Advanced Medical Systems, Inc.

DEFINITIONS	Procedure: RSP-002	Revision No.: 000
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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. 34-19089-01.

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 of 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 the 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 lead to a significant release of radioactive material and that could require a response by off-site 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 external 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 MENTS

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