.5 The package shall be transported to a designated Radioactive Material Storage Area.

5.5.4.6 The Radioactive Shipment Receiving Record shall be completed and forwarded to the RSO.

5.6 Receiving New Sealed Sources

5.6.1 The package containing the new sealed source shall be opened in the designated Radioactive Material Storage Area and inspected for damage.

5.6.2 The contents of the package shall be checked to ensure that it corresponds with the items listed on the bill of lading.

5.6.3 The bill of lading, the leak test certificate and the test report shall be forwarded to the RSO.

5.6.4 The package shall be closed and secured in the designated Radioactive Material Storage Area

5.7 Receiving Used Sealed Sources

5.7.1 The package containing the new sealed source shall be opened in the designated Radioactive Material Storage Area and inspected for damage.

5.7.2 A leak test on accessible surfaces of the source shall be performed pursuant to RSP-019.

5.7.3 If leak test results exceed 0.005 microcurie:

5.7.3.1 The RSO shall be notified;

5.7.3.2 The source, housing and all packaging shall be secured.

5.7.3.3 The RSO shall contact the USNRC for additional instructions.

5.7.4 The contents of the package shall be checked to ensure that it contains the items on the bill of lading.

5.7.5 The bill of lading, the leak test certificate and the test report shall be forwarded to the RSO.

5.7.6 The package shall be closed and secured in the designated Radioactive Material Storage Area

5.8 Contamination Control

At the completion of receiving activities, Radiation Protection Technicians shall perform a contamination survey of their hands pursuant to RSP-008 and RSP-009.

5.9 Radioactive Materials Inventory

5.9.1 Radioactive materials received pursuant to this procedure shall be entered onto the radioactive materials inventory log (Attachment 1, "Amount Acquired").

5.9.2 The log shall be maintained by the RSO and shall be updated at least quarterly to reflect usage and new acquisitions.

5.9.3 The log shall contain, as applicable:

5.9.3.1 The capsule serial number

5.9.3.2 The radionuclide.

5.9.3.3 The activity of the source (millicuries or microcuries)

5.9.3.4 The date of activity calibration

5.9.3.5 The location where the source will be stored at the London Road facility.

5.9.3.6 The date of arrival.

6 EXEMPTION PROVISIONS

Variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the Vice President.

7 DOCUMENTATION

7.1 All Records pertinent to this procedure shall be maintained pursuant to RSP-004, "Radiation Protection Records".

7.2 The RSO shall maintain the records necessary to demonstrate the current inventory of radioactive materials at the London Road facility.

7.3 The RSO shall submit a copy of AMS's current USNRC license as requested by the vendor supplying the radioactive material.

7.4 All personnel receiving or opening packages containing radioactivity shall forward pertinent records and information to the RSO.

8 ATTACHMENTS

Attachment 1 - Radioactive Materials Inventory Log

ATTACHMENT 1
RADIOACTIVE MATERIALS INVENTORY LOG

Radionuclide: ☐ Cs-137 ☐ Co-60 ☐ DU ☐ Other ____________

Source Identifier (Serial Number)	Storage Location	Amount Acquired		Amount Shipped		Current Inventory (Ci)
		Activity (Ci)	Date of Calibration	Activity (Ci)	Date of Calibration	

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JAN 0 8 1996

David Cesar, Vice President
Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, OH 44041

Dear Mr. Cesar:

We have completed our review of your decommissioning financial assurance submittal dated January 27, 1995 and subsequent submittals dated March 31, 1995, July 27, 1995, and December 14, 1995. Within the scope of our review, no further deficiencies were identified. A copy of this information will be placed in your license file.

Please note, however, that we are still in the process of reviewing your cost estimate and conceptual decommissioning plan. A letter addressing these issues will be mailed to you in the near future. In the event that the cost estimate to decommission the facility changes, it will be necessary for you to amend your existing financial assurance documents, or submit a new financial assurance instrument for the new amount. Our acceptance of your letter of credit dated January 27, 1995 does not imply acceptance of your cost estimate of 1.8 million dollars.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

Kevin G. Null
Nuclear Materials Licensing Branch

License No. 34-19089-01
Docket No. 030-16055

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

January 15, 1996

Mr. Hubert Miller
Regional Administrator, Region III
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Strategic Plan (USNRC License No. 34-19089-01)

Dear Mr. Miller:

On August 29, 1995, a meeting was held at the request of Advanced Medical Systems, Inc. (AMS) to discuss an action plan for addressing outstanding issues that are of mutual interest to AMS and the USNRC in a timely fashion but within the resources currently available to AMS. In that meeting, AMS agreed to submit to the USNRC a written plan for meeting its short-term, intermediate-term and long-term objectives. That plan was, in fact, submitted on October 11, 1995.

Included in the plan was a commitment to provide quarterly updates on AMS's progress toward meeting its goals. Enclosed is Revision 1 of the "Strategic Plan for the London Road Facility", which is being submitted in response to our commitment.[1] If you have any questions or if I can provide you with additional information, please call me at (216) 692-3270. You may expect to receive Revision 2 of the plan in April of 1996.

Sincerely,

Robert Meschter, R.S.O.

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM
Assistant General Counsel for Hearings and Enforcement, USNRC
D. A. Cool - Director, Division of Industrial and Medical Nuclear Safety, USNRC
C. D. Pederson - Director, Division of Radiation Safety and Safeguards, USNRC
J. Caldwell - Deputy Director, Division of Radiation Safety and Safeguards, USNRC
M. Weber - Region III, USNRC

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[1] AMS is in recept of your letter dated December 6, 1995 wherein comments on Revision 0 of the "Strategic Plan for the London Road Facility" are provided. You will note, during review of Revision 1, that certain of those comments have already been incorporated. The remainder will be addressed in our formal response to the December 6th letter, which will be submitted within 30 days after AMS receives the structural integrity report from USNRC Headquarters.

JAN 19 19[illegible]

STRATEGIC PLAN FOR THE LONDON ROAD FACILITY

Submitted by:

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110
(216) 692-3270

Report No. 94009/G-3113, Revision 1
January 15, 1996

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INTRODUCTION

Advanced Medical Systems, Inc. (AMS) manufactured and fabricated sealed sources of ^{60}Co for teletherapy and radiography machines. Under the provisions of U. S. Nuclear Regulatory Commission (USNRC) license No. 34-19089-01, and as of the date of this report, AMS possesses 56,269 curies of ^{60}Co, and 2,200 kilograms of depleted uranium (nickel plated) for use as shielding material.[1] Included are approximately 40 curies of radioactive material in a potentially dispersible form. This material, which consists primarily of dry solid waste, carbon granules and ion exchange resins, is stored in sealed 55-gallon drums or B-25 (steel) boxes. The types and quantities of all licensed materials currently in the possession of AMS are shown in Table 1.

As part of its license compliance efforts, AMS is faced with completing a number of tasks ranging from license renewal efforts to significant reductions in the existing radionuclide inventory. Timely completion of these activities is critical since they will ultimately result in streamlined routine operations, recovery of needed building/facility capabilities, and reduced regulatory demands on the operating staff.

However, due to limited personnel and financial resources, it is not possible for AMS to complete all of the outstanding activities in a single campaign. Therefore, to avoid unnecessary and negative financial impacts on the company, yet ensure steady and well-managed progress toward completion, the activities were prioritized based upon an activity's ability to improve the implementability of other activities, AMS's ability to fund the activity in the near-, intermediate- and long-term, and on the cost/benefit associated with the activity's timely completion. Table 2 shows the listing of the outstanding activities, along with their priorities (e.g., high priority, intermediate priority, and lower priority).[2]

A number of additional activities not shown in Table 2 will run concurrent with the prioritized activities. These include audit/assessment of the radiation protection program, upgrade of standard operating procedures, improvements in housekeeping, and attempts to increase community relations.

The remainder of this report contains additional discussion on each of the outstanding activities. Included is a brief discussion of the AMS strategy for each activity, the plan of action for completing the activity, a description of the current status (as of the date of this report) and an implementation schedule, where appropriate.

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[1] There is negligible radiological hazard associated with the depleted uranium inventory. Therefore, it is not addressed further in this report.

[2] In general, high priority items are scheduled for completion within the next year, intermediate priority items within the next one to three years, and lower priority items within the next three to five years.

Over the intermediate and long term, as actions are completed and as the scope/approach of specific activities (subitems) become solidified, the individual action plans will be expanded and specific dates will be entered in the implementation schedules. Therefore, this report will be revised on a quarterly basis and numbered revisions will be issued.

HIGH PRIORITY ACTIONS

Complete the Remediation Report

In late 1994, the Northeast Ohio Regional Sewer District (NEORSD) intentionally isolated AMS access to regional sewage treatment system. This action rendered the facility drainage system non-functional, increased the hydrostatic pressure on the foundation structure, and caused groundwater to enter the basement of the AMS facility.

After AMS made timely notification to the USNRC about the deteriorating conditions at the building, AMS initiated action to drain the basement, remove the ^{60}Co from the water in the basement, remediate the foundation drainage system, isolate the residual radioactivity in the manhole and sewer line exiting the facility to the London Road Interceptor, and remediate the residual radioactivity in the London Road interceptor.[3]

One commitment made to the USNRC as part of the remediation project was to provide a final report that contains a description of the events that led to the site conditions, a review of the remedial actions implemented and their results, and a summary of all data acquired during the process.

Since all remedial activities are not yet complete, the final remediation report is still being compiled. Outstanding items are disposition of water in the collapsible storage tanks, disposition of contaminated solids (e.g., soils and water treatment media), implementation of the long-range surveillance plan for residual radioactivity that exists outside of the AMS building (e.g., in the abandoned footer drains and lateral connection from the building to the London Road Interceptor), disposition of water in the WHUT Room, and remediation of the London Road Interceptor.

In regard to the residual water in the WHUT Room, AMS is investigating the use of a stabilizing agent known as STERGO™. This product is a solid granular, cross-linked polymer that rapidly absorbs and retains large quantities of aqueous-based liquids. It is being considered because it is non-toxic, will hold from 12 to 40 times its weight in aqueous solutions, and testing indicates that its capacity to retain liquids at high dose rates and large integrated doses is good. AMS's intent is to inject STERGO™ directly into the WHUT Room through the existing access holes where it will absorb residual liquids. The ventilation in the area then will be increased to facilitate slow evaporation. However, even after full de-hydration, STERGO™ does not lose its capacity to re-absorb moisture. Therefore, should there be future incursions of water into the WHUT Room, its outward migration will be prevented. AMS is awaiting the vendor's final testing of the holding capacity of STERGO™ under conditions of very high integrated exposures before proceeding further. The testing results are due in early February of 1996.

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[3] As of the date of this report, the NEORSD has not permitted AMS access to the London Road Interceptor. AMS's ability to complete the remediation is beyond its control.

In regard to the contaminated solids from the excavation (rock, soil) that exist outside the AMS facility, a structure is being built to secure and house them. The lined wooden structure will be built on the south west quadrant of the property, approximately 200 feet from the building. Once constructed, the solids will be transferred to the structure. The structure and its environs will be posted pursuant to RSP-011, "Posting and Labeling", and will be included in the quarterly radiological surveillance program pursuant to RSP-008, "Instrumentation and Surveillance".

In regard to the long-range surveillance plan for residual radioactivity, AMS submitted the plan to the USNRC on September 5, 1995. The USNRC issued a request for additional information on December 7, 1995. AMS forwarded responses to that request on December 14, 1995. To date, USNRC approval of the plan, as modified, has not been received.

Once all of the actions associated with the water treatment and sewer remediation project are complete, the remediation report will be finalized and submitted to the USNRC. However, for reasons that are beyond AMS's control, final implementation of the surveillance plan and remediation of the London Road Interceptor may be delayed significantly. Therefore, AMS may elect to submit the Remediation Report in advance and exclusive of these items. Table 3 shows the action plan for this task.

License Renewal Application

In early 1995, AMS submitted an application to renew its USNRC license under the provisions of timely renewal. After initial USNRC review of the application, a letter of deficiency was issued and additional information was requested. Subsequently, an in-house review of the application, in light of the short- and long-range plan of AMS, was completed. This review confirmed that the application was indeed cumbersome and permitted AMS little flexibility in achieving its intermediate- and long-term goals. Therefore, a significantly revised application was submitted on October 30, 1995. To date, AMS has received no response from the USNRC and continues to operate under the provisions of the existing license. Table 3 shows the action plan for this task.

Emergency Plan

As part of license renewal efforts, an emergency plan was submitted to the USNRC for review and comment. On June 7, 1995, after initial USNRC review of the Plan, a letter of deficiency was issued and additional information was requested. Because the magnitude of deficiencies was significant, a revised Plan was submitted on September 22, 1995. This revision was consistent with the guidance contained in USNRC Regulatory Guide 3.67 (1992), "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities". To date, AMS has received no response from the USNRC in regard to this plan.[4] Table 3 contains the action plan for this task.

[4] Comments have been received, however, from the Ohio Environmental Protection Agency, the Ohio Department of Health, and the Cuyahoga Emergency Assistance Center.

Decommissioning Funding Plan

As part of the recent license renewal efforts, a decommissioning funding plan was submitted to the USNRC for review and comment. On August 17, 1995, after initial USNRC review of the Plan, a letter of deficiency was issued and additional information was requested. Specifically, the USNRC indicated that the January 1995 cost estimate and site characterization submitted by AMS "are no longer valid". However, the January 1995 estimate was based upon a "decontaminate and release" decommissioning option, which is not suitable for a facility like AMS where the primary radionuclide of concern has a radiological half life of only five years. Therefore, AMS prepared a Conceptual Decommissioning Plan for the facility pursuant to 10 CFR 40.46(d) that is based upon a "safe storage" decommissioning option.[5]

The Plan, which was submitted to the USNRC on October 20, 1995, describes the decommissioning objective for the facility and its basis, a description of the items to be decommissioned, the proposed decommissioning methodology, an ALARA analysis to support the proposed methodology, a cost estimate (1995 costs) for implementing the methodology, and a review schedule for ensuring the Plan's continued applicability for the duration of License No. 34-19089-01. Once approved by the USNRC, the Plan will be funded by the corporation and reviewed for continued applicability on a planned and periodic basis. Table 3 contains the action plan for this task.

Train First Responders in Emergency Plan Provisions

As part of its emergency response requirements, AMS must provide annual radiation safety training for first responders. Pursuant to the revised Emergency Plan, this training must include a review of items of mutual interest, instruction in emergency procedures, radiation protection guidelines, and the responder's anticipated role in an emergency. During the training session, the emergency response team activation scheme, notification procedures, and overall response coordination process will be reviewed.

Within 60 days after USNRC approval of the revised Emergency Plan, a training session for first responders will be scheduled. After training is complete, agency attendance will be documented and letters of agreement will be updated, as necessary. The training sessions will be scheduled annually thereafter. Table 3 contains the action plan for this task.

Stage Emergency Exercise and Perform Critique

As part of its emergency response requirements, and in order to maintain emergency preparedness, AMS must conduct an emergency exercise on a planned and periodic basis. Within 60 days after all first responders have received initial training in the provisions of the AMS Emergency Plan, the emergency exercise will be scheduled and staged.

Pursuant to the revised Emergency Plan, the exercise will include one or more of the accident scenarios postulated for the facility, and will involve off-site agencies that have provided letter

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[5] Pending its concurrence with the Conceptual Decommissioning Plan, the USNRC did, in a January 8, 1996 letter to AMS, accept AMS's decommissioning financial assurance submittal based upon the January, 1995 cost estimate.

agreements for support services (e.g., first responders). The scenario will not be known in advance by exercise participants, and a non-participating observer will provide an evaluation of the effort, along with recommendations for improvement.

The critique of the exercise will be used as a basis for modifying the Emergency Plan or for supplementing the training of off-site agencies. Deficiencies identified during critiques will be corrected and closure will be documented. As necessary, changes to the Emergency Plan, based upon the findings of the critique, will be implemented. Table 3 contains the action plan for this task.

INTERMEDIATE PRIORITY ACTIONS

Recover Hot Cell Capabilities

In order to decontaminate, leak test, package and ship sealed sources of ^{60}Co from the AMS facility, a functional hot cell is needed. Currently, the Hot Cell contains significant residual removable radioactivity. Consequently, cross-contamination of items that enter the Hot Cell is a concern. Therefore, AMS intended to recover sufficient Hot Cell capabilities to support inventory reduction efforts.

Shortly after issue of the initial version of this Strategic Plan, the Hot Cell capabilities that were needed to facilitate inventory reduction were evaluated. From this evaluation, it was determined that improved lighting and construction of a source transfer mechanism were the only items necessary to support initial inventory reduction. These items were implemented, a successful "trial run" of the system occurred on December 19, 1995, and the system became fully operational on December 27, 1995. Table 3 contains the action plan for this task.

Return NPI Sources

There are currently 35 sealed sources in the AMS inventory that belong to Neutron Products Inc. (NPI). As part of on-going operations, AMS purchases sources from NPI for delivery to a customer. When the shipping cask is sent to NPI, one of the sources in the AMS permanent inventory is enclosed, thereby reducing the inventory. AMS intends to escalate the return of all of the remaining sources now that Hot Cell capability has been recovered.

For this task, AMS evaluates whether there is residual radioactivity on the remaining NPI sources, decontaminates and leak tests the sources as necessary, packages the sources, and ships them to NPI. As sources leave the London Road facility, the inventory log is debited appropriately. Since the initial version of this Strategic Plan was issued, a total of two (2) sources have been returned to NPI, and two (2) additional sources are staged for shipment. Table 3 contains the action plan for this task.

Identify a Market for Remaining Bulk Material

There are approximately 11,750 curies of bulk ^{60}Co metal in the AMS inventory. AMS is attempting to identify a domestic or foreign market for this material, prepare and submit whatever permit or license applications are necessary, package the material, and ship it to a buyer.

AMS has initiated discussions with a variety of source distribution firms, with brokers, and with public health departments in a number of countries. Possible foreign uses being pursued include medical (therapy), industrial (gauges and sensors), health (food and medical products irradiation), and education (universities). Once one or more markets are identified, permitting requirements will be determined, applications will be filed, and materials will be packaged/shipped. Table 3 contains the action plan for this task.

LOWER PRIORITY ACTIONS

Remove Plug in the Hot Cell

An estimated 4,000 curies of ^{60}Co in the form of sealed sources are located in a storage well in the Hot Cell. Because the well plug has become lodged in the well, these sources cannot be removed and included in the inventory reduction efforts. Therefore, AMS intends to dislodge the plug.

A methodology for dislodging the plug has been determined, and a contract for services has been let. Once the decision is made to proceed and the work plan and Radiation Work Permit have been completed, equipment and personnel will be staged, "dry runs" will be completed, and the plug will be removed. Table 3 contains the action plan for this task.

Decontaminate the Hot Cell

After the plug removal project is complete, significant residual radioactivity will likely exist within the Hot Cell. In order to ensure its continued usefulness, AMS intends to decontaminate the Hot Cell to levels necessary to support planned future operations.

The first step in the process will be determination of the methodology for Hot Cell decontamination. Once complete, the work plan will be prepared, outside services, if necessary, will be contracted, and the project will begin. Table 3 shows the action plan for this task.

Complete/Confirm the Physical Inventory and Transfer/Ship Remaining Sources

After removal of the plug, AMS will be able to confirm the physical inventory of licensable radioactive material present at the London Road facility. (AMS is obliged, by License Condition 14, to complete a physical inventory of all sources in its custody. In light of the low priority associated with this task, an amendment to License No. 34-19089-01 to postpone the inventory requirement may be necessary, depending upon the timeliness of action on AMS's recent license renewal application.) AMS then intends to identify a market for the remaining sources, evaluate their levels of residual radioactivity, decontaminate and leak test the sources as necessary, package the sources, and ship them to the purchaser. As sources leave the London Road facility, the inventory log will be debited appropriately. Table 3 contains the action plan for this task.

Disposition of Solid Waste at the Facility

As shown in Table 1, there is a significant quantity of solid waste at the AMS facility. These materials are stored either within the AMS facility, or in a secured storage location within the fenced portion of the property. The disposition of this solid waste is dependent upon the decommissioning methodology selected for the facility, and upon the availability/cost of off-site disposal at the time of project initiation.

AMS intends to evaluate disposition options and select/implement the one that results in the lowest personnel exposures and disposal costs. Justification for the preferred option will be prepared and presented. Table 3 contains the action plan for this task.

Disposition of Treated Water in Collapsible Storage Tanks

As part of the 1995 sewer remediation project, approximately 100,000 gallons of water was treated by the methodology of sub-micron filtration and reverse osmosis in order to reduce its radionuclide content to below drinking water standards. There are approximately 40 microcuries of ^{60}Co in the water, which is currently stored in collapsible storage tanks at the London Road facility. The solubility of the residual radioactivity was confirmed using American Public Health Association's Method 7110 "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)" from Standard Methods for Examination of Water and Wastewater.

AMS requested and received permission from the U. S. Environmental Protection Agency (USEPA) and the USNRC to evaporate this water. However, due to delays and difficulties in implementing the treatment process that were beyond AMS's control, more than four times the original amount of water had to be treated to reduce its concentration of radioactive cobalt at a cost that went well-beyond the original projection. In light of the magnitude of these unbudgeted expenses, the evaporation option became significantly more costly. Therefore, AMS is pursuing other options for disposing of the water.

Since the treated water meets the USEPA's criteria for man-made radionuclides in drinking water pursuant to 40 CFR 141, and since it contains no other hazardous substances, its presence at the AMS facility poses no radiological risk. Therefore, there is no urgency to ensure its final disposition. Nonetheless, AMS will pursue a direct discharge option until such time as it becomes patently unattainable. At that time, the evaporation option will be re-visited in light of available financial resources. Table 3 contains the action plan for this task.

ON-GOING ACTIONS

Audit/Assessment of Radiation Protection Program

In light of changing operational issues, pending licensing activity, and the desire to "streamline" compliance efforts, AMS intends to perform a series of audits of its radiation protection program in order to compare AMS's performance to that required and/or recommended by existing license/permit provisions, U. S. Nuclear Regulatory Commission regulations, and standard industry practices (e.g., USNRC Regulatory Guides, ANSI, ASME and ASTM Standards, ICRP Publications, NCRP Publications). The audits will be performed by AMS personnel and consultants to AMS. They will involve initial review of applicable operating procedures, quality assurance procedures, and other pertinent documentation related to a particular performance issue.[6] The initial document review is performed in order to identify possible areas of failure or liability, and to derive an efficient schedule for on-site assessments. While on site, AMS compliance with existing procedures will be determined and areas of inefficiency or poor function, as compared to industry standards and practices, will be identified.

While the results of the audits are intended to be used for demonstrating compliance and/or to guide future program modifications or improvements, any findings of significant regulatory non-compliance or conditions of imminent hazard will be immediately reported to and addressed by the RSO. The audit schedule for 1996 will be set during the Quarter 1, 1996 Radiation Safety Committee meeting.

Upgrade of Standard Operating Procedures

In response to audit findings, and in light of changing operational demands and licensing activities, the current collection of standard operating procedures (ISPs) are being reviewed for continued applicability. Wherever possible, multiple procedures that address a single topic will be combined, out-dated procedures will be revised, and obsolete procedures will be deleted. Consistency between procedures will be confirmed and compliance with the requirements of the AMS Radiation Protection Program Plan will be assured. Since October 10, 1995, the following new/revised procedures have been developed and approved by the Radiation Safety Committee:

- RSP-001, Radiation Protection Program Plan
- RSP-002, Definitions
- RSP-003, Control of Radiation Safety Procedures

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[6] The following programmatic issues will be audited on a planned and periodic basis: Organization and Administration; Facilities and Equipment; Training in Radiation Protection; Radiation Exposure Control; ALARA Program; Contamination Control; Instrumentation and Surveillance; Posting and Labeling; Receipt and Control of Radioactive Material; Packaging and Transportation of Radioactive Materials; Control of Radioactive Waste; Radiation Protection Records; Documentation; Emergency Response and Notifications; and Quality Assurance in Radiological Protection.

- RSP-004, Radiation Protection Records
- RSP-005, ALARA Program
- RSP-007, Training in Radiation Protection
- RSP-009, Contamination Control
- RSP-011, Radiological Areas and Posting
- RSP-012, Control of Work
- RSP-014, Receipt, Handling, and Identification of Radioactive Materials
- RSP-015, Packaging and Transportation of Radioactive Materials
- RSP-016, Emergency Response and Notifications
- RSP-017, Stop Work Authority

Housekeeping Improvements

Currently, there are only three permanent employees at the London Road facility. Therefore, only a small fraction of the available space is used for routine operations, office areas and storage. However, AMS has instituted improvements in housekeeping in the useable areas of the facility. Additional improvements will be implemented on an on-going basis. Since October 10, 1995, the following has taken place:

- The stairwell to the basement has been fully decontaminated and released for unrestricted use.
- The temporary restricted area in the warehouse that housed the water treatment equipment has been cleared and released for unrestricted use.
- Two (2) of the three (3) process batch tanks used for the water treatment project have been decontaminated.

Community Relations

In the past, issues or activities at AMS that required state, federal and local approvals were hampered due to lack of knowledge of AMS operations and/or an understanding of the fundamental principles of radiation and radioactivity on the part of decision-makers. In an effort to streamline future decision-making, AMS intends to mount a community relations program to acquaint various officials and members of the print and broadcast media with the AMS function, its capabilities, and its short-, intermediate-, and long-range plans. This will be accomplished

through briefings, tours, and development/publication of hand-out materials and brochures. Since October 10, 1995, the following has taken place:

- A briefing with local print media representatives was held on October 31, 1995, which resulted in publication of an article that was favorable to AMS in the local press.

- Two briefings with City of Cleveland officials were arranged and invitations were issued. The briefing dates were August 29, 1995 and October 31, 1995. Although AMS received acceptances from the office of the Mayor and other individuals, no officials appeared for either briefing.

- A Cleveland City Council member (R. Coates) visited the London Road facility on November 22, 1995.

Reconnection of Sewer System to London Road Interceptor

Currently, the London Road facility does not have a direct connection to the regional sewer system. There are no sanitary discharges from the building, the roof drains discharge onto the ground surface, and all groundwater is pumped from a manhole on the property into a storage tank. Once the tank is full, the water is sampled and discharged. For operational reasons, and because current discharge paths do not comply with local building codes, AMS continues to pursue re-connection of all drainage paths to the London Road Interceptor through legal channels.

TABLES

Table 1 - Current Cobalt-60 Inventory

Item	Form	Material Description	Estimated Activity (Ci)
Licensed Material	Solid	Bulk Metal and Sealed Sources	56186
Packaged waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	29
Packaged waste	Solid	Solid waste generated during the water treatment project.	0.4
Unpackaged waste	Solid/sludge	Materials contained in WHUT Room	53
Surface radioactivity	Solid	Uncharacterized surface activity in the restricted areas of the facility	1
TOTALS			56269

Table 2 - Action Plan Summary[7]

High Priority Activity	Intermediate Priority Activity	Lower Priority Activity
Submit the Remediation Report for the water treatment and sewer remediation project	Recover the capabilities of the Hot Cell.	Remove the plug in the Hot Cell and extract the remaining sources
Finalize site emergency plan.	Reduce the inventory of sealed sources and bulk cobalt.	Decontaminate the Hot Cell.
Submit conceptual decommissioning plan		Complete the physical inventory of sources.
Finalize decommissioning funding plan.		Ship out remaining sources
Finalize license renewal activities.		Address solid waste issues.
		Pursue disposition of treated water that currently exists in the collapsible storage tanks.
Implement training requirements of the approved site emergency plan (e.g., train first responders and perform emergency exercise and critique)		

[7] Shaded areas denote closure.

Table 3 - Action Plan for Each Task[8]

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Complete Remediation Report	Determine remedial alternative for the WHUT Room	8/29/95	10/3/95	Closed. Solidification has been identified as the preferred alternative.
	Determine storage methodology for contaminated solids	8/29/95	10/3/95	Closed. Construction of an above-ground storage container has been identified as the preferred alternative.
	Stabilize liquids that currently exist in the WHUT Room	10/3/95	3/1/96	Open
	Implement storage option for contaminated solids	10/3/95	1/31/96	Open
	Finalize and submit remediation report	8/1/95	TBD	Pending resolution of AMS/NEORSD litigation
	Begin direct discharge of ground and surface water from the AMS foundation drainage system.	1/15/96	TBD	Pending resolution of AMS/NEORSD litigation and reconnection of sewer system
License Renewal Application	Submit revised application	9/11/95	10/31/95	Closed. Application mailed to USNRC on 10/31/95
	Begin operations under provisions of renewed license.	1/1/96	TBD	Pending USNRC action on renewal application
Emergency Plan	Submit revised Emergency Plan to the USNRC	8/15/95	9/30/95	Closed. Plan mailed to USNRC and first responders on 9/26/95.
	Begin operations under provisions of approved plan.	1/1/96	TBD	Pending USNRC approval of Emergency Plan.
Decommissioning Funding Plan	Submit Conceptual Decommissioning Plan	9/8/95	10/23/95	Closed. Plan mailed to USNRC on 10/20/95.
	Submit Decommissioning Funding Plan	10/21/95	TBD	Pending USNRC approval of Conceptual Decommissioning Plan
	Scheduled review of Conceptual Decommissioning Plan and Decommissioning Funding Plan for continued applicability	TBD	One (1) year after USNRC approval	Pending USNRC approval of Decommissioning Funding Plan
Recover Hot Cell Capabilities	Determine Hot Cell requirements for inventory reduction.	8/29/95	10/27/95	Closed.
	Specify Hot Cell recovery actions	11/1/95	12/1/95	Closed

[8] As actions are completed and as the scope/approach of specific activities (subitems) become solidified, the individual action plans will be expanded and specific dates will be entered in the implementation schedules. Changes will be noted in future revisions of this Plan. Shaded entries denote closure.

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
	Implement recovery actions	12/1/95	1/1/95	Closed
Return NPI Sources	Evaluate residual radioactivity on NPI Sources	9/11/95	9/15/95	Closed.
	Determine decontamination methodology	9/25/95	11/24/95	Closed.
	Perform "trial run" of decontamination methodology.	11/1/95	12/20/95	Closed
	Decontaminate and leak test sources	12/20/95	1/1/97	Open
	Package and ship sources	12/20/95	1/1/97	Open
Identify a Market for Remaining Bulk Cobalt	Identify domestic market possibilities	8/1/95	12/31/96	Open
	Identify foreign market possibilities	11/1/95	12/31/96	Open
	Determine and implement permitting requirements	12/31/96	6/1/97	Unscheduled
	Complete contracts with purchasers	TBD	TBD	Unscheduled
	Package and ship sources	TBD	TBD	Unscheduled
Train First Responders in Emergency Plan Provisions	Receive USNRC approval of the Emergency Plan	10/20/95	TBD	Pending response from USNRC
	Schedule initial first responder training session	10 days after USNRC approval	TBD	Unscheduled pending USNRC approval of the Emergency Plan
	Complete training and documentation	60 days after USNRC approval	TBD	Unscheduled
	Obtain updated letters of agreement, as necessary	TBD	TBD	Unscheduled
	Schedule refresher training	TBD	TBD	Unscheduled
Implement an Emergency Exercise and Critique	Schedule emergency exercise	60 days after completion of training	TBD	Unscheduled pending completion of first-responder training
	Prepare scenario	TBD	TBD	Partially complete
	Contract outside observer	TBD	TBD	List of qualified personnel prepared.
	Initiate emergency exercise	TBD	TBD	Unscheduled
	Generate critique report	TBD	TBD	Unscheduled
	Modify Emergency Plan in light of critique findings	TBD	TBD	Unscheduled

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Remove Plug in Hot Cell	Determine methodology for plug removal	7/1/95	8/1/95	Closed
	Generate specifications plan for plug removal	7/1/95	8/1/95	Closed
	Issue Request for Quotation for plug removal	7/1/95	8/1/95	Closed
	Review bids and issue contract for services	7/1/95	8/1/95	Closed
	Prepare work plan and Radiation Work Permit	TBD	TBD	Unscheduled
	Mobilize personnel and equipment	TBD	TBD	Unscheduled
	Train personnel in provisions of work plan	TBD	TBD	Unscheduled
	Perform dress rehearsals	TBD	TBD	Unscheduled
	Remove plug	TBD	TBD	Unscheduled
Decontaminate the Hot Cell	Specify Hot Cell decontamination methodology and clean-up criteria	TBD	TBD	Unscheduled pending plug removal
	Generate work plan for decontamination activities	TBD	TBD	Unscheduled
	Contract decontamination services, as necessary	TBD	TBD	Unscheduled
	Mobilize equipment and personnel	TBD	TBD	Unscheduled
	Complete decontamination	TBD	TBD	Unscheduled
Complete/Confirm Inventory and Transfer/Ship Remaining Sources	Request amendment to License Condition 14 to postpone the physical inventory requirement pending plug removal.	5/1/98	6/30/98	Open pending action by USNRC on October, 1995 license renewal application
	Confirm physical inventory of remaining sealed sources	TBD	TBD	Unscheduled pending final decontamination of Hot Cell
	Evaluate residual radioactivity on remaining sources	TBD	TBD	Unscheduled
	Decontaminate and leak test sources	TBD	TBD	Unscheduled
	Obtain shipping cask	TBD	TBD	Unscheduled
	Package and ship sources	TBD	TBD	Unscheduled
Disposition of Solid Waste at the Facility	Evaluate disposition options in light of Conceptual Decommissioning Plan	10/1/95	TBD	Pending USNRC approval of Conceptual Decommissioning Plan
	Select the preferred option based upon an ALARA analysis.	TBD	TBD	Unscheduled
	Characterize the materials.	TBD	TBD	Unscheduled
	Prepare necessary permits and licenses	TBD	TBD	Unscheduled
	Implement the preferred option	TBD	TBD	Unscheduled

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Disposition of Treated Water in Collapsible Storage Tanks	Identify disposition options.	8/1/95	TBD	Open
	Prepare necessary permits and licenses	TBD	TBD	Unscheduled
	Implement preferred disposition option.	TBD	TBD	Unscheduled

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JAN 18 1996

Robert Meschter
Radiation Safety Officer
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

Dear Mr. Meschter:

Enclosed is Amendment No. 40 to your NRC Material License No. 34-19089-01 in accordance with your request.

This amendment acknowledges approval of your "Surveillance Plan for the London Road Facility." The Plan was submitted to NRC as required in License Condition Number 19.E.ii (see Amendment No. 39). Based upon our review and approval of the Plan, we have deleted License Condition Number 19.E.ii.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (708) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when

dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Kevin Null
Nuclear Materials Licensing Branch

License No. 34-19089-01
Docket No. 030-16055

Enclosure: Amendment No. 40

NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 40

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

399566

Licensee	
1. Advanced Medical Systems, Inc.	In accordance with letter dated September 5, 1995 3. License Number 34-19089-01 is amended in its entirety to read as follows:
2. 1020 London Road Cleveland, OH 44110	4. Expiration Date December 31, 1994
	5. Docket or Reference No. 030-16055/040-08764/030-17154

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical-Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Cobalt-60	A. Solid Metal	A. 150,000 curies
B. Cobalt-60	B. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	B. 135,000 curies (no single source to exceed 13,700 curies)
C. Cesium-137	C. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	C. 40,000 curies (no single source to exceed 2,200 curies)
D. Depleted Uranium	D. Nickel Plated	D. 4,040 kilograms
E. Cobalt-60	E. Sealed Sources	E. 15,000 curies

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-19089-01

Docket or Reference number
030-16055/040-08764/030-17154

Amendment No. 40

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
F. Cobalt-60	F. Sealed Sources (any sealed source approved by the NRC or an Agreement State)	F. 15 millicuries

9. Authorized Use:

A. For storage only incident to waste disposal or transfer to an authorized recipient. This license does not authorize the manufacture of sealed sources.

B. For installation, maintenance of, dismantling and servicing of Picker Corporation and Advanced Medical Systems, Inc. teletherapy units and Picker Model 6145 radiography units possessed by licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For installation and removal of sealed sources into Picker Corporation, Advanced Medical Systems, Inc. and Keleket Barnes teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For training Hospital or Clinic personnel for in-house service operations on teletherapy equipment, on unit model per course, in accordance with letter dated August 15, 1988 and September 29, 1988.

C. For installation, maintenance, dismantling and servicing of Picker Corporation and Advanced Medical Systems radiography and teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State.

D. Shielding material in Picker Corporation and Advanced Medical System, Inc., radiography and teletherapy devices.

E. For storage only, those non-NRC approved sources in the possession of the licensee prior to the issuance of this amendment.

F. For use in devices (including Tech OP Model 571 Calibrator described in application dated November 12, 1984) approved by the Nuclear Regulatory Commission or an Agreement State to calibrate radiation survey instruments.

CONDITIONS

10. Licensed material in Items 6.A., 6.E. and 6.F. shall be used only at the licensee's facility at 1020 London Road, Cleveland, Ohio. Licensed material in Items 6.B. and 6.C. shall be used only at 1020 London Road, Cleveland, Ohio and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material. Licensed material in Item 6.D. shall be used only at the licensee's facilities at 1020 London Road, Cleveland, Ohio or 121 North Eagle Street, Geneva, Ohio, and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material.

11. A. The Radiation Protection Officer for service operations described in Subitems 9.B. and 9.C. and routine health physics activities is Robert Meschter.

The licensee shall not perform service operations described in Subitems 9.B. and 9.C. until Robert Meschter has completed the required training.

B. Licensed material shall be used by, or under the supervision of and in the physical presence of users listed in the table below. The users are only authorized to perform the indicated services on the teletherapy or radiography units specified in the table below:

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	CS 600	C 1000	C 2000	C 3000	C 5000	C 10,000	C4	C8	C9	C12	Cyclops
USER											
Curtis Perry				3	1,2	1,2	1,2	1,2	1,2		1,2
Haddock	5	5	5	5	5	5	5	5	5	5	5

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	V 1000	V 2000	V 3000	V 10,000	C V4	C V9					
USER											
Curtis Perry		1,2	1,2	1,2	1,2	1,2					
Haddock	5	5	5	5	5	5					

1. Authorizes the servicing of AMS/Picker units, excluding source exchange.
2. Authorizes sealed source exchange.
3. Authorizes removal of unit and head from customer sites only.
4. Authorizes the training of AMS personnel in the manufacture of AMS/Picker sealed sources.
5. Authorizes the handling of sealed sources only.

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries of less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designated for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in what the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records o leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action.

13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Inventory Requirements:

A. An inventory system will be established that accounts for the receipt, movement, transfer and disposal of all radioactive material possessed under this license. Records of inventories will be maintained for 10 years from the date of each inventory.

B. A complete examination of records will be completed every six months to confirm the location of all radioactive material and ensure that possession is within the limits specified in this license.

C. A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory.

15. The licensee's field service audits (as described in the ATC Medical Group Management Plan, revised April 1, 1989, and submitted with letter dated April 17, 1989) shall be performed unannounced by the Radiation Protection Officer (i.e., Radiation Safety Officer).

16. The licensee shall follow the recommend survey frequencies outlined in Regulatory Guide 8.21, Revision 1, October 1979, in work areas where radioactive materials are handled or used.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 1020 London Road, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

18. The licensee shall maintain and execute the response measure of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR [30.32(i), 40.31(j), 70.22(i)] that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall furnish the Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR 20, a report, within six months after the change is made, containing a description of each change.

19. The licensee is authorized to begin the following activities no sooner than March 17, 1995, and must complete them by the date specified in each item in accordance with letters dated January 27, February 2, 10, and 14, and March 1, 3, 8, and 10, 1995, wherein the licensee proposed and clarified its plans for: (1) dealing with the accumulation of ground water in and around its facility basement; (2) immobilizing and/or remediating contamination that has collected in below ground sewer piping and manholes; and (3) processing future ground water that builds up around the facility. These plans address the following actions the licensee will take.

    A. Process water that is currently stored outside its facility in above-ground tanks.

        i. Tanked water will be processed in-situ using a submersible water treatment system that includes filtration and ion-exchange demineralization as described in letters dated March 1, 3, 8, and 10, 1995.

        ii. Water will be treated until it contains no detectable non-soluble cobalt-60 and less than 1000 pCi/l of soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8 and 10, 1995.

    B. Simultaneously pump and process water currently residing in the sewer manhole and lateral, building sump pit and basement. This project shall be completed by June 30, 1995.

        i. Pumping will be sequenced as described in letter dated March 1, 1995, to ensure a positive hydrostatic pressure is maintained from outside to inside the facility's basement.

ii. Water in the sewer manhole, lateral, building sump pit, and basement will be pumped to a radiologically controlled area of the facility and processed using a skid mounted, multi-stage filtration and ion-exchange system as described in letters dated March 1, 3, 8 and 10, 1995. Spill procedures and radiological controls will be implemented as described in letter dated February 14, 1995, and Attachment 2 to letter dated March 1, 1995.

iii. Water removed from the sewer manhole, lateral, building sump pit, and basement will be treated to contain no detectable non-soluble cobalt-60 and less than 1000 pCi/l soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8, and 10, 1995.

C. Water sampling and analytical protocols will be as described in letter dated February 2, 1995, as clarified in letters dated February 14, and March 3, 1995. Solubility of cobalt-60 in samples containing detectable activity will be demonstrated in accordance with the reference in Supplement 2 to letter dated March 3, 1995. All solid radwaste generated from the water processing activities, including filter and demineralizer resin wastes, will be collected and stored at the London Road facility pending its ultimate disposal as radioactive waste.

D. Excavate areas around the facility to allow: (i) access to the radioactively contaminated four-inch waste discharge line; and (ii) the radiological evaluation of the facility's underdrain system and surrounding soils.

i. Excavate the soil in the vicinity of the building's four-inch waste discharge line and underdrains and disconnect these drains as described in letter dated March 1, 1995. Evaluate the radiological contamination status of the underdrain system and remediate or replace the system. Reconnect the underdrain system to the building sump pit and pump, test and process the underdrain system waters as described in letter dated March 1, 1995. The testing and processing of water pumped from the underdrain system will continue until sampling of the water consistently reveals no detectable non-soluble cobalt-60 and less than 200 pCi/l soluble cobalt-60.

ii. Evaluate the radiological status of the soil in the vicinity of the underdrain system and building sump pit as described in the letter dated March 1, 1995.

E. Immobilize the radioactive contamination present in the sewer manhole, lateral and four-inch discharge line.

i. Completely grout-in the radioactively contaminated four-inch sewer discharge line and the manhole and lateral up to the sewer interceptor as described in "Issue 4" of letter dated January 27 and letter dated March 1, 1995. The grouting will render the existing sewer discharge piping system inoperable and immobilize (fix) the radioactive contamination that resides in the system.

F. Remediate the London Road interceptor in the vicinity of the abandoned lateral, as described in letter dated January 27, 1995. The remediation activities will be coordinated with the Northeast Ohio Regional Sewer District.

G. i. The licensee shall notify the NRC Region III office no later than July 14, 1995, regarding the status of the completion of License Condition Numbers 19.B., 19.D. and 19.E.

ii. The licensee shall notify the NRC Region III office no later than July 14, 1995, to confirm initiation of the remediation project described in License Condition Number 19.F., and provide an estimated completion date.

H. The licensee shall notify the NRC Region III office in writing of any change in projected milestone dates specified in letter dated July 19, 1995 for the projects described in License Condition Nos. 19.D., E. & F. Included in the notification must be the reason for the change and the revised milestone date.

20. The licensee is authorized to install a new manhole and lateral and re-connect this to the existing under drain system. The purpose of the new manhole is strictly to act as a means of collecting water from the under drain system which will be pumped to storage containers and subsequent analysis for cobalt-60 concentration.

The licensee is authorized to install and operate the water evaporation equipment described in letters dated March 22, 1995, June 8, 1995 and June 29, 1995.

22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 12, 1984;

B. Letters dated November 12, 1984 (excluding Item 4), February 12, 1985, June 7, 1985 (excluding letter Item 4), September 6, 1985 (excluding change to Page 29 of ISP-1 manual);

22. (Continued)

C. Letters dated May 29, 1986 (Response to Enclosure A, Significant Licensing Deficiencies of NRC letter dated March 7, 1986);

D. Letter dated July 23, 1986 (Response to Enclosure B, Additional Licensing Issues for Renewal Applications of NRC letter dated March 7, 1986) excluding approval of the licensee's in-house training program;

E. Letters dated August 22, 1986, October 28, 1986, November 13, 1986, November 14, 1986 and December 4, 1986 (with Revised ISP-1 Manual, Appendices A and B attached), May 7, 1987, August 3, 1987, December 31, 1987, January 15, 1988 (Item V only), August 15, 1988 (with attached course manual), September 29, 1988 (with attachments) and November 21, 1988; and

F. Letters dated March 29, 1989 (except Section 3.4 "Hot Cell Entry and Action Levels"), April 7, 1989, August 25, 1989 (except Item B(4)), July 23, 1990 (except Sections 3.0 and 5.0 of ISP-14 procedure), March 1, 1991 (with attachments), March 27, 1991 (with attachments), May 9, 1991, May 14, 1991, February 27, 1992, February 28, 1992, March 2, 1992, and March 5, 1992.

G. Letters dated April 16, 1992 (with enclosures), June 15, 1992 (with attachments), August 10, 1992, September 18, 1992, December 29, 1992 (with enclosures), January 20, 1993, March 30, 1993, March 31, 1994 (with enclosure), April 11, 1994, and September 21, 1994.

H. Letters with attachments dated January 27, 1995, February 2, 10, and 14, 1995, and March 1, 3, 8, and 10, 1995.

Notwithstanding any reference to the specific activities in the above listed letters, the following activities are not addressed by this license.

i. The discharge of treated water to the sanitary sewer system.

ii. Installation of a composite sampler and flow gage.

iii. Conventional disposal of excavated soils exhibiting cobalt-60 concentrations greater than 8 pCi/g.

I. Letters dated May 3, 1995, May 17, 1995, June 6, 1995, June 13, 1995 and June 14, 1995 (received June 21, 1995) March 22, 1995 (Item 1 related to water evaporation use and associated attachments), June 8, 1995, June 14, 1995 (received June 19, 1995), June 29, 1995, July 19, 1995, July 20, 1995 and July 21, 1995.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-19089-01

Docket or Reference number
030-16055/040-08764/030-17154

Amendment No. 40

22. (Continued)

J. Surveillance Plan for the London Road Facility submitted in letters dated September 5, 1995 and December 18, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 1/16/96

By _____
Nuclear Materials Licensing Branch, Region III

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