ADVANCED MEDICAL SYSTEMS, INC.

Application for Renewal of USNRC License No. 34-19089-01

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110

October 30, 1995

NRC FORM 313
(8-89)
10 CFR 30, 32, 33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO. 3150-0120
EXPIRES 8/30/92

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 3.75 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1 THIS IS AN APPLICATION FOR (Check appropriate item.)

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 34-19089-01

2 NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

3 ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

1020 London Road
Cleveland, OH 44110

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Robert Reschter

TELEPHONE NUMBER: (216) 692-3270

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5 RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time: See Attachment 1

6 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED: See Attachment 1

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE: See Attachment 2

8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS: See Attachment 3

9 FACILITIES AND EQUIPMENT: See Attachment 4

10 RADIATION SAFETY PROGRAM: See Attachment 3 & 5

11 WASTE MANAGEMENT: See Attachment 3

12 LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY: 2B, 3P
AMOUNT ENCLOSED: $ 2,200.00

13 CERTIFICATION (Must be completed by applicant)

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10 CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
D. Cesar	David Cesar	Vice President	10-27-92

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER

APPROVED BY | DATE

NRC FORM 313 (8-89)

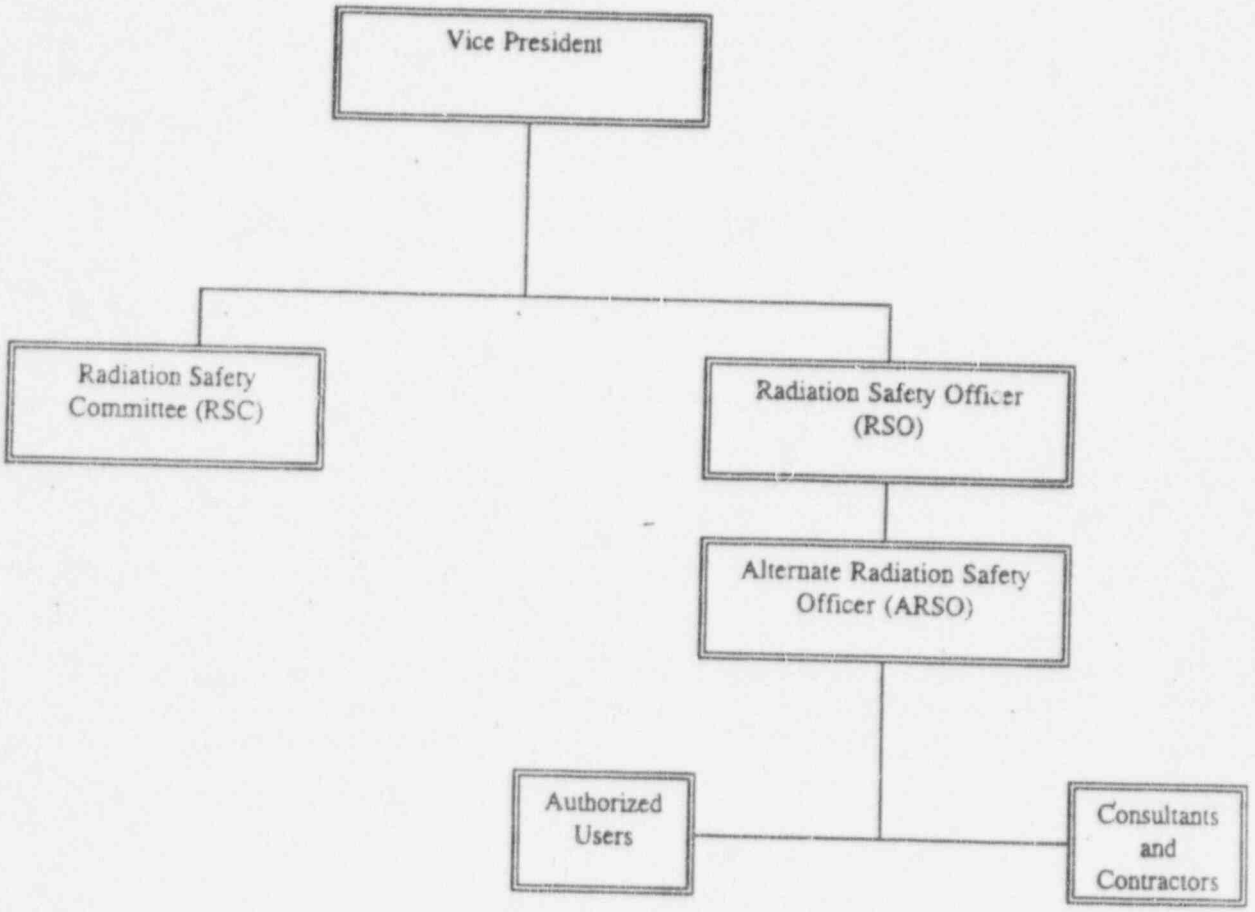
ATTACHMENT 1
Authorized Uses of Licensed Materials

Radioactive Material (Type, Form and Use):

Radionuclide	Chemical/Physical Form	Site Limit (Ci)	Intended Use
Cobalt-60	Solid metal (bulk)	23000	Storage incident to sale or transfer to authorized third party
Cobalt-60	Sealed sources	70000	Storage incident to sale or transfer to authorized third party
Cesium-137	Sealed sources	665	Use in devices, and storage incident to disposal, discharge and/or decommissioning.
Uranium (depleted)	Nickel-plated solid	4,404 (kg)	Shielding for AMS and Picker teletherapy and radiography units.
Cobalt-60	Sealed sources	0.015	Use for survey instrument response checks.
Cobalt-60 in Packaged waste	Solid	35	Materials contained in waste storage, LSA boxes and drums in the basement and waste storage room of the facility.
Cobalt-60 in Unpackaged waste	Solid/sludge	60	Materials contained in WHUT Room
Cobalt-60 in the form of Surface Contamination	Solid	15	Un-characterized surface activity in restricted areas of the facility

ATTACHMENT 2
Individuals Responsible for Radiation Safety Program and their Experience

RADIATION SAFETY ORGANIZATION



RADIATION SAFETY OFFICER

Robert Meschter

Education

A.S. (Radiological Health Technology), Central Florida Community College (1975, with honors).
Training course, "ALARA Engineering", General Dynamics, 1982.
Training course, "Microshield Use", Grove Engineering, 1992.
Training course, "Radioactive Material Shipping", IEM, 1995.
Various employer-sponsored courses (i.e., Revised 10 CFR 20, supervision and management training)

Experience and Background

Advanced Medical Systems, Inc. (1994 to present) - Radiation Safety Officer. Authority and responsibility for the Isotope facility at 1020 London Road. Responsible for radiation safety, regulatory compliance, maintenance of ISP Manual, personnel training, radiation dosimetry, and emergency response. Member of the Management Committee and Safety Committee.

Cleveland Electric Illuminating Company (1984 to 1993) - Senior Engineering Technician. Health Physics and other related duties during the past nine years included, but was not limited to, engineering analysis and evaluations, project economic and cost benefit analysis, preparation of procurement specifications, bid proposal evaluations, procedure writing, correspondence preparation, emergency planning, regulatory issues review, technical and program reviews, and work crew supervision.

Commercial Nuclear Power Industry (1975 to 1984) - Health and safety technician, chemistry technician, consultant and engineering technician for a variety of commercial nuclear installations.

ALTERNATE RADIATION SAFETY OFFICER

Stephen J. Haddock

Education

B. A. (Health), Baldwin-Wallace College, (1986)
Training course, "Radioactive Material Shipping", IEM, 1995.

Experience and Background

Advanced Medical Systems, Inc. (1991 to present) - Isotope Handler and Technician. Provided health physics support in all aspects of the facility's operation, including in hign radiation areas with accessible dose rates in excess of three (3) R per hour, transfer and handling of radiation sources, equipment maintenance and calibration, packaging and shipping of radioactive materials, radioactive materials inventory, and procedure implementation.

Coyne-Kangesser - Facility Coordinator. Managed 15 employees, which involved hiring, payroll, termination and scheduling of personnel as well as marketing functions. Responsible for customer complaints, billing and deposits. Position included customer contact.

Baldwin-Wallace College - Athletic Trainer. Part-time student athletic trainer with the Athletics Department. Duties included all facets of injury assessment including emergency procedures, first-aid including physical therapy and preventative procedures. Assisted doctors with field emergencies and physicals.

CHAIR, RADIATION SAFETY COMMITTEE

David Cesar
Vice President

Education

Bachelor of Business Administration (Accounting), Cleveland State University.

Registrations/Certifications

Certified Public Accountant

Professional Affiliations

American Institute of Certified Public Accountants
Ohio Society of Certified Public Accountants

Experience and Background

Five years of public accounting experience specializing in auditing and tax.

Nine years of industry management experience as treasurer and member of board of directors for seven (7) corporations.

Trustee of two retirement plans.

SECRETARY, RADIATION SAFETY COMMITTEE

Robert Meschter
Radiation Safety Officer

Education

A.S. (Radiological Health Technology), Central Florida Community College (1975, with honors).
Training course, "ALARA Engineering", General Dynamics, 1982.
Training course, "Microshield Use", Grove Engineering, 1992.
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Commercial Nuclear Power Industry (1975 to 1984) - Health and safety technician, chemistry technician, consultant and engineering technician for a variety of commercial nuclear installations.

MEMBER, RADIATION SAFETY COMMITTEE

Stephen J. Haddock
Licensed Isotope Handler

Education

B. A. (Health), Baldwin-Wallace College, (1986)
Training course, "Radioactive Material Shipping", IEM, 1995.

Experience and Background

Advanced Medical Systems, Inc. (1991 to present) - Isotope Handler and Technician. Provided health physics support in all aspects of the facility's operation, including in high radiation areas with accessible dose rates in excess of three (3) R per hour, transfer and handling of radiation sources, equipment maintenance and calibration, packaging and shipping of radioactive materials, radioactive materials inventory, and procedure implementation.

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Baldwin-Wallace College - Athletic Trainer. Part-time student athletic trainer with the Athletics Department. Duties included all facets of injury assessment including emergency procedures, first-aid including physical therapy and preventative procedures. Assisted doctors with field emergencies and physicals.

MEMBER, RADIATION SAFETY COMMITTEE

Edward L. Svigel
Engineering Manager

Education

Bachelor of Mechanical Engineering (BME), Gannon College (1970)
Communication/Electronics Staff Officers School (1971)
SPC/QC Training, Lakeland Community College (1988)
Training Course: "Users of Radioactive Materials at AMS", RAD Services, 1987.
Training Course: "Safe Handling, Packaging, and Shipment of Depleted Uranium", 1983.

Professional Affiliations

American Society of Mechanical Engineers (ASME)

Experience and Background

Advanced Medical Systems (1982 to present) - Engineering Manager
Gould/Engine Parts Division (1978-1982) - Machine Design Engineer
True-Temper Corporation (1976-1977) - Plant Engineer
U. S. Army Signal Corps (1971-1973) - Signal Officer
True-Temper Central Engineering (1970-1976) - Research Engineer
Diamond Shamrock (1963-1965) - Draftsman.

MEMBER, RADIATION SAFETY COMMITTEE

Carol D. Berger, C.H.P.
Integrated Environmental Management, Inc.

Education

M.S., Health Physics, San Diego State University, San Diego, California; 1979
M.S., Radiation Physics, San Diego State University, San Diego, California; 1977
B.S., Physics/Chemistry, San Diego State University, San Diego, California; 1972

Registrations/Certifications

Certified Health Physicist (Comprehensive), American Board of Health Physics: 1983
Re-certified: 1987, 1991

Professional Affiliations

American Academy of Health Physics (President, 1995)
Health Physics Society
East Tennessee Chapter - Health Physics Society (President, 1986; President-Elect, 1985; Secretary, 1981-1982)
San Diego Chapter - Health Physics Society (Charter member)
Baltimore-Washington Chapter - Health Physics Society (Treasurer, 1993-1994)
Sigma Xi - Scientific Research Society
American Board of Health Physics, Comprehensive Panel of Examiners, 1989-1993.
ASTM Task Group E-10.04.27 "Transuranic Wound Analysis"; 1986 to present
ANSI Standards Committee (ANSI N13.41) on Multiple Badging; 1986 to present (Chairman, PlanCo-59 Working Group, 1990 to present)
ANSI Standards Committee (ANSI N13.39) on Internal Dosimetry Programs; 1994 to present
NCRP Scientific Committee 46-10, "Assessment of Occupational Exposures from Internal Emitters", 1989 to present.
Member of the Health Sciences Advisory Council for the School of Health Sciences, Purdue University, 1995 to 1998.
DOE/IAEA Whole Body Counter Intercalibration Committee (1980-1986)
Consultant to Knoxville Academy of Medicine, Mass Casualty Simulation (1984-1985)
Consultant to the National Cancer Institute to Evaluate Devices and Techniques to Determine Previous Radiation Exposure under Public Law 98-54 (Award for participation presented by Oak Ridge Associated Universities, April, 1988.)
Steering Committee Member, U. S. Department of Energy Task Group on the Education of Future Health Physicists - 1989 to 1991.
Technical reviewer and referee for *Health Physics*, *Nuclear Technology*, and *Radiation Protection Management*
IT Corporation *Distinguished Technical Associate* - June, 1992.

Experience and Background

Integrated Environmental Management, Inc. (1994 to present) - President. Provides strategic environmental management services and consulting to commercial and government clients on internal and external dosimetry, applied health physics, regulations and compliance, environmental monitoring, instrumentation, emergency response, laser safety, site decommissioning, waste management, risk assessment, training, long-range business planning and cost forecasting.

IT Corporation, Nuclear Sciences Department (1086 to 1994) - Senior Technical Consultant. Performed health physics consulting for government and commercial facilities in Internal and External Dosimetry; Radiation Monitoring; Environmental Monitoring; Instrumentation; Emergency Response and Preparedness; Site Decommissioning; Radioactive Waste Management; Radiation Risk Assessment; Training; Licensing and Regulatory Negotiations; and Non-ionizing Radiation

Martin Marietta Energy Systems, Oak Ridge National Laboratory (1983 to 1986) - Radiation Dosimetry Group Leader. Responsible for internal and external dose assessment and programs for ORNL employees, visitors and contractors. Experience included Internal and External Dose Assessment; Monitoring Program Design and Implementation; Instrumentation Development; Site Characterizations; Personnel Management; and Training.

Union Carbide Corporation, Oak Ridge National Laboratory (1978 to 1983) - Internal Dose Group Leader. Responsible for development of the ORNL Whole Body Counter Facility for detection and quantification of the actinides in-vivo. Experience included: Internal Dose Assessment; Monitoring Program Design and Implementation; Instrumentation Development; Special Studies; Personnel Management; and Training.

Oak Ridge Associated Universities (1978 to 1986) - Teaching Staff. Provided professional training courses and general classes in the following health physics and radiation protection areas: Internal Dose Assessment; In-vivo Monitoring and Bioassay Methodologies, and Instrumentation.

President's Commission on the Accident at Three Mile Island (1979 to 1980) - Health Physics and Dosimetry Task Group Member. Tasks included: Internal Dose Assessment from Whole Body Counting Results; Estimates of Source Term from in-plant Monitoring Systems; Atmospheric Dispersion Modeling and Population Dose Assessment; and Development of Health Physics Sequence of Events.

ATTACHMENT 3
Radiation Protection Program Plan

TABLE OF CONTENTS

CONTROLLED COPY NO. : _____

1 PURPOSE

The goals of the Advanced Medical Systems, Inc. (AMS) policy on radiological protection are to minimize the total risk of harm or injury incurred by employees, contractors, or visitors as a result of work-related activities at sites that are licensed to possess radioactive materials, and to demonstrate compliance with applicable laws and regulations on control of radioactive materials. This Radiation Protection Program Plan (Plan) has been developed to guide generation and implementation of AMS Radiation Safety Procedures (RSPs) as they pertain to licensing and radiation protection issues. The following sections contain a description of the programmatic elements of the AMS radiation protection program.

2 SCOPE

This procedure applies to all AMS facilities, equipment and operations at the London Road facility that are licensed by the USNRC to possess radioactive materials. Facilities, equipment and operations that do not require a license are exempt from the requirements of this Radiation Safety Procedure.

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 Title 10, Code of Federal Regulations, Part 30, "Domestic Licensing of By-product Material".

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

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

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 Radiation Protection Organization and Administration

5.1.1 Vice President

5.1.1.1 Overall control and authority for radiation protection at the London Road facility shall rest with the Vice President.

5.1.1.2 The responsibility of the Vice President shall include, but is not limited to, the following:

5.1.1.2.1 Establish AMS policy and prepare/amend this Plan accordingly;

5.1.1.2.2 Appoint and empower the AMS Radiation Safety Committee (RSC); and

5.1.1.2.3 Assure that the capability of AMS radiation protection services are sufficient to meet the requirements of this Plan and USNRC license requirements.

5.1.2 Radiation Safety Officer (RSO)

5.1.2.1 The Vice President has designated the authority for implementing the radiation protection program described herein to the RSO.

5.1.2.2 The RSO shall be responsible for recommending the type and quantity of staff and resources necessary for full implementation of the Radiation Protection Program Pan.

5.1.2.3 The RSO shall have the responsibility and authority to terminate any work activities that do or may violate regulatory or AMS requirements for radiological protection.

5.1.2.3.1 Specific work activities shall be permitted to proceed to a safe condition after issuance of the stop-work order.

5.1.2.3.2 Stop-work orders shall be lifted after the initiating conditions have been alleviated.

5.1.2.4 The qualifications of the RSO shall be as described in RSP-006, "Training and Qualifications of Radiation Safety Personnel".

5.1.3 In the absence or unavailability of the RSO, the authority for implementing the radiation protection program described herein shall be delegated to the Alternate Radiation Safety Officer (ARSO).

5.1.4 Radiation Safety Committee (RSC)

5.1.4.1 The AMS Radiation Safety Committee shall provide oversight for the radiation protection program.

5.1.4.2 The permanent members of the AMS Radiation Safety Committee (RSC) shall include the RSO, the ARSO, the Vice President, the Engineering Manager, and a Certified Health Physicist.

5.1.4.3 The RSO shall serve as the Secretary of the RSC.

5.1.4.4 Depending upon the topic(s) to be addressed, the composition of the RSC may be expanded to include other individuals deemed appropriate by the Vice President or the RSO.

5.1.4.5 The RSC is responsible for the review and approval of all elements of the radiation protection program and for assessing compliance with USNRC license requirements.

5.1.4.6 The RSC is responsible for confirming that activities are performed safely and in a manner that will protect health and minimize hazards to life, property, and the environment.

5.1.4.7 Other responsibilities of the RSC shall include the following:

5.1.4.7.1 Monitoring compliance with Radiation Safety Procedures;

5.1.4.7.2 Reviewing and approving Radiation Safety Procedures for currency and adequacy, recommending revisions as appropriate;

5.1.4.7.3 Reviewing unusual incidents involving radioactive materials or radiation-producing machines and provide recommendations on how their recurrence shall be prevented; and

5.1.4.7.4 Initiating safety evaluations of all proposed uses of radioactive material or radiation-producing machines.

5.1.5 Authorized Users

5.1.5.1 The RSO may designate authority for implementing certain aspects of the radiation protection program to Authorized Users.

5.1.5.2 The responsibilities and authority of Authorized Users may include the following:

5.1.5.2.1 Monitoring and maintaining equipment associated with the use, storage, and disposal of licensed radioactive material under their control.

5.1.5.2.2 Preparing products for shipment;

5.1.5.2.3 Performing product testing;

5.1.5.2.4 Performing non-domestic (outside of the United States) field services;

5.1.5.2.5 Performing decontamination activities; and

5.1.5.2.6 Ensuring that personnel under their supervision comply with the requirements of this Plan.

5.1.6 Radiation Protection Technicians

5.1.6.1 The RSO may designate authority for implementing certain aspects of the radiation protection program to AMS or contract Radiation Protection Technicians.

5.1.6.2 The responsibilities and authority of Radiation Protection Technicians may include the following:

5.1.6.2.1 Ascertain compliance with rules and regulations, license conditions, and the guidelines approved and specified by the AMS Radiation Safety Committee (RSC);

5.1.6.2.2 Provide technical support for some or all aspects of radiation protection, including field operations,

5.1.6.2.3 Monitor and maintain equipment associated with the use, storage, and disposal of radioactive material and radiation-producing machines;

5.1.6.2.4 Provide consultation on all aspects of radiation protection to personnel at all levels of responsibility;

5.1.6.2.5 Administer and coordinate the distribution of personnel and area dosimeters on an as-needed basis;

5.1.6.2.6 Maintain personnel/area monitoring records, notify personnel and management of exposures approaching maximum permissible limits, recommend appropriate corrective action, and evaluate exposures reported by contract dosimetry services;

5.1.6.2.7 Perform an investigation in cases of apparent overexposure to radiation or radioactive materials;

5.1.6.2.8 Coordinate or conduct training programs and instruction in the acceptable methods for the use of radioactive materials and radiation-producing machines;

5.1.6.2.9 Provide refresher training as appropriate (e.g., changes in procedures, equipment, regulation);

5.1.6.2.10 Monitor the storage of all radioactive materials;

5.1.6.2.11 Monitor the shipping and receiving of all radioactive materials;

5.1.6.2.12 Maintain a radioactive materials inventory to assure continued compliance with the possession limits specified in the USNRC license.

5.1.6.2.13 Coordinate and conduct emergency response activities pursuant to RSP-016, "Emergency Response and Notifications".

5.1.6.2.14 Maintain stop-work authority pursuant to RSP-017, "Stop Work Authority".

5.1.6.2.15 Perform other monitoring/surveillance tasks as directed by the RSO.

5.2 Facilities and Equipment

5.2.1 Licensed radioactive materials shall be used/stored in restricted areas.

5.2.2 Temporary restricted areas may be instituted by the RSO, subject to the provisions of RSP-012, "Control of Work".

5.2.3 Laboratory facilities, remote handling equipment, storage containers, shielding, fume hoods, ventilation systems, and other items may be used for controlling exposures from licensed radioactive materials.

5.3 Training in Radiation Protection

5.3.1 All personnel permitted unescorted access to the controlled area shall be trained in radiation protection in accordance with RSP-007, "Training in Radiation Protection".

5.3.2 Training may consist of General Employee Training (GET), Radiation Worker Training, and/or special briefings, as determined by the RSO.

5.3.3 Other license-specific training may be substituted, at the discretion of the RSO.

5.4 Radiation Exposure Control

5.4.1 Radiation Dose Limits

5.4.1.1 Internal and external exposure limits for employees, visitors and contractors shall be consistent with those established by the USNRC in 10 CFR 20.1201.

5.4.1.2 The administrative exposure limits for monitored personnel shall be less than 4500 millirem TEDE.

5.4.1.3 The Vice President shall ensure that sufficient trained personnel are made available (to the RSO) to perform each operation such that administrative exposure limits are not reached.

5.4.1.4 Persons under 18 years of age are not permitted access to restricted areas at AMS.

5.4.1.5 Exposure limits for the unborn child shall not exceed 500 millirem for the entire gestation period.

5.4.1.5.1 Any employee, contractor or visitor that has the potential for occupational exposure shall be informed of the potential effects that may result to an embryo-fetus at low exposure levels.

5.4.1.5.2 Employees shall be encouraged to notify the RSO regarding declared pregnancies.

5.4.1.5.3 An evaluation shall be performed by the RSO to determine the potential for an employee to exceed the regulatory exposure limit during the nine month gestation period.

5.4.1.5.4 If the potential exists or if an employee's request for transfer is approved, the employee shall be transferred to a different job assignment.

5.4.1.5.5 Declared pregnant females with the potential to exceed 50 millirem CEDE during a calendar year shall be monitored for internal and external exposure.

5.4.1.6 All employees with the potential to exceed 500 millirem deep dose equivalent (H_d) shall be assigned a personnel dosimeter to wear while on site.

5.4.1.6.1 The personnel dosimetry program shall be accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

5.4.1.6.2 A formal investigation shall be performed by the RSO in the event that a personnel dosimeter shows an unexpected exposure or if a personnel dosimeter is lost.

5.4.1.6.3 A written report shall be submitted to the RSC within ten working days for review and approval of follow-up actions intended to prevent the exposure or loss from re-occurring.

5.4.1.7 All employees with the potential to exceed 500 millirem CEDE or 5,000 millirem CDE from internal sources shall participate in a routine internal radiation monitoring program.

5.4.1.7.1 The routine internal radiation monitoring program may consist of direct or indirect bioassay sampling at the beginning and end of employment, and on a planned and periodic basis thereafter as described in RSP-010, "Exposure Control".

5.4.1.7.2 Special monitoring may be performed whenever an administrative goal may have been exceeded, a nasal smear reveals the presence of detectable radioactivity, or whenever the RSO deems it appropriate.

5.4.1.7.3 Routine monitoring methodologies and frequencies shall be appropriate for detecting the types and quantities of radioactive materials in use by the employee, and shall be determined by the RSO.

5.4.1.7.4 A formal investigation shall be performed by the RSO in the event that a monitoring result is unexpected.

5.4.1.7.5 A written report shall be submitted to the RSC within ten working days for review and approval of follow-up actions intended to prevent the exposure from re-occurring.

5.4.2 Control of Work

5.4.2.1 Routine working conditions that subject an individual to exposures that are less than 100 millirem TEDE per calendar year shall require no specific controls.

5.4.2.2 Control of work that may subject an individual to exposures in excess of 100 millirem TEDE per calendar year shall be accomplished by:

5.4.2.2.1 Establishing radiological standards and responsibilities.

5.4.2.2.2 Using operations line management and the RSO to monitor performance of radiological work.

5.4.2.2.3 Training workers in recognition of radiation hazards and their responsibility to prevent their occurrence.

5.4.2.2.4 Providing personnel with RSPs and/or Radiation Work Permits that include the radiological protection measures and controls necessary for safe completion of the job.

5.4.2.3 Authorized Users shall not initiate work in areas that may subject members of the general population to exposures in excess of 100 millirem per year TEDE.

5.5 ALARA Program

5.5.1 While occupational radiation exposures incurred by employees or visitors of AMS historically are low, all exposures shall be assumed to entail some risk to the employee.

5.5.2 Line management shall adopt the following three principles to govern all work activities with the potential for exposure to radiation or radioactive materials:

5.5.2.1 Activities and operations shall produce a positive net benefit.

5.5.2.2 All radiation exposures shall be kept as low as reasonable achievable (ALARA) in light of economic and societal costs.

5.5.2.3 Radiation exposures received by individuals shall not exceed the radiation dose limits described above.

5.5.3 ALARA activities shall be performed as described in RSP-005, "ALARA Program".

5.6 Contamination Control

5.6.1 Loose and fixed radioactive contamination shall be maintained at concentrations that are as low as reasonably achievable (ALARA).

5.6.2 Equipment, components or surfaces where loose or total (loose plus fixed) contamination is detected shall be classified as described in RSP-009, Contamination Control.

5.6.3 Loose and total contamination shall be measured as described in RSP-008, "Instrumentation and Surveillance" and RSP-009, "Contamination Control".

5.6.4 Contaminated areas shall be clearly defined and posted.

5.7 Instrumentation

5.7.1 Instrumentation used by the RSO, ARSO, Radiation Protection Technicians, Authorized Users, and other Employees, visitors or contractors shall be of sufficient sensitivity and accuracy to assess radiation exposure levels found at AMS facilities, detect the presence of radioactivity on tools, equipment, clothing, and personnel at all levels found at AMS facilities, and shall be of sufficient quantity to support on-going or planned operations.

5.7.2 Instrumentation shall be purchased, tested, calibrated and used as described in RSP-008, "Instrumentation and Surveillance".

5.7.3 Calibration and repair records shall be maintained as described in RSP-004, "Radiation Protection Records".

5.7.4 Instrumentation used for other than radiation protection or license compliance purposes are exempt from these requirements.

5.8 Surveillance

5.8.1 Routine ambient exposure rate surveys and contamination surveys of restricted areas and certain unrestricted areas at the London Road facility shall be performed at a minimum frequency of once per calendar quarter.

5.8.2 Non-routine surveys may be performed at the discretion of the RSO or any time there is reason to suspect that radiation or contamination levels may have changed unexpectedly.

5.8.3 The methodology for performing surveillance activities shall be as described in RSP-008, "Instrumentation and Surveillance" and RSP-009, "Contamination Control".

5.9 Posting

Posting/labeling requirements shall be as described in RSP-011, "Radiological Areas and Posting".

5.10 Receipt and Control of Radioactive Material

5.10.1 Incoming packages, known or suspected to contain radioactivity at levels significantly higher than background, shall be monitored for exposure rate and removable external contamination, pursuant to RSP-014, "Receipt, Handling and Identification of Radioactive Material".

5.10.2 Radioactive material shall be marked as such to ensure proper handling and storage.

Note: Markings may include tags or stickers (in yellow and magenta) indicating "Radioactive Materials".

5.10.3 Items identified as radioactive materials shall be maintained in a radioactive material storage area that has been established within a restricted area specifically for this purpose.

5.10.4 Radioactive material received by AMS shall be entered in a radioactive material inventory log pursuant to RSP-014, "Receipt, Handling and Identification of Radioactive Material".

5.10.4.1 The log shall be maintained to assure compliance with maximum possession limits established in the USNRC license.

5.10.4.2 The radioactive material inventory shall be updated at least twice per calendar year to reflect new acquisitions.

5.11 Packaging and Transportation of Radioactive Materials

5.11.1 Licensed radioactive material shipped from AMS shall be packaged, surveyed, and labeled in accordance with RSP-015, "Packaging and Transportation of Radioactive Materials".

5.11.2 Prior to shipment of specifically-licensed materials, the RSO shall obtain confirmation that the receiver is licensed to receive the type, quantity and form of radioactive material present in the shipment.

5.11.3 The radioactive material inventory shall be updated at least twice per calendar year to reflect outgoing shipments.

5.12 Control of Radioactive Waste

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

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

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

5.12.1.3 Monitoring materials for radioactivity and removing non-radioactive materials prior to disposal; and

5.12.1.4 Using waste volume reduction techniques when practical.

5.12.2 Radioactive waste may be stored on site or disposed of by one of the following means:

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

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

5.12.2.3 Any other means specifically approved in advance by the USNRC.

5.12.3 Manifests, Certificates of Disposal or other documentation to confirm transfer/disposal shall be maintained by the RSO pursuant to RSP-004, "Radiation Protection Records".

5.13 Radiation Protection Records

5.13.1 The RSO shall maintain records in order to document implementation of this Plan and to demonstrate compliance with applicable USNRC license requirements.

5.13.2 Records shall be maintained as described in RSP-004, "Radiation Protection Records".

5.14 Documentation

5.14.1 Radiation Safety Procedures shall be controlled and distributed pursuant to RSP-003, "Control of Radiation Safety Procedures".

5.14.2 The following Radiation Safety Procedures shall require amendment to USNRC License No. 34-19089-01 prior to revision or discontinuation:

5.14.2.1 RSP-001, "Radiation Protection Program Plan"

5.14.2.2 RSP-003, "Control of Radiation Safety Procedures"

5.15 Emergency Response and Notifications

5.15.1 For emergencies where radioactive materials may be involved, consideration shall be given to exposure to radioactive materials and ionizing radiation in addition to the other hazards present.

5.15.2 Emergency response actions shall be performed pursuant to RSP-016, "Emergency Response and Notifications".

5.15.3 If it is known or suspected that an internal or external dose limit has been exceeded or that contamination levels are not as expected:

5.15.3.1 The RSO shall be notified immediately.

5.15.3.2 The RSO shall evaluate the likelihood and magnitude of the exposure or contamination status, and shall implement appropriate follow-up actions as soon as possible after notification.

5.16 Quality Assurance in Radiological Protection

5.16.1 All activities conducted as part of this Plan shall be subject to quality assurance provisions.

5.16.2 These provisions should include the following:

5.16.2.1 Radiation Safety Procedures shall be developed to implement this Plan.

5.16.2.2 Limited-scope audits/assessments of the radiation protection program should be conducted by the RSO (or designee) to determine compliance with applicable federal/state regulations, applicable license requirements, and this Plan.

5.16.2.3 Audits/assessments of the provisions of this Plan should be performed by the Quality Assurance Department.

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

None

8 ATTACHMENTS

None

ATTACHMENT 4
Facilities and Equipment

Description of Facilities, Equipment at
Advanced Medical Systems, Inc.

Advanced Medical Systems, Inc. (AMS) manufactured and fabricated sealed sources of ^{60}Co for teletherapy and radiography machines. The AMS operation, which occupies approximately 25% of an 80,000 square foot warehouse/manufacturing building at 1020 London Road (Cleveland, Ohio), is contained on three floors. The main floor includes an office area, the Isotope Shop area, a hot cell, a shielded work room, and miscellaneous unoccupied areas. The second floor contains additional unoccupied office space, a mechanical equipment room, and the HEPA ventilation system equipment room. The basement contains a source storage area and irradiation facility, waste storage areas, additional unoccupied space, and a liquid waste holdup tank room (WHUT room). The majority of the 6.3-acre property is covered with asphalt or concrete. Figures 1 through 3 show the layout of the three floors of the AMS building.

Licensed radioactive materials are located in specific areas within the AMS building. The following is a description of the various areas of the building.

Hot Cell

The Hot Cell was designed and equipped to encapsulate large sources of radioactive material used for medical therapy and industrial radiography. The cell is six (6) feet square and has 5.5-foot thick concrete walls and a four-foot thick floor and ceiling. There is a stainless steel floor pan in the cell, and 0.25-inch thick by 11 foot tall steel wall plates. The cell has a six foot wide, 42-ton concrete hinged door at the rear. Two small access ports are located on the south wall of the cell.

There is a 60-inch thick viewing window at the cell front.[1] It is composed of an eight (8) inch inside cover plate of non-browning glass, two (2) inches of plate glass, 48 inches of zinc bromide solution, and a two (2) inch outside cover plate of laminated safety glass. This construction provides shielding that is equivalent to 66 inches of 150 lb/ft^3 concrete.

Remote handling in the Hot Cell is accomplished with a pair of manipulators and a two-ton overhead crane. Every item of equipment in the Hot Cell and every item within the cell structure are removable. The location of the Hot Cell on the first floor of the AMS building is shown in Figure 1. The Hot Cell is a "Restricted Area".

Isotope Shop

The Isotope Shop is located on the first floor next to the Hot Cell as shown in Figure 2. This area has a concrete floor, ceiling, and interior walls. The exterior walls are of painted brick. Cobalt-

[1] The window was designed and constructed in 1984 by Hot Cell Services Corporation, Kent, Washington.

60 sources are transported around this area in shielded containers.[2] The Isotope Shop also contains a table-mounted hood, a table, a sink, an old trash compactor, and three-ton overhead hoist with trolley, and a Tow Motor.[3] Within the Isotope Shop is the Source Garden. The Isotope Shop is a "Restricted Area".

Source Garden

The Source Garden is located in the southwest corner of the Isotope Shop as shown on Figures 1 and 2. This area houses vertical tubes in a six-foot square well that extends from the first floor to the basement. An L-shaped shield around the well at the basement level is provided by two sand-filled shield vaults which are accessible through manholes in the first floor. The high-density concrete walls containing the sand shield are two-feet thick.

There are 54 storage tubes in the Source Garden's nine-by-seven rectangular array. The nine center spaces of the array are open and fitted with an irradiation plug which accommodates objects up to 8.5 inches square by 12 inches high. The source tubes terminate in a metal container through which cooling air is drawn from the room to the high-efficiency air- (HEPA-) filtered exhaust system. The Source Garden is in a "Restricted Area".

Decontamination Room

The Decontamination Room is located behind the Hot Cell and at the side of the Isotope Shop as shown in Figure 2. This area has a concrete floor and walls. The room provides space enough for opening the Hot Cell door into the ventilation controlled space of the Decontamination Room.

The room is equipped with water outlets and a floor drain, which was used during previous decontamination operations. This drain has since been sealed. In this area is a vault that contains ancillary Hot Cell items and lead blankets, along with beam shields made of lead. The Decontamination Room is a "Restricted Area".

High Level Waste Storage Room and Shielded Work Room

The High Level Waste Storage Room is located next to the Hot Cell on the first floor as shown in Figure 2. This room has a concrete floor, walls (three-foot thick) and ceiling, and a labyrinth entrance. There are drums of waste stored here, along with spent HEPA filters. The High Level Waste Storage Room is a "Restricted Area".

Clean Equipment Room

The Clean Equipment Room is located on the second floor as shown on Figure 3. This room has a concrete floor, walls and ceiling. It contains all of the facility service equipment with the exception of the HEPA ventilation equipment. It also contains the emergency generator for use in the event of power failure. The Clean Equipment Room is a "Restricted Area".

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[2] One such container is the "transfer monster", which is used to move sources in and out of the Hot Cell.

[3] The Tow Motor is an electric fork lift.

HEPA Equipment Room

The HEPA Equipment Room is located on the second floor of the facility as shown in Figure 3. This room has a concrete floor, walls and ceiling. It contains the facility HEPA ventilation equipment. There is one large HEPA exhaust blower that holds four two-foot by two-foot HEPA filters in a housing. This system services all of the isotope areas except the Hot Cell. There is also a small HEPA exhaust blower with only one HEPA filter in its housing. This system services the Hot Cell. The HEPA Equipment Room is a "Restricted Area".

Back Basement

The Back Basement is located in the basement as shown in Figure 1. This room has a concrete floor and walls. There is a drum storage area along one wall, with temporary shielding erected between the storage area and the main part of the room. There are approximately 500 high-density concrete blocks in the room that are positioned to provide additional shielding from materials in the WHUT room. The Back Basement is a "Restricted Area".

WHUT Room

The Waste Hold-Up Tank (WHUT) Room is located in the basement directly under the Hot Cell as shown on Figure 1. This room has a concrete floor, walls and ceiling. The room walls are three feet thick to provide shielding from the room's contents, with additional shielding as described above.

The room contains a 100-gallon and a 500-gallon tank for liquid wastes. When the room was still in use, wastes were "held up" in the tanks until sampling/analysis confirmed that they could be discharged to the sewer system. However, in 1989 AMS ceased discharging liquid radioactive waste to the sewer system. Shortly thereafter, the WHUT Room was sealed. The WHUT Room is a "Restricted Area".

Front Basement

The Front Basement is located on the east side of the basement next to the WHUT room, as shown in Figure 1. It consists of three rooms: the passageway between the front and back basement, the Chart Room, and the Blue Tank Room. The rooms have concrete floors, ceiling, and exterior walls. The interior walls are wood-framed with painted drywall surfaces. There are 45 high-density concrete blocks in the Blue Tank Room that are positioned to provide additional shielding from the WHUT room. The Front Basement is a "Restricted Area".

Miscellaneous Restricted Areas

There are a number of miscellaneous areas within the AMS facility. These include the air lock, the Isotope Shop warehouse, portions of a caged storage area, and office areas on the second floor. These areas have been designated as "Restricted Areas".

Other Areas

There are other miscellaneous areas within the AMS facility that are not restricted for purposes of radiological control. These are a former chemistry laboratory, the Hot Cell control office, the first floor office areas, portions of a caged storage area, and the counting room.

Security and Fire System

The AMS facility on London Road is equipped with a security system that is composed of fire detection and burglar alarm functions. Both facets of the system are remotely monitored by ADT Security Systems, Inc.

The burglar alarm system employs a variety of electronic techniques to detect intrusion. If intrusion occurs, the Cleveland Police Department is notified and ADT Security Systems, Inc. Personnel are dispatched to the facility. AMS personnel are also notified and respond to the facility.

The fire detection system consists of a combination of heat, smoke, and sprinkler system flow detectors. In the event that one of these detectors is activated after normal hours, ADT Security Systems, Inc. Notifies the Cleveland Fire Department and AMS personnel. During normal business hours, the system may be activated by a local fire alarm switch located at the main entrance to the facility on London Road, or by the installed detectors.

Fire alarm annunciator displays are located at the main entrance and at the alternate entrance. Also at these locations are facility layout diagrams denoting the radiologically restricted areas within the building.

The fire suppression capability in the building consists of a sprinkler system that covers all locations outside of the restricted areas. A variety of ABC-type fire extinguishers (hand-held) are placed throughout the building (restricted and unrestricted areas).

Air Handling Systems

Air handling at the AMS facility is via four separate systems. These support the isotope area, the first floor office area, the second floor office area, and the lobby and reception area.

The isotope area system has once-through airflow, with a carefully balanced flow gradient to the Hot Cell as the low pressure point. Supply air is drawn through pre-filters before entering the building.[4] The supply air is distributed to the isotope areas by ventilating ducts containing manually-adjustable dampers. The airflow pattern is adjusted by balancing the supply and exhaust systems to obtain the desired flow pattern. Periodic checks of manometers are made to assure the desired pattern is maintained.

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[4] The heavy burden of industrial pollutants from neighboring plants and the railroad tracks is removed by the pre-filters in order to extend the useable lifetime of the HEPA filters.

The doors at either end of the change area are electrically interlocked to prevent simultaneous opening which might disturb the air flow pattern. The doors at either end of the air lock, used to move shipping containers in and out of the isotope areas, are similarly interlocked.

The exhaust system has two centrifugal blowers which are located on the second floor directly above the Hot Cell. Both blowers exhaust through separate filters and a common high-velocity stack. The larger blower removes air from all isotope areas except the Hot Cell, and routes it through an array of absolute (HEPA) filters. The exhaust fan for the Hot Cell is independently operated, and has a single absolute filter. The balanced air flow pattern is from the change areas, through the Isotope Shop area, to the Decontamination Room, and finally to the Hot Cell.

The Hot Cell exhaust fan is driven by a two-speed motor which is controlled by the position of the double doors connecting the Decontamination Room with the Isotope Shop area. With the doors closed, the fan operates at normal speed and the Decontamination Room receives its air supply through a duct at the south side of the doorway. When the door is opened, the supply air is diverted from inside to outside the Decontamination Room by means of a switch which also increases the Hot Cell exhaust fan capacity by about 50%. This prevents reverse flow of the potentially contaminated air of the Decontamination Room into the lower level Isotope Shop area.

The air from both exhaust systems exits the system from a stack with a height of 12.2 meters above ground. The system flow rate is 971 scfm. The filtration efficiency is 99.97% for particulates with a physical diameter of 0.3 micrometer or larger. An air sampling tube is mounted across a diameter of the exhaust stack at a height of eight (8) feet above the roof level. An air monitor located in the Hot Cell control area draws a continuous sample of 5 cfm (minimum) from the stack for analysis. The results are indicated on a chart recorder. The stack monitor is also connected to the security system.

The air handling system is under continuous control by a monitoring and safety system. Any increase of activity above a pre-set level immediately stops the exhaust fans and the supply fan. There is also automatic shutdown of either exhaust fan if a sudden pressure drop occurs across its absolute filters, indicating a possible rupture in the filter media.

Emergency Power and Lighting

Continuous operation of the air handling equipment, the monitoring devices and other electrically-powered systems is maintained in the event of electrical power failure by a natural-gas-burning emergency generator with automatic rapid changeover. The facility emergency lighting system is also powered by this generator.

Alarm Systems

All safety and monitoring devices are connected to a Master Alarm Panel in the Hot Cell control area of the AMS facility. Separate lights for each controlled item are always lit on the panel so that faulty operation of the panel itself is readily identified.

When a controlled item malfunctions, the alarm light increases in intensity and flashes on and off until an acknowledgment button is depressed. An audible alarm also sounds on the first and second floors until acknowledged. The alarm will continue to indicate the difficulty even though it may have corrected itself before the operator has checked the Master Alarm Panel since the alarm signal can only be terminated when the acknowledgment button has been depressed. The following are examples of conditions which will cause an alarm:

- Hot Cell Exhaust Fan: Shut down from lack of power or switch turned off; Sudden pressure drop across air filter indicating ruptured filter; Improper pressure across filter indicating broken belts, fan inoperative or plugged filter; and Excessive radiation on the air monitor.

- Isotope Shop Area Exhaust Fan: Shut down from lack of power or switch turned off; Sudden pressure drop across air filters indicating ruptured filter; Improper pressure across filter indicating broken belts, fan inoperative or plugged filters; and Excessive radiation on the air monitor.

- Air Monitor: Excessive radiation on filter paper in air monitor or electronic malfunction of monitoring equipment.

- Cell Temperature: Two thermostats, one located in Cell Control Area, and one located in Decontamination Room immediately behind the cell, are set to give an alarm signal for temperatures below 40^0 F. or above 85^0 F.

- Supply Fan: A thermostat in the intake system after the heaters will give an alarm signal for temperatures below 50^0 F.

- Emergency Generator: Signal given on power failure when generator starts.

Alarms for fan shutdown, excessive heat, or excessive cold are also transmitted to the contracted security service. During non-working hours, the security service files a report with an AMS representative and the applicable response agency.

There are also a variety of alarm and interlock systems in specific locations of the restricted area. For the Hot Cell, there is a door interlock that secures the door in the closed position until two switches, one on the outside of the door and one on the cell face in the Cell Control Area, are depressed simultaneously. This safety feature makes it impossible for the cell door to be opened without the knowledge and consent of the cell operator, or for the door to be opened by a person working alone.

Also in the Hot Cell is a gamma alarm mounted opposite the cell face in the Cell Control Area. Since it is connected to a loud buzzer, it gives both an audible and a visible alarm (flashing red light) continuously when radiation levels are in excess of the preset level of approximately 2

mR/hr. The gamma alarm features fail-safe circuitry to provide a signal at all times. Failure of any element either turns on the red lamp or turns off the green (safe) lamp, signaling improper operation.

In the Isotope Shop area, there is a gamma alarm mounted on the west wall between the storage garden and the Decontamination Room adjacent to the source transfer operation. This will give a visible flashing red light when radiation exceeds the preset level of 5 mR/hr. Also, when the basement door is opened, a steady red light turns on above the door and on the Master Alarm Panel.

In the air locks, the doors at either end of the change area are electrically interlocked to prevent simultaneous opening which might disturb the air flow pattern. The entrance to the change area from the cell control area is an air lock by itself. The first door is interlocked with the door on the opposite side of the change area leading into the Isotope Shop area.

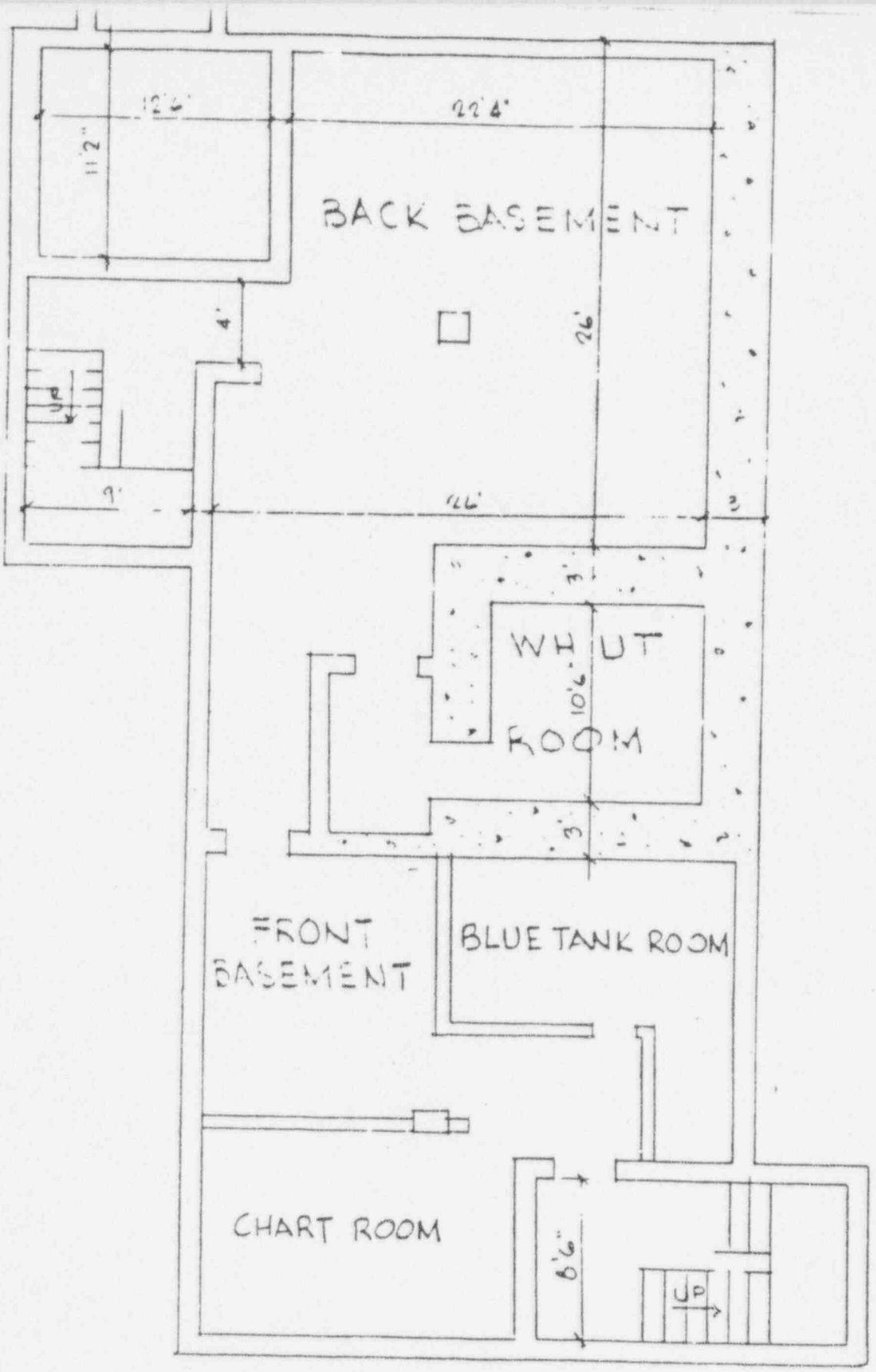
The air lock on the west side of the Isotope Shop area has three (3) electrically interlocked doors. One set of doors leads to the Isotope Shop area, one set leads to the warehouse and the last set, on the north side of the air lock, leads to the unrestricted area. When the Isotope Shop area doors are open, the other two doors cannot be opened. When one of the other two doors is open, the Isotope Shop area doors cannot be opened.

Instrumentation

The AMS facility possesses a variety of portable and stationary radiation detection instruments. The following table shows the types of equipment and the minimum number available in the operating inventory at any point in time (with the exception of the Multichannel Analyzer and the Single Channel Analyzer):

Purpose	Instrument Type	Detector Type	Minimum Number in Operating Inventory
Ambient gamma surveys	Portable GM Survey Meter	GM	1
Ambient gamma surveys	Portable Ion Chamber Survey Meter	Ion chamber	1
Ambient gamma surveys	Micro-R Meter	Sodium Iodide Detector	1
Personnel exposure monitoring	Pocket Ionization Chambers	Ion chamber	5
Air Monitoring	Breathing Zone Samplers	Filter cartridge and pump	1
Sample Analysis	Stationary Counter	GM	1
Sample Analysis	Multichannel Analyzer	Sodium Iodide Detector	1 total
Sample Analysis	Single Channel Analyzer	Sodium Iodide Detector	1 total

FIGURE 1 - BASEMENT OF AMS FACILITY

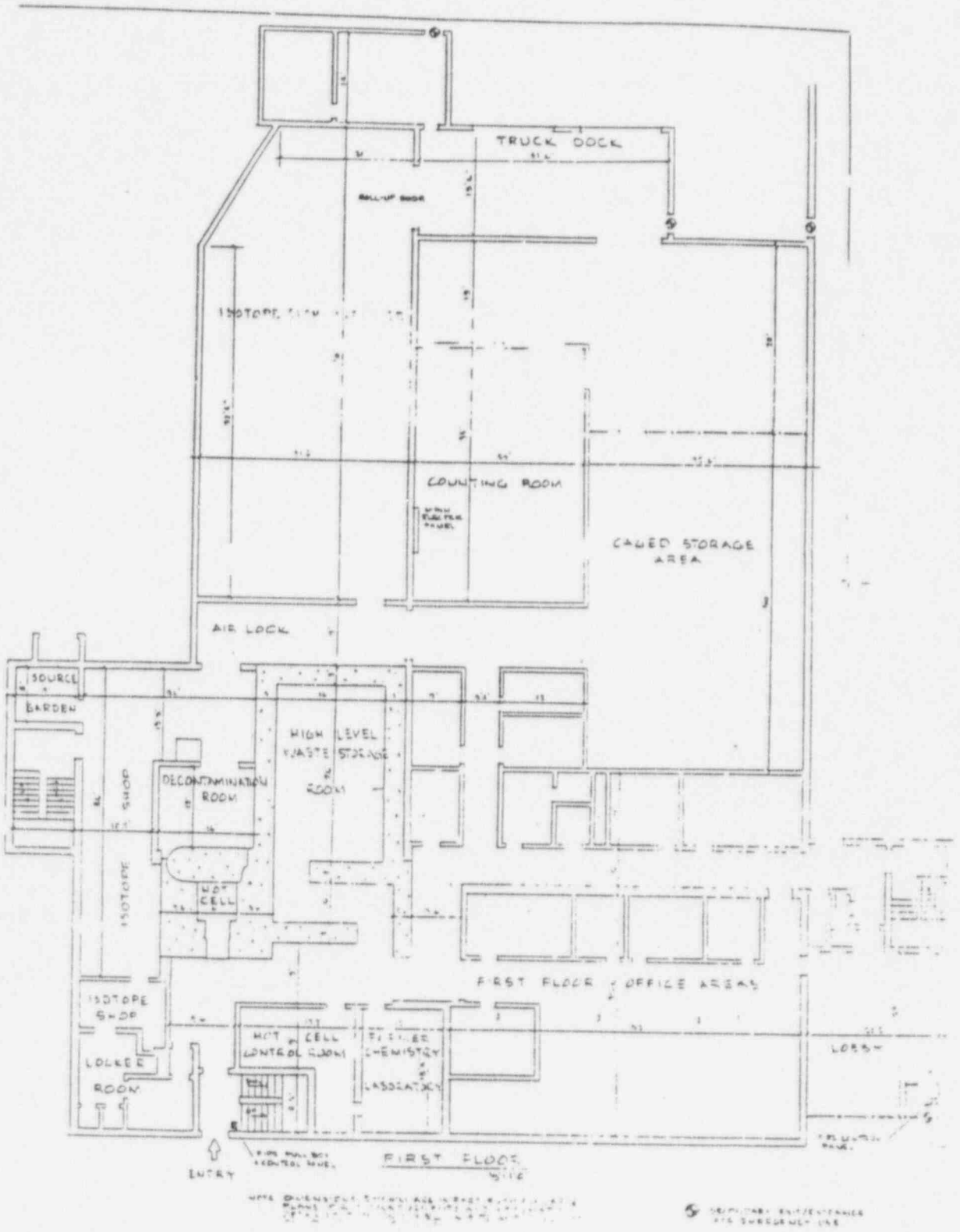


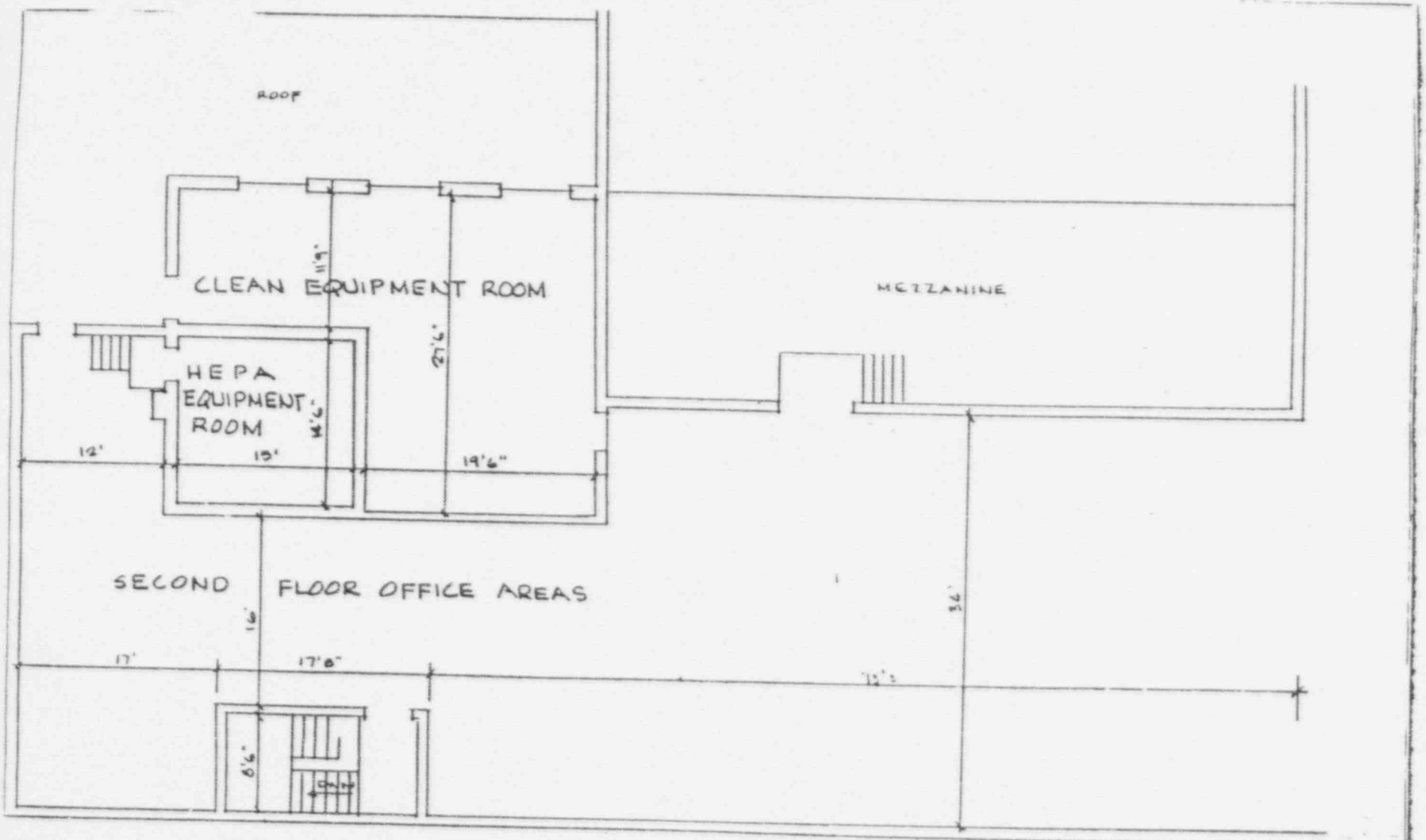
BASEMENT

1/8" = 1'0"

NOTE: DIMENSIONS SHOWN ARE IN PART FROM AVAILABLE PLANS, FIELD MEASURMENTS AND INFORMATION OBTAINED FROM PERSONNEL ON SITE AND IS ACCURATE FOR ITS INTENDED FUNCTION.

FIGURE 2 - FIRST FLOOR OF AMS FACILITY


TRUCK DOCK
ISOTOPE STORE
COUNTING ROOM
CAGED STORAGE AREA
AIR LOCK
SOURCE GARDEN
HIGH LEVEL WASTE STORAGE ROOM
DECONTAMINATION ROOM
ISOTOPE SHOP
HOT CELL
FIRST FLOOR OFFICE AREAS
ISOTOPE SHOP
LOCKER ROOM
HOT CELL CONTROL ROOM
FISSION CHEMISTRY LABORATORY
ENTRY
FIRST FLOOR



SECOND FLOOR

1/8" = 1'0"

NOTE: DIMENSIONS SHOWN ARE IN PART FROM AVAILABLE PLANS, FIELD MEASURMENTS AND INFORMATION OBTAINED FROM PERSONEL ON SITE AND IS ACCURATE FOR ITS INTENDED FUNCTION.

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CONTROLLED COPY NO. : _____

5.1.2.4 Audit manual issuance and control requirements for compliance with the provisions of this RSP.

5.1.2.5 Ensure historical procedure files for RSPs are maintained.

5.1.2.6 Provide distribution coordination.

5.1.3 The Radiation Safety Committee (RSC) shall review and approve all RSPs to ensure compliance with corporate safety and operational requirements as well as with the AMS Radiation Protection Program Plan.

5.1.4 AMS personnel shall:

5.1.4.1 Comply with all applicable RSPs.

5.1.4.2 Notify the RSO or line management if an RSP is found to be inaccurate or lacking sufficient detail for the activity.

5.2 Procedure Format

5.2.1 Each page of each RSP shall utilize the header format as shown on this page.

5.2.1.1 The header shall specify the title of the procedure.

5.2.1.2 The procedure number and the approval date shall be specified in the header.

5.2.1.3 The page designation shall specify both the specific page and the total number of pages of the RSP.

5.2.2 The format for all RSPs shall include seven major sections: Purpose; Scope; References; Definitions; Procedure; Exemption Provisions; and Documentation.

5.2.2.1 The Purpose Section shall specify the reason for the RSP and if appropriate, shall denote why the activity is to be performed.

5.2.2.2 The Scope section shall specify the range of activities covered by the RSP and any limitations on the use of the RSP.

5.3.4 RSP-004, "Radiation Protection Records"

5.3.5 RSP-005, "ALARA Program"

5.3.6 RSP-006, "Training and Qualifications of Radiation Protection Personnel"

5.3.7 RSP-007, "Training in Radiation Protection"

5.3.8 RSP-008, "Instrumentation and Surveillance"

5.3.9 RSP-009, "Contamination Control"

5.3.10 RSP-010, "Exposure Control"

5.3.11 RSP-011, "Radiological Areas and Posting"

5.3.12 RSP-012, "Control of Work"

5.3.13 RSP-013, "Control of Radioactive Waste"

5.3.14 RSP-014, "Receipt, Handling, and Identification of Radioactive Materials"

5.3.15 RSP-015, "Packaging and Transportation of Radioactive Materials"

5.3.16 RSP-016, "Emergency Response and Notifications"

5.3.17 RSP-017, "Stop Work Authority"

5.4 Review of Procedures

5.4.1 Prior to submittal for approval, each RSP shall receive editorial and technical reviews.

5.4.2 An editorial review shall be performed by someone other than the author of the procedure and should address clarity, grammar, punctuation, spelling, and consistency in abbreviations.

5.4.3 A technical adequacy review shall be performed by a technically competent individual who is not directly responsible for the generation of the RSP.

5.7.3 The RSO shall assign a number to each PCN for a given RSP, numbered sequentially as each is submitted for production and distribution.

5.7.4 Copies of PCNs shall be distributed to all holders of controlled copies within one week of approval.

5.7.5 Temporary RSP changes shall be noted as such on the PCN, along with effective dates.

5.7.6 Revised RSPs with permanent changes shall be issued within six months of the procedure change approval.

5.8 Minor Changes

5.8.1 Minor changes in RSPs may be made if approved by the RSO.

5.8.2 Minor changes shall be written by hand on the affected page.

5.8.3 The date and originator shall be noted at the top of the affected page.

5.8.4 The RSO shall distribute the affected pages to all holders of controlled copies within one (1) week.

5.9 Procedure Manual Issuance and Control

5.9.1 All RSPs shall be maintained under a controlled distribution system.

5.9.2 Authorized recipients:

5.9.2.1 The RSO shall determine who is to be issued manuals to assure that all individuals needing the RSPs will have access to them in the area in which the work is to be performed..

5.9.2.2 If requested, and if a recipient name/address is provided, the USNRC shall be an authorized recipient of one copy of the manual and all RSPs.

5.9.3 A master list of procedure manuals and individual procedures issued shall be maintained by the RSO.

ATTACHMENT 1
PROCEDURE CHANGE NOTICE

Modification to existing RSP ( ) or Supplement to exiting RSP ( )

RSP Number: _____

RSP Title: _____

Time Period from _____ to _____

Specific Activities affected: _____

Description of changes including pages and paragraphs affected (attach additional sheets as needed):

_____

_____

_____

_____

_____

_____

_____

Justification for changes:

_____

_____

_____

Approved by: _____ Approved by: _____
Vice President Radiation Safety Committee (Chair)

Approved by: _____
Radiation Safety Officer

_____

ATTACHMENT 3
RADIATION SAFETY PROCEDURE TRANSMITTAL FORM

To:

Date:

From: Radiation Safety Officer (RSO)

Subject: Radiation Safety Procedure Transmittal

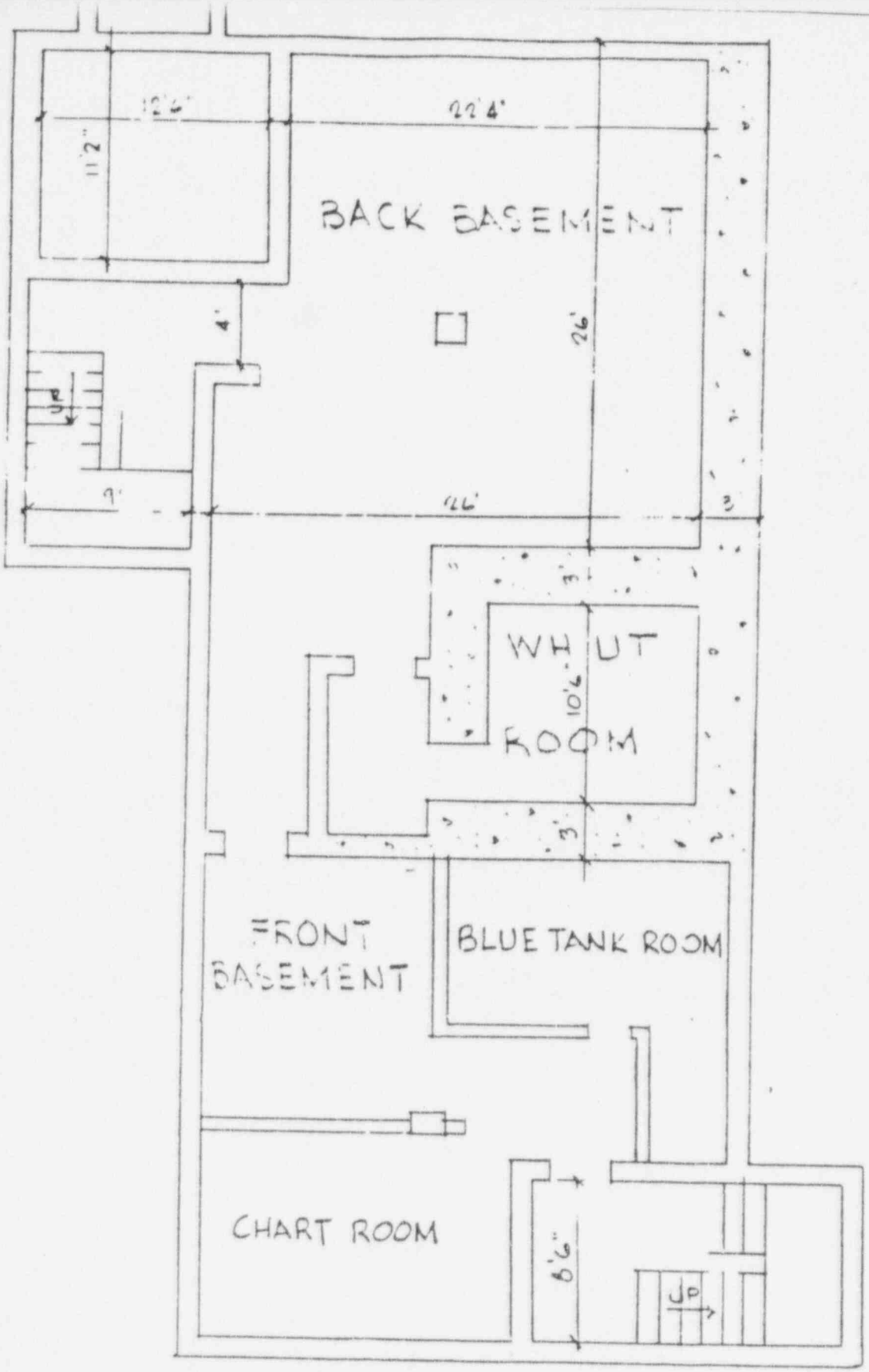
Attached is a new or revised copy of the procedure(s) listed below for incorporation into your Radiation Safety Procedure Manual. Within ten working days, please place the attached document(s) into your manual and remove and return all superseded documents. Procedure Change Notices (PCNs) should be placed at the front of the existing procedure and all pages retained until the next revision. When you have updated your manual, please sign and date this form and return it to the RSO.

ision number	Date	Pages Affected	Description of Change

I verify by my signature that the above item(s) have been placed in my controlled manual and superseded procedures/PCNs have been removed and returned.

Name/Date

FIGURE 1 - BASEMENT OF AMS FACILITY

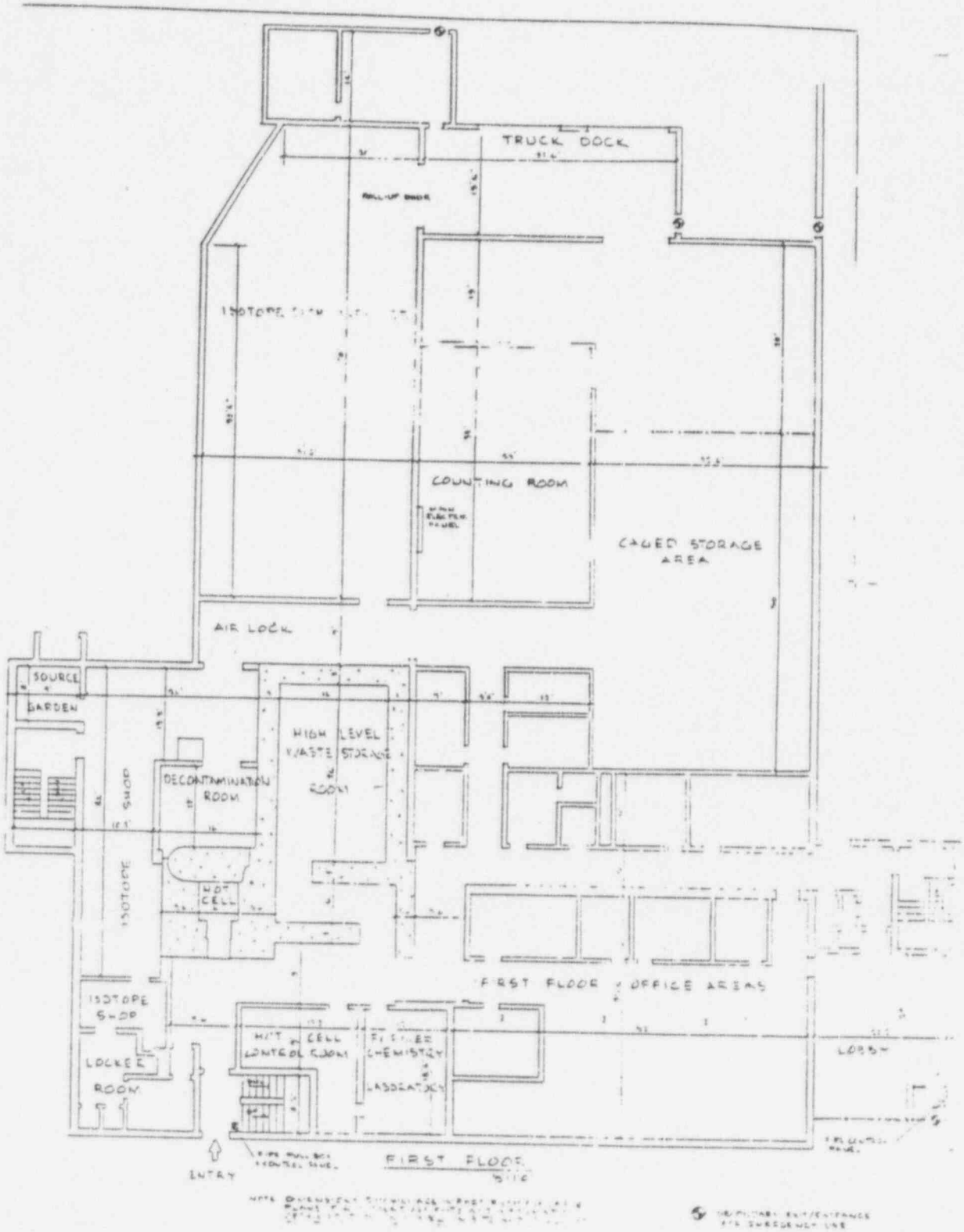


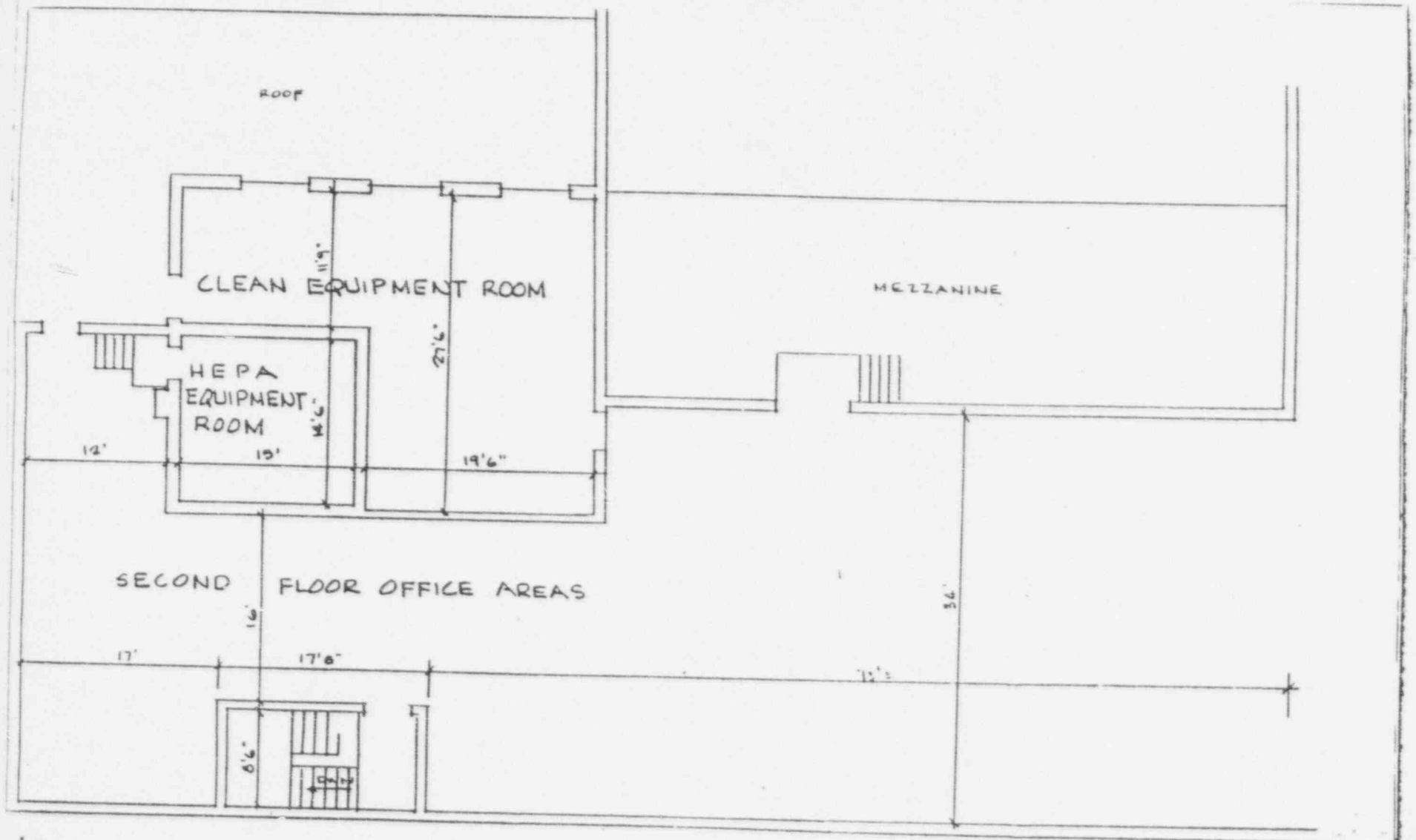
BASEMENT

1/8" = 1'0"

NOTE: DIMENSIONS SHOWN ARE IN PART FROM AVAILABLE PLANS, FIELD MEASURMENTS AND INFORMATION OBTAINED FROM PERSONEL ON SITE AND IS ACCURATE FOR ITS INTENDED FUNCTION.

FIGURE 2 - FIRST FLOOR OF AMS FACILITY


TRUCK DOCK
ROLL-UP DOOR
ISOTOPE STORE
COUNTING ROOM
ELECTRIC PANEL
CAGED STORAGE AREA
AIR LOCK
SOURCE GARDEN
HIGH LEVEL WASTE STORAGE ROOM
DECONTAMINATION ROOM
SHOP
ISOTOPE
HOT CELL
ISOTOPE SHOP
LOCKER ROOM
HOT CELL CONTROL ROOM
FISSILE CHEMISTRY LABORATORY
FIRST FLOOR OFFICE AREAS
LOBBY
ENTRY
FIRST FLOOR



SECOND FLOOR

1/8" = 1'0"

NOTE: DIMENSIONS SHOWN ARE IN PART FROM AVAILABLE PLANS, FIELD MEASURMENTS AND INFORMATION OBTAINED FROM PERSONEL ON SITE AND IS ACCURATE FOR ITS INTENDED FUNCTION.

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CONTROLLED COPY NO. : _____

5.1.2.4 Audit manual issuance and control requirements for compliance with the provisions of this RSP.

5.1.2.5 Ensure historical procedure files for RSPs are maintained.

5.1.2.6 Provide distribution coordination.

5.1.3 The Radiation Safety Committee (RSC) shall review and approve all RSPs to ensure compliance with corporate safety and operational requirements as well as with the AMS Radiation Protection Program Plan.

5.1.4 AMS personnel shall:

5.1.4.1 Comply with all applicable RSPs.

5.1.4.2 Notify the RSO or line management if an RSP is found to be inaccurate or lacking sufficient detail for the activity.

5.2 Procedure Format

5.2.1 Each page of each RSP shall utilize the header format as shown on this page.

5.2.1.1 The header shall specify the title of the procedure.

5.2.1.2 The procedure number and the approval date shall be specified in the header.

5.2.1.3 The page designation shall specify both the specific page and the total number of pages of the RSP.

5.2.2 The format for all RSPs shall include seven major sections: Purpose; Scope; References; Definitions; Procedure; Exemption Provisions; and Documentation.

5.2.2.1 The Purpose Section shall specify the reason for the RSP and if appropriate, shall denote why the activity is to be performed.

5.2.2.2 The Scope section shall specify the range of activities covered by the RSP and any limitations on the use of the RSP.

5.3.4 RSP-004, "Radiation Protection Records"

5.3.5 RSP-005, "ALARA Program"

5.3.6 RSP-006, "Training and Qualifications of Radiation Protection Personnel"

5.3.7 RSP-007, "Training in Radiation Protection"

5.3.8 RSP-008, "Instrumentation and Surveillance"

5.3.9 RSP-009, "Contamination Control"

5.3.10 RSP-010, "Exposure Control"

5.3.11 RSP-011, "Radiological Areas and Posting"

5.3.12 RSP-012, "Control of Work"

5.3.13 RSP-013, "Control of Radioactive Waste"

5.3.14 RSP-014, "Receipt, Handling, and Identification of Radioactive Materials"

5.3.15 RSP-015, "Packaging and Transportation of Radioactive Materials"

5.3.16 RSP-016, "Emergency Response and Notifications"

5.3.17 RSP-017, "Stop Work Authority"

5.4 Review of Procedures

5.4.1 Prior to submittal for approval, each RSP shall receive editorial and technical reviews.

5.4.2 An editorial review shall be performed by someone other than the author of the procedure and should address clarity, grammar, punctuation, spelling, and consistency in abbreviations.

5.4.3 A technical adequacy review shall be performed by a technically competent individual who is not directly responsible for the generation of the RSP.

5.7.3 The RSO shall assign a number to each PCN for a given RSP, numbered sequentially as each is submitted for production and distribution.

5.7.4 Copies of PCNs shall be distributed to all holders of controlled copies within one week of approval.

5.7.5 Temporary RSP changes shall be noted as such on the PCN, along with effective dates.

5.7.6 Revised RSPs with permanent changes shall be issued within six months of the procedure change approval.

5.8 Minor Changes

5.8.1 Minor changes in RSPs may be made if approved by the RSO.

5.8.2 Minor changes shall be written by hand on the affected page.

5.8.3 The date and originator shall be noted at the top of the affected page.

5.8.4 The RSO shall distribute the affected pages to all holders of controlled copies within one (1) week.

5.9 Procedure Manual Issuance and Control

5.9.1 All RSPs shall be maintained under a controlled distribution system.

5.9.2 Authorized recipients:

5.9.2.1 The RSO shall determine who is to be issued manuals to assure that all individuals needing the RSPs will have access to them in the area in which the work is to be performed..

5.9.2.2 If requested, and if a recipient name/address is provided, the USNRC shall be an authorized recipient of one copy of the manual and all RSPs.

5.9.3 A master list of procedure manuals and individual procedures issued shall be maintained by the RSO.

ATTACHMENT 1
PROCEDURE CHANGE NOTICE

Modification to existing RSP ( ) or Supplement to exiting RSP ( )

RSP Number: _____

RSP Title: _____

Time Period from _____ to _____

Specific Activities affected: _____

Description of changes including pages and paragraphs affected (attach additional sheets as needed):

_____

_____

_____

_____

_____

_____

Justification for changes:

_____

_____

Approved by: _____
Vice President

Approved by: _____
Radiation Safety Committee (Chair)

Approved by: _____
Radiation Safety Officer

_____

ATTACHMENT 3
RADIATION SAFETY PROCEDURE TRANSMITTAL FORM

To:

Date:

From: Radiation Safety Officer (RSO)

Subject: Radiation Safety Procedure Transmittal

Attached is a new or revised copy of the procedure(s) listed below for incorporation into your Radiation Safety Procedure Manual. Within ten working days, please place the attached document(s) into your manual and remove and return all superseded documents. Procedure Change Notices (PCNs) should be placed at the front of the existing procedure and all pages retained until the next revision. When you have updated your manual, please sign and date this form and return it to the RSO.

ision number	Date	Pages Affected	Description of Change

I verify by my signature that the above item(s) have been placed in my controlled manual and superseded procedures/PCNs have been removed and returned.

Name/Date /

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

November 13, 1995

MEMORANDUM TO: James L. Caldwell, Deputy Director
Division of Nuclear Material Safety, RIII

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST CONCERNING AMS' PROPOSED DISCHARGE OF 100,000 GALLONS OF PROCESSED WATER

In your Technical Assistance Request (TAR) dated September 26, 1995, you raised three questions concerning Advanced Medical Systems' (AMS) proposed discharge of 100,000 gallons of processed water to the waste treatment plant of the city of Geneva, Ohio. The questions raised were:

1. Are there any NRC regulations which would prohibit this action?

2. If not, is AMS required to obtain permission from NRC before discharging this water into Geneva's waste treatment plant?

3. Are the methods used to determine solubility (described in the TAR) acceptable?

With respect to the first question, the answer is no. The Office of the General Counsel (OGC) has informed us that under 10 CFR 20.2003, if the requirements for release are satisfied as far as solubility, concentration, and total quantity of radioactive material, the release appears to be acceptable, and there is no legal objection to the proposal. Regarding your comparison with the exempt concentration limits, 10 CFR Part 30 regulations do not apply to disposal of radioactive material; they pertain to quantities and concentrations that require licensing.

In response to the second question, OGC informed us that 10 CFR 20.2003 is "permissive," which means the licensee need not apply to NRC to do what the regulation allows, in this case, discharge to the sanitary sewerage system, if all applicable requirements are met. It is always incumbent upon the licensee to be able to demonstrate compliance with the conditions of the regulation. However, the quality and quantity of the documentation is not addressed in the rule (see 10 CFR 20.2103(b)(4)). It may be appropriate, and advisable, for NRC to have on record AMS' notification of its intent to release the water to Geneva, and for NRC to respond, acknowledging the intent. However, NRC should acknowledge in a way that does not involve approval of the release, but rather offer a statement that under NRC regulations (10 CFR 20.2003), NRC approval is not required.

CONTACT: Joe DeCicco, IMNS
(301) 415-7833

Dike
9511170179 2pp

F112

The third question has both a legal response and a technical response. NRC has consistently stated that its definition and acceptable methods of determining solubility/insolubility are set forth in Information Notice (IN) 94-07. A member of the public could challenge NRC's and AMS' determination of solubility, in correspondence to NRC or through petition for enforcement action under 10 CFR 2.206, and NRC would have to be prepared to defend its acceptance of the methods given in IN 94-07.

As to the technical acceptability of the methods used to determine solubility, it was stated earlier that it is incumbent on the licensee to make that determination to show compliance with the regulations. From your TAR, we understand that all samples analyzed by AMS have been shown to be below NRC release limits for Co-60 and that the Co-60 samples have been soluble. As far as acceptability of the methods used by Region III to confirm solubility, we reviewed your procedures used in the analysis, and they appear adequate, per the criteria in IN 94-07, to verify the licensee's determination that the cobalt-60 is soluble.

I talked to
DeCroco - 1st 11 para
NRC responsibility not
RIII 2nd para may
need to send RIII
samples to an acredit.
lab ?