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

OFFICE OF THE
GENERAL COUNSEL

April 3, 1996



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Frederick, MD 21701

Dr. Harry Foreman
Special Assistant
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St. Paul, MN 55108

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

Dear Administrative Judges:

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

53. Letter to Mr. J.R. Madera, Chief, Nuclear Materials Licensing Section, United States Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems, re: Advanced Medical Systems Inc. (License No. 34-19089-01) Emergency Plan, September 21, 1995, with attachment. (A review of the hearing file indicated that this document had not yet been placed in the hearing file).

54. Letter to Kevin G. Null, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems re: Radiation Safety Procedures for USNRC License No. 34-19089, February 13, 1996, with attachment.

55. Letter to Mr. David Cesar, Vice President, Advanced Medical Systems, Inc., from John R. Madera, Chief, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission, re: Review of Emergency Plan, February 28, 1996.

56. Letter to Robert Meschter, Radiation Safety Officer, Advanced Medical Systems, Inc. from Geoffrey C. Wright, Acting Deputy Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory System, re: NRC Inspection Report No. 030-16055/95006(DNMS), with attachment, March 12, 1996. (Please note that this inspection report is included in the hearing file because its conclusions are related to the Staff's review of licensee's emergency plan).

57. Letter to Kevin G. Null, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems re: Radiation Safety Procedures for USNRC License No. 34-19089, March 13, 1996, with attachment.

Sincerely,

Marian L. Zobler
Counsel for NRC Staff

Enclosures: As stated

cc w/encl.: Service List

# Advanced Medical Systems, Inc.

1020 London Rd.
Cleveland, Ohio 44110
216-692-3270


R2

398538

September 21, 1995

Mr. J. R. Madera, Chief
Nuclear Materials Licensing Section
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

**Re: Advanced Medical Systems Inc. (License No. 34-19089-01) Emergency Plan**

Dear Mr. Madera:

Enclosed is a copy of the Advanced Medical Systems, Inc., (AMS) Emergency Plan. This revised plan is being submitted in order to address the comments provided in your letter dated June 7, 1995.[1] Because significant changes to the Plan were made, enclosed also are your comments, our August 4, 1995 response to your comments, and reference to where in the revised Plan the comment was addressed, if applicable. If I can answer any questions or provide you with additional information, please call me at (216) 692-3270.

Sincerely,

Robert Meschter

Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

[1] To assist you in commenting on this version, line numbers have been added to the left side of each page of the revised Plan.

R2

# EMERGENCY PLAN FOR THE LONDON ROAD FACILITY

# *EMERGENCY PLAN FOR THE LONDON ROAD FACILITY*

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

September 21, 1995

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# 1. FACILITY DESCRIPTION

## 1.1 Description of Licensed Activity

Advanced Medical Systems, Inc. (AMS) manufactured and fabricated sealed sources of $^{60}Co$ for teletherapy and radiography machines. Under the provisions of U. S. Nuclear Regulatory Commission (USNRC) license No. 34-19089-01, AMS currently possesses 60,974 curies of $^{60}Co$, and 2,200 kilograms of depleted uranium (nickel plated) for use as shielding material.[1]

At AMS, there are approximately 40 curies of radioactive material in a potentially dispersible form. This material, which consists primarily of dry solid waste, carbon granules and ion exchange resins, is stored in sealed 55-gallon drums or B-25 (steel) boxes. The types and quantities of all licensed materials currently in the possession of AMS are shown in Table 1.

## 1.2 Description of Facility and Site

AMS is located at 1020 London Road, Cleveland, Ohio, 44110. Figure 1 shows the location of AMS within the Cleveland area.

The AMS operation, which occupies approximately 25% of an 80,000 square foot warehouse/manufacturing building at the London Road address, 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 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 2 through 4 show the layout of the three floors of the AMS building.

The findings of a recent inspection indicate that the structure at 1020 London Road is classified as a Noncombustible, Type 2, Unprotected Building under the Ohio Basic Building Code, constructed primarily of a structural steel frame with masonary walls, and founded in hardpan

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

shale.[2] The facility was built specifically for the manufacture and distribution of sealed sources. Rooms and restricted areas were designed to contain and confine abnormal conditions, should they occur.[3] In addition, the air handling, monitoring and alarm systems were designed to support emergency as well as routine conditions. Appendix A contains a description of these systems.

Licensed radioactive materials are located in specific areas within the AMS building. Large (22-in x 17-in) facility drawings that show these areas are contained in Appendix B. The following is a description of the various areas of the building.

### *1.2.1 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.[4] 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 3.

The Hot Cell is a "Restricted Area". It currently contains approximately 4,000 curies of $^{60}$Co. Because of the structural integrity of the hot cell, this radioactivity is not readily dispersible in the

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2 Denega, J., Neff & Associates "Engineers Opinion Report, Structural Adequacy of Building", September, 1995.

3 In general, the design follows the philosophy of restricting work activities to small working areas.

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

event of a fire, flood or building damage.[5] The average ambient exposure rates within the cell are approximately 12 R per hour, with rates up to 200 R per hour on contact with certain surfaces.

### *1.2.2 Isotope Shop*

The Isotope Shop is located on the first floor next to the Hot Cell as shown in Figure 3. This area has a concrete floor, ceiling, and interior walls. The exterior walls are of painted brick. Cobalt-60 sources are transported around this area in shielded containers.[6] 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.[7] Within the Isotope Shop is the Source Garden.

The Isotope Shop is a "Restricted Area". However, with the exception of the Source Garden, it does not contain a significant inventory of licensed material. The radiation exposure rates in this area currently average between five (5) and 10 mR per hour, with a maximum of 80 mR per hour on the outside of the Decontamination Room doors. The contamination levels currently average about 50,000 disintegrations per minute (dpm) per 100 $cm^2$.

### *1.2.3 Source Garden*

The Source Garden is located in the southwest corner of the Isotope Shop as shown on Figures 2 and 3. 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.

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5 Denega, J., Neff & Associates, "Engineers Opinion Report, Structural Adequacy of Building", September, 1995.

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

7 The Tow Motor is an electric fork lift.

The Source Garden is in a "Restricted Area". It currently contains approximately 30,000 curies of $^{60}Co$ in a non-dispersible (sealed) form. Exposure rates over the Source Garden are approximately 200 mR per hour.

### *1.2.4 Decontamination Room*

The Decontamination Room is located behind the Hot Cell and at the side of the Isotope Shop as shown in Figure 3. 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" that contains approximately two (2) millicuries of dispersible activity. The contamination levels in this 12 ft. by 12 ft. room are approximately 3,000,000 dpm per 100 $cm^2$. The average ambient exposure rates are approximately 80 to 100 mR per hour.

### *1.2.5 High Level Waste Storage Room*

The High Level Waste Storage Room is located next to the Hot Cell on the first floor as shown in Figure 3. 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" that contains approximately 10 curies of potentially-dispersible activity. It currently has average ambient exposure rates of about 300 to 400 mR per hour. Contamination levels are insignificant (e.g., below the site release criteria).

### *1.2.6 Clean Equipment Room*

The Clean Equipment Room is located on the second floor as shown on Figure 4. 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 (see Appendix A).

The Clean Equipment Room is a "Restricted Area", however it does not contain any dispersible activity. It currently has average ambient exposure rates of less than one (1) mR per hour, with

a maximum exposure rate of 30 mR per hour on the wall that adjoins the HEPA Equipment Room. Contamination levels are insignificant.

### *1.2.7 HEPA Equipment Room*

The HEPA Equipment Room is located on the second floor of the facility as shown in Figure 4. 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" that currently contains approximately two (2) curies of potentially-dispersible activity. It has average ambient exposure rates of about 80 mR per hour, with a maximum of 2,000 mR per hour on the exhaust duct from the Hot Cell. Contamination levels in the area average 11,000 dpm per 100 $cm^2$.

### *1.2.8 Back Basement*

The Back Basement is located in the basement as shown in Figure 2. 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" that contains approximately 15 Ci of potentially-dispersible activity. It currently has average ambient exposure rates of about 10 mR per hour, with a maximum ambient rate 50 mR per hour. Drums located behind the storage shield have contact exposure rates that range from 100 to 1,000 R per hour. Contamination levels in the Back Basement average 10,000 dpm per 100 $cm^2$.

### *1.2.9 WHUT Room*

The Waste Hold-Up Tank (WHUT) Room is located in the basement directly under the Hot Cell as shown on Figure 2. 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 in section 1.2.8, 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" that contains approximately 50 curies of non-dispersible activity.[8] The exposure rates in the room currently range from 50 to 240 R per hour, however the room is not accessible.

### *1.2.10 Front Basement*

The Front Basement is located on the east side of the basement next to the WHUT room, as shown in Figure 2. 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", however it does not contain significant dispersible activity. It currently has average ambient exposure rates of about one (1) mR per hour, with a maximum exposure rate of 20 mR per hour in the Blue Tank Room. Contamination levels average about 1,250 dpm per 100 $cm^2$.

### *1.2.11 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". The average ambient exposure rates in these areas currently range from "background" to one (1) mR per hour (isotope warehouse and caged storage area). Average contamination levels range from zero to 5,000 dpm per 100 $cm^2$ in the contaminated side of the air lock.

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8 Integrated Environmental Management, Inc., "Evaluation of the WHUT Room Source Term", Report No. 94002/G-3104, June 16, 1995.

### *1.2.12 Other Areas*

There are a number of 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. The exposure rates and contamination levels in these areas are not distinguishable from background.

## *1.3 Description of Area Near the Site*

The AMS building is located in a manufacturing and residential area. The areas to the west, south and east are mainly industrial facilities. The area to the north of the plant is a mix of small businesses and residential units. The transient population within one (1) mile radius of the facility is primarily a function of employment associated with the surrounding factories/businesses.

Figure 5 shows the region within approximately one (1) mile of the facility and identifies its relative proximity to near-site structures. The locations of schools, hospitals and fire stations are also shown on Figure 5. There are approximately seven (7) industrial facilities and 80 homes within a two (2) block radius of AMS. The nearest off-site resident is located 100 yards to the north of AMS. In the event of a radiological emergency, these locations may require special consideration. The remainder are sufficiently far from AMS that radiological impacts for any postulated accident would be negligible.

# 2. TYPES OF ACCIDENTS

## 2.1 Description of Postulated Accidents

The range of postulated accidents for AMS includes scenarios from both outside and inside the building. The postulated exposure rates for the various scenarios have the potential to exceed the USNRC criteria for unrestricted areas.[9] However, when averaged over a year, most are well-below the 100 millirem per year dose limit for members of the general population given 10 CFR 20.1301. The following are the descriptions of the postulated accidents at AMS.

### 2.1.1 Fire in the Building

Fires in the AMS London Road facility with a significant radiological impact are unlikely due to: (1) The fire resistant nature of the structure; (2) the existence of a fire suppression system; (3) the small quantities of combustibles in the restricted areas; and (4) the fire prevention program established at AMS. Minor fires, such as refuse fires are not likely to result in release of radioactivity. Fires in the ventilation system are unlikely because the HEPA filters are fire-resistant and because of the lack of combustibles located in the areas that feed the system. The only type of fire that could result in major emergency would be one that engulfs large portions of the building.

The restricted areas of AMS are in a metal and concrete block building which is fully covered by a monitored fire alarm system (see Appendix A). The unrestricted areas of the building are fully covered with sprinklers as well as the alarm system. The security system/service monitors the fire alarm system and tests is function once each month. The optimal fire department response time to the London Road facility is between five (5) and 15 minutes. The presence of the sprinkler/alarm system, rapid fire department response time, the building construction and the negligible amount of flammable materials stored on-site minimizes the possibility of a major fire at AMS.

The majority of the dispersible inventory of radioactive materials at the site is stored in drums or boxes that meet the normal conditions of transport described in Subpart F, 10 CFR 71.71. As such, they must meet the criteria for heat, cold, reduced external pressure, increased external pressure, vibration, water spray, free drop, corner drop, compression, and penetration described

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9 Appendix B, 10 CFR 20.

in §71.71(c). The remainder the sources are contained in either the subterranean Source Garden, the vault-like Hot Cell, or in lead/steel-encased source heads weighing approximately 5,000 pounds each. Consequently, the probability for major fires with a resulting release of significant quantities of radioactivity is considered to be low. Nonetheless, a major fire is included in this Plan due to its potential for off-site impacts.

For this scenario, it is assumed that a fraction of the site inventory of dispersible materials shown in Table 1 could be released during the fire, and that 100% of the radioactive materials released will become airborne over a period of one hour. The dose to the nearest off-site resident (e.g., 100 meters north of the building stack) from this scenario is 0.2 millirem. The dose to the maximally-exposed member of the off-site population within 10,000 meters of the building is 0.3 millirem. The dose to a fire fighter positioned nine (9) meters from the building is approximately 0.4 millirem. Appendix C contains a discussion of the assumptions and methodologies used to derive these values.

The International Commission on Radiological Protection (ICRP) provides guidance on when and how to institute countermeasures and recovery actions in the event of a major radiation accident.[10] However, the ICRP also acknowledges that the countermeasures and recovery actions themselves involve some risk to the public. Consequently, to ensure that the "cure is not more harmful than the illness", they have set a population dose limit below which they recommend that no follow-up action whatsoever be taken. The ICRP dose limit for early-phase countermeasures ranges from 500 to 5,000 millirem for sheltering, and 5,000 to 50,000 for evacuation. The lowest limit of 500 millirem is also consistent with the maximum permissible dose to maximally-exposed members of the general public promulgated by the USNRC.[11] Therefore, for the major fire scenario at the AMS site, wherein an off-site individual might receive up to 0.3 millirem, countermeasures or recovery actions for purposes of protecting that individual are not indicated.

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10 International Commission on Radiological Protection, "Protection of the Public in the Event of Major Radiation Accidents: Principles for Planning", ICRP Publication 40, 1984.

11 Title 10, Code of Federal Regulations, Part 20.1301.

### *2.1.2 Earthquakes*

Although earthquakes and similar natural disasters are possible, their probability of occurrence is extremely low.[12] Furthermore, the structural integrity of the AMS building appears to be sufficient to withstand seismic forces as great as 5.2 Richter, and that seismic events in excess of this value in this region is highly improbable.[13,14]

However, in the event of an earthquake, one ramification with potential radiological significance might be movement of the earth surrounding the southwest side of the building such that an outside wall proximal to the Source Garden becomes exposed. This would result in an exposure rate of greater than 10 R per hour on contact with the wall of the building immediately proximal to the sources (e.g., below grade), 1.8 R per hour at a distance of three (3) feet from the wall of the building, and 0.1 R per hour at a distance of 20 feet from the wall of the building. Appendix C contains a discussion of the assumptions and methodologies used to derive this value. Pursuant to the ICRP, no countermeasures or recovery actions are necessary for this scenario.

An earthquake also has the potential to crack or break the viewing window into the Hot Cell. In the event of a rupture of the cell window, the exposure rate at the main entrance to the AMS building would be less than 500 mR per hour (see Appendix C).

### *2.1.3 Tornados*

Tornados are violent vortex storms that occur in the atmosphere. The design-basis tornado characteristics for the AMS site are assumed to have maximum wind speeds of 360 mph, rotational speed of 290 mph, and pressure drop of three (3) psi.[15]

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12 There have been 114 earthquakes with magnitude of I (Modified Mercalli Intensity) or greater within 50 miles of the AMS facility since 1893. Their size has ranged from I to VI, with the largest (January 31, 1986, Leroy, Ohio) having a MBLG Magnitude of 5.0 (Weston Geophysical Corporation Report, and N.O.A.A. Earthquake Data File).

13 Denega, J., Neff & Associates, "Engineers Opinion Report, Structural Adequacy of Building", September, 1995.

14 The AMS building incurred only minor, non-structural damage from the January, 1986 event, which had a Richter Local Magnitude of 5.2.

15 U. S. Nuclear Regulatory Commission, Regulatory Guide 1.76, "Design Basis Tornado for Nuclear Power Plants", April, 1974.

While the AMS building may incur structural damage in the event of tornado impact, the structural integrity of the restricted areas, with their "bunker-type construction", would not be compromised.[16] Therefore, the radiological impact of a tornado is likely to be minimal.

If a tornado event did, nonetheless, result in significant destruction of the facility, the potential exists for dispersal of only a small portion of the inventory within the building. This is due to the short tornado impact time on the building, and the fact that the majority of the dispersible inventory is located in the facility basement, rendering it somewhat inaccessible to the tornado's effects.[17]

Projectiles from a tornado have the potential to crack or break the viewing window into the Hot Cell. In the event of a rupture of the cell window, the exposure rate at the main entrance to the AMS building would be less than 500 mR per hour (see Appendix C).

### *2.1.4 Vandalism*

Scavengers and vandals may attempt removal of materials at the AMS facility. However, the existing security system, with its intruder sensors and monitored alarm systems, is an effective deterrent. The response time for the Cleveland Police Department after notification by the security service, under normal circumstances, is 15 minutes.

The probability of scavenging and removal of licensed materials is considered to be negligible. This is due to the time required for an intruder to enter the restricted area in advance of discovery, and the lack of economic value of the materials should the intruder be able to reach them in time.

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16 Denega, J., Neff & Associates, "Engineers Opinion Report, Structural Adequacy of Building", September, 1995.

17 In this unlikely scenario, the tornado must lift material (e.g., waste drums), along with the top two stories of the building, up into the cloud. As a result, the ground-level radionuclide concentrations within the first few miles of the AMS facility would be negligible. When the material did return to ground after being transported by the storm for a distance of between two (2) and 20 miles, it is not likely that the waste container would rupture due to its design basis. However, even if a rupture occurred, this would not result in a release of significance since the contents of the drums are not readily dispersible (e.g., solid waste, paper, plastic, absorbed liquids, etc.). Therefore, only minimal impact on local air concentrations would be noted. While the ruptured waste drum contents could cause an external exposure to members of the general population in its close proximity, fly-over surveys are well-suited for locating containers of $^{60}Co$, therefore exposure durations, if any, would be minimal.

### *2.1.5 Floods*

In the vicinity of AMS, the maximum monthly precipitation of 9.7 inches occurred in August, 1881, and the maximum precipitation in 24 hours (4.97 inches) occurred in September, 1901.[18] Since AMS began operations at the London Road facility, there have been no river flooding occurrences and, with two exceptions, no street/sewer occurrences. The first exception occurred in May of 1989 when an over-taxed sewer system caused two-inches of water to accumulate in the basement of the facility. The second exception occurred in 1994 when the regional sewer district intentionally blocked the only water discharge path from the London Road facility. The end result of this event was almost immediate flooding of the basement to a depth of over 40 inches.

The foundation drainage system that currently exists around the building is completely disconnected from the building itself.[19] Therefore, there is no direct pathway for flood water to enter the building other than by seepage through building cracks if the drainage system should become overwhelmed. The 1994 incursion of 100,000 gallons of water into the basement of the AMS facility demonstrated that release of radioactivity to the surrounding environment in the event of a flood is negligible. Therefore, the radiological impacts of localized flooding on the off-site population is considered to be inconsequential.

### *2.1.6 Industrial Facility Impacts*

In the immediate vicinity of AMS, there are approximately seven (7) industrial facilities. These include a chemical products plant, a die casting company, a sewer cleaning company, and a number of other light-industries. Because combustibles and flammables may be in use at these facilities, the potential exists for an explosion to impact AMS. However, since there is a minimum of 1,000 yards between the AMS building and the nearest facility with the potential for explosion (e.g., the chemical products plant), the probability of structural damage to AMS is considered to be inconsequential.

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18 National Weather Service, Cleveland, Ohio.

19 Integrated Environmental Management, Inc.,"Final Report of Water Treatment and Sewer Remediation", Report No. 94009/G-2110, 1995.

### *2.1.7 Underground Gas Line Explosion*

The natural gas feed system to the AMS building runs under London Road and along with south wall of the AMS building at a depth of approximately three (3) feet. The line wraps around the outside wall of the Source Garden. In the event of a natural gas explosion, the potential exists for disrupting the earthen cover such that an outside wall proximal to the Source Garden is exposed. Similar to the earthquake scenario, this would result in an exposure rate of 10.6 R per hour on contact with the wall of the building immediately proximal to the sources (e.g., below grade), 1.8 R per hour at a distance of three (3) feet from the wall of the building, and 0.1 R per hour at a distance of 20 feet from the wall of the building. Appendix C contains a discussion of the assumptions and methodologies used to derive this value. Pursuant to the ICRP, no countermeasures or recovery actions are necessary for this scenario.

### *2.1.8 Transportation Accidents*

There is significant truck traffic on London Road. Also, approximately three (3) trains per hour run on the Conrail track located 100 feet from the AMS building. While the road and the train track are straight as they run past AMS, a run-away truck or derailed train in this vicinity is possible.[20]

While the likelihood of impact on the side of the building is considered to be minimal, for the purposes of this scenario, it is assumed that such an impact could occur and that the southwest corner of the building would be leveled. This would result in no change in the exposure rate directly measured over the exposed Source Garden (see Section 1.2.3, above).[21] Furthermore, in the event that the building collapses, additional shielding over the Source Garden would result.

## *2.2 Detection of Accidents*

During normal business hours, accidents are detected by AMS staff observation and by a monitored alarm system (see Appendix A). During non-business hours, events such as fire and intrusion are detected by the monitored alarm system.[22] The security service that provides and monitors the alarm system notifies the Cleveland Police Department, the Cleveland Fire Department and an AMS representative in the event of an alarm.

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20 Explosions and/or fires caused by a derailed train will not result in consequences more sever than those presented previously.

21 In the highly unlikely event that the east or the south side of the building were impacted, it is not likely that the structural integrity of the Hot Cell would be compromised. Therefore, this scenario was not considered.

22 ADT Security Systems, Inc.

# 3. CLASSIFICATION AND NOTIFICATION OF ACCIDENTS

## 3.1 Classification System

There are four accident classifications at AMS. These range from small personnel injuries without contamination, to off-site releases due to a major fire or natural disaster. The following is a description of the four classifications.

### 3.1.1 Incidents

An incident is defined as an occurrence or situation of seemingly minor importance. It may involve an in-plant injury or incident requiring emergency treatment of one or more individuals. There would be no potential for escalation to more severe conditions.

The Emergency Action Levels (EALs) that trigger an incident are shown in ISP-37 (see Appendix D). Personnel actions in the event of an incident are:

- Notify the Radiation Safety Officer (RSO).
- Administer first aid and/or call for off-site assistance from the Cleveland Emergency Medical Service at the discretion of the RSO.

RSO actions include:

- Performing a radiation survey (frisk) of individuals to ensure the absence of measurable contamination.
- Investigating the accident conditions and initiates corrective actions.

No change in the facility operational status is necessary in response to an incident. Off-site agency response, other than the Cleveland Emergency Medical Service, is not required.

### 3.1.2 Unusual Event

An unusual event is defined as an occurrence or situation of potentially significant importance. It may involve a man-made or natural phenomenon with the potential for increased escalation or

severity. The EALs that trigger an unusual event are listed in ISP-37 (see Appendix D). Personnel actions in the event of an unusual event are:

- Notify the RSO.
- Assist the RSO with any precautionary actions that may be necessary.

The RSO makes a preliminary assessment of the hazards associated with the condition and notifies the appropriate local, state or federal agencies as required. No change in facility operational status is anticipated however precautionary actions should be taken as instructed by the RSO. Off-site agency response is not required.

### *3.1.3 Alert*

An alert is defined as an event or occurrence that is in progress or has occurred that could lead to a release of radioactive material. However, the release is not expected to require a response by offsite response organizations in order to protect persons off-site. The EALs that trigger an alert are listed in ISP-37 (see Appendix D). Personnel actions in the event of an alert are:

- Notify RSO and Vice President of AMS.
- Initiate appropriate measures to establish control over the situation.
- Activate the on-site emergency response team.
- Place off-site emergency response agencies (first responders) on alert.
- Activate in-house fire response efforts, if applicable.
- Activate major spill procedures, if applicable.

The RSO assesses the hazard and implements appropriate protective or corrective action(s):

- All operations not related to control of the emergency shall be terminated.
- Non-essential personnel shall be evacuated, as necessary.
- Recovery operations shall be initiated.

### *3.1.4 Site Area Emergency*

A site area emergency is defined as an event that may occur, is in progress, or has occurred that could lead to a significant release of radioactive material. A response by off-site response organizations may be necessary to protect persons off-site. An uncontrolled fire is an example of this condition.

The EALs that trigger a site area emergency are listed in ISP-37 (see Appendix D). Personnel actions in the event of a site area emergency are:

- Notify the RSO and Vice President of AMS.
- Activate the on-site emergency response team.
- Activate off-site emergency response agencies (first responders)

The RSO assesses the hazard and implements appropriate protective or corrective action(s):

- All operations not related to control of the emergency shall be terminated.
- Non-essential personnel shall be evacuated, as necessary.
- Recovery operations shall be initiated.

### *3.2 Notification and Alert*

In the event of an emergency, the RSO will immediately activate this Plan and determine the necessary level of activation as described herein. First responders are notified within one hour after an alert is declared, and 15 minutes after a site area emergency is declared. The USNRC Operations Center is notified within one hour after an alert or site area emergency is declared. The RSO (acting Emergency Manager) renders the decision to terminate the emergency.

### *3.3 Information to be Communicated*

In the event of an emergency, AMS communicates the following general information to off-site emergency response agencies:

- My name is:
- I am calling from telephone number 216-692-3270.

- I am calling from Advanced Medical Systems, which is located at 1020 London Road, in Cleveland.
- We are experiencing an emergency in the form of a [fire, explosion, flood, spill, or other (describe)].
- There have/have not been injuries. [Describe injuries].
- The emergency does/does not involve potential radiation exposures.
- The emergency does/does not involve potential contamination with radioactive materials.
- The radionuclide(s) involved are [cobalt-60, cesium-137, depleted uranium].
- Medical assistance is/is not required.

If a report of an emergency is received by AMS, the following is the general information that is solicited from the caller:

- Name of caller
- Telephone number from which call is being made
- Nature of emergency
- Location of emergency

# 4. RESPONSIBILITIES

## 4.1 Normal Facility Organization

The radiation safety organization at AMS is shown in Figure 6. Overall control and authority for radiation protection at the London Road facility rests with the Vice President of Operations. The responsibility of the Vice President of Operations includes, but is not limited to, the following:

- Establish AMS policy and prepare/amend the Radiation Protection Program Plan accordingly;
- Appoint and empower the AMS Isotope Committee (IC); and
- Assure that the capability of AMS radiation protection services are sufficient to meet the requirements of the Radiation Protection Program Plan and USNRC license requirements.

The Vice President of Operations has designated the authority for implementing the radiation protection program to the RSO. The RSO is responsible for recommending the type and quantity of staff and resources necessary for full implementation of the Radiation Protection Program Plan. During normal working hours, the RSO is typically present at the AMS facility.

The IC provides oversight for the radiation protection program. The permanent members of the IC includes the Vice President of Operations, the RSO, the Licensed Isotope Handler, the Engineering Manager, and a Certified Health Physicist. The IC is responsible for review and approval of all elements of the radiation protection program and for assessing compliance with USNRC license requirements. The IC is also 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.

The RSO has designated authority for implementing certain aspects of the radiation protection program to Authorized Users. The responsibilities and authority of Authorized Users may include the following:

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

- Preparing products for shipment;
- Performing product testing; and
- Ensuring that personnel under their supervision comply with the requirements of the Radiation Protection Program Plan.

### *4.2 On-site Emergency Response Organization*

The on-site emergency response organization is shown in Figure 7. The small corporate structure of AMS permits a precise and clear chain of command during both normal and emergency operating conditions. In the event of an off-hours emergency, the AMS response time back to the London Road facility is approximately one hour.[23]

During an emergency, the RSO serves as the Emergency Manager and implements the provisions of this Plan. In the absence of the RSO, any AMS staff member can serve as the acting Emergency Manager until the arrival of the RSO. All AMS staff members at the facility during an emergency are assigned to support the Emergency Manager.

During the emergency, one of the two AMS staff members is assigned to site access and security, where he/she is responsible for personnel monitoring and providing radiation protection assistance to the first responders (e.g., fire department, police, and emergency management agency). The other AMS staff member is assigned to radiation surveys and assessments where he/she is responsible for acquisition of site and environmental monitoring data and for assessing the off-site dose consequences of the incident.

The Emergency Manager is responsible for contacting off-site emergency response agencies for assistance if the Plan is activated. In addition, an environmental consulting firm and a Certified Health Physicist have been retained by AMS to assist in all matters relating to radiation safety and environmental issues.

### *4.3 Local Offsite Assistance to Facility*

Certain offsite agencies have agreed to respond and supply support for certain emergency conditions at AMS. These agencies, designated as "first responders" or "secondary responders",

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23 From their homes, the Vice President for Operations is able to reach the London Road site within 20 minutes; the RSO within 50 minutes, and the two AMS staff members within 15 and 20 minutes, respectively.

are shown in Table 2. Appendix E contains the letters of agreement between AMS and applicable first responders, along with information on the agreed upon means of communication and notification of these agencies. The decision to mobilize first responders is made by the Emergency Manager.

### *4.4 Coordination with Participating Government Agencies*

The following is a description of the principal local, county, state and federal agencies with responsibilities for radiological or other emergencies at AMS

- The USNRC maintains regulatory authority over all licensed materials at AMS. This agency provides regulatory oversight and, if necessary, radiological assistance. The regional office is located in Illinois, with a nominal flight time to AMS of two (2) hours.

- The U. S. Environmental Protection Agency (USEPA) maintains regulatory authority over off-site releases, should they occur. The regional office is located in Illinois, with a nominal flight time to AMS of two (2) hours.

- The Ohio Environmental Protection Agency (OEPA) maintains regulatory authority over off-site releases, particularly as they impact air and the waters of the state. The regional office is located in Ohio, with a nominal driving time to AMS of one (1) hour.

- The Cleveland City Fire Department provides fire control and rescue services. In the event of an emergency, AMS personnel call "911", and a dispatcher directs emergency services to the London Road facility. In general, the response time to AMS is approximately 15 minutes.

- The Cleveland City Police Department provides security and crowd control services. In the event of an emergency, AMS personnel call "911", and a dispatcher directs emergency services to the London Road facility. In general, the response time to AMS is approximately 15 minutes.

- The Cleveland Emergency Medical Services provides first-aid and ambulance services. In the event of an emergency, AMS personnel call "911", and a dispatcher directs emergency services to the London Road facility. In general, the response time to AMS is approximately 15 minutes.

- The University Hospital of Cleveland provides medical care for the injured. The hospital is located at 11100 Euclid Avenue, Cleveland, Ohio. The nominal transit time from AMS to the hospital is approximately 15 minutes.

AMS meets with these agencies at least annually in order to review items of mutual interest and confirm the conditions of emergency response services.

# 5. EMERGENCY RESPONSE MEASURES

## 5.1 Activation of Emergency Response Organization

The initial step in an emergency is the activation of the emergency response team. The initial reporting of most incidents will depend on the personnel working in the AMS facility. Due to the small size of the facility, any individual may contact the RSO directly. The RSO becomes the Emergency Manager until the incident is brought under the control and the facility is returned to operation.[24] The Emergency Manager is responsible for activating this Plan and establishing communications with the appropriate off-site agencies.

## 5.2 Assessment Actions

The Emergency Manager will determine the class of the emergency based upon an assessment actual conditions. In general, the Emergency Manager will rely on site inspection, release and/or site boundary dose estimates, and monitoring information. The first method is visual observation and discussion with personnel. The incident will be characterized as a fire, natural phenomenon, tornado, vandalism or flood. The Emergency Manager will also assess the physical damage to the facility and/or injuries to personnel. Throughout the emergency, radiation doses will be monitored using personnel dosimeters, self-reading dosimeters and/or portable survey instrumentation.

## 5.3 Mitigating Actions

A facility fire should be detected and brought under control rapidly since the building is monitored with an alarm system and protected by a sprinkler system. The facility staff will assist the fire department by providing monitoring capabilities during the fire fighting effort. Once the fire is under control or has been put out, the cause of the fire will be determined, and appropriate corrective action will be taken.

In the event of a tornado, flood, or severe natural phenomenon, there are no corrective actions that can be taken. However, appropriate recovery action will be initiated as soon as possible.

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[24] In the absence of the RSO, any AMS staff member serves as the Emergency Manager until the arrival of the RSO.

### *5.4 Protective Actions*

To prevent or minimize radiation exposures during the emergency, one or more protective actions may by instituted. The following is a description of each.

#### *5.4.1 Personnel Evacuation and Accountability*

Personnel will be evacuated from the facility by fire alarm, PA system, or word of mouth. Personnel will exit through any available door and assemble at the designated muster area. The RSO will account for all personnel.

#### *5.4.2 Use of Protective Equipment and Supplies*

Protective clothing and respirators may be worn by qualified personnel for any rescue operations during fires.[25] Radiation monitoring instrumentation will be made available to survey evacuated personnel and off-site personnel that have responded to the emergency.

#### *5.4.3 Contamination Control Measures*

Site personnel, under the direction of the Emergency Manager will perform contamination measurements using portable survey instrumentation. Contaminated areas will be designated, and entry/exit procedures for contaminated areas will be established. Contaminated run-off due to fire containment efforts will return to the basement of the facility where it can be readily controlled.[26,27] Radioactive materials dispersed due to a tornado or other severe natural phenomenon cannot be controlled but can be monitored and collected after the fact.

### *5.5 Exposure Control in Radiological Emergencies*

The primary goal of this Plan is to limit exposures to personnel. All efforts will be made to maintain exposure to personnel as low as reasonably achievable. However, members of the Emergency Response Team and/or off-site responders may be exposed to radiation levels up to the EPA 400-R-92-001 guidelines. Using these guidelines as its basis, the Protective Action Guides (PAGs) for whole body doses to emergency workers at AMS are 25 rem for lifesaving activities and 10 rem for entry into hazardous areas to protect the facility or control fires. Only

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25 In the event of a fire, only self-contained breathing apparatus should be worn. Full- or half-face respirators are not permitted.

26 AMS has recommended that $CO_2$-based fire extinguishers, or other non-liquid fire suppression systems, be used for fires in the restricted area.

27 Accumulated water will be monitored, tested, and, as necessary, placed in on-site storage.

the Emergency Manager may authorize emergency workers to receive an emergency radiation dose.

During the emergency, workers will carry survey meters, and their work time in a restricted area will be limited to the amount of time multiplied by the dose rate which equals the PAG. All emergency personnel will be supplied with personnel monitoring devices, the issue and collection of which will be logged by an AMS staff member. Personnel exiting the area will be monitored for surface contamination by an AMS staff member.[28]

### *5.6 Medical Transportation*

Transportation of injured personnel will be provided by Cleveland Emergency Medical Service. Cleveland Emergency Medical Service personnel receive annual training in general radiation safety and contamination control techniques.

Depending upon the type/form of accident, licensee personnel will accompany the injured, if contaminated, to the hospital. However, the hospital is equipped with a nuclear medicine department and a Radiation Safety Officer who provides surveillance and radiological control services in the event of a contaminated patient being transferred to the facility.

### *5.7 Medical Treatment*

AMS has arranged for the treatment of injuries involving radioactive contamination at the University Hospital of Cleveland. This facility hospital has the capability to respond to the classes of accidents postulated for AMS.

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28 Minimal decontamination of injured personnel will be attempted at the AMS facility. Cases of severe injury with contamination will be directed to the local hospital immediately.

# 6. EMERGENCY RESPONSE EQUIPMENT AND FACILITIES

## 6.1 Command Center

During a radiological emergency with possible offsite impact, emergency response activities will be directed from the first floor office area of the London Road facility as shown in Figure 3. The alternate location from which control and assessment will be exercised is the fire Pump House located on Mandalay Avenue, approximately 300 feet west of the facility.

## 6.2 Communications Equipment

The telephone system and public address system at the London Road facility are used for communications. After-hours, the Cleveland Fire Department or the Cleveland Police Department will be contacted by direct line from the facility alarm system or the security service company. Both groups maintain a current AMS Emergency Response call list for contacting AMS personnel. Alternate communications methods be provided by the City of Cleveland Fire Department.

## 6.3 Onsite Medical Facilities

There are two (2) industrial first aid kits at the London Road facility. These are located in the former chemistry lab and in the Isotope Shop warehouse (see Figure 3). No other on-site medical facilities exist.

Injuries requiring medical attention will receive first aid from offsite ambulance crews, although initial first aid will be provided by onsite personnel. Injured individuals will be taken offsite to the facilities with which AMS has arrangements.

## 6.4 Emergency Monitoring Equipment

Equipment for assessing and handling an emergency involving radioactive materials are maintained in the instrument calibration room (see Figure 3). The following items are calibrated and checked pursuant to ISP-23 to ensure continuous operability:

- A minimum of two (2) each 200 mR, 1,000 mR and 5,000 mR pocket dosimeters
- A minimum of one (1) dosimeter charger
- A minimum of one (1) high-range (to 1,000 R per hour) survey meter.
- A minimum of one (1) low-range (to 1 R per hour) survey meter.

- A minimum of one (1) frisker.

In the locker room or storage room, there are a minimum of 10 complete suits of protective clothing and a minimum of four (4) particulate respirators (full-face).

In the event the AMS building becomes unaccessible, emergency supplies are also stored in the alternate control location. Table 3 contains a listing of these supplies. Their status and availability are checked quarterly and confirmed to be present.

# 7. MAINTAINING EMERGENCY PREPAREDNESS CAPABILITY

## 7.1 Written Emergency Plan Procedures

The RSO reviews this Plan annually and updates it as needed. Changes of substance to the Plan (e.g., other than typographical, editorial or minor changes) results in issue of a complete revision. Page changes only will not be made. The RSO is responsible for distributing revised Plans to those that are on the authorized distribution list.

A standard operating procedure, ISP-37, "Emergency Response and Notifications", has been written to address emergencies within the AMS facility. A copy of this procedure is contained in Appendix D.

## 7.2 Training

Operations personnel at AMS are trained in radiation safety procedures and techniques pursuant to the provisions of the ISP Manual and license requirements. All AMS staff members, the RSO and applicable management personnel participate in comprehensive annual and refresher training in the provisions of ISP-37 (see Appendix D).

AMS also provides annual radiation safety training for first responders. This training includes a review of items of mutual interest and relevant changes in this Plan, instruction in emergency procedures, radiation protection guidelines, and the agency's anticipated role in an emergency. During the training session, the emergency response team activation scheme, notification procedures, and overall response coordination process is reviewed. Agency attendance at the annual training session is documented.

## 7.3 Drills and Exercises

In order to maintain proficiency in emergency response, AMS conducts an emergency exercise once every two years. The exercise includes one or more of the accident scenarios postulated for the facility, and involves off-site agencies that have provided letter agreements for support services. However, the scenario is not known by exercise participants. A non-participating observer provides an evaluation of the effort, along with recommendations for improvement. The critique of the exercise is used as a basis for modifying this Plan or supplementing the training for the off-site agencies.

Communications drills are performed quarterly. The purpose of communications drills are to maintain and update the emergency call list and to verify the telephone numbers of off-site agencies.

### *7.4 Critiques*

A critique of certain emergency events and of each drill/exercise is conducted. Critiques are used to evaluate the appropriateness of this Plan, ISP-37, facilities, equipment, training of personnel, and the overall effectiveness of the response effort. Deficiencies identified during critiques will be corrected and closure will be documented. ISP-37 contains a listing of those emergencies that trigger the critique requirement.

### *7.5 Independent Audit*

AMS participates in planned and periodic audits of all aspects of its radiation protection program and radiation safety procedures. Audits are performed by persons that are not directly responsible for implementing the emergency response program. Included in the audit is the emergency response function and associated records. The audit findings are presented at the next scheduled meeting of the IC. Actions necessary to correct non-confirming items are reviewed and closure is confirmed within 90 days of the IC meeting.

### *7.6 Maintenance and Inventory of Emergency Equipment, Instrumentation, and Supplies*

Emergency instrumentation and decontamination supplies are inventoried quarterly. Instruments are calibrated at least annually. Inoperable or missing equipment are repaired/replaced as soon as possible. Operational checks of instruments are performed prior to use.

### *7.7 Letters of Agreement*

Letters of agreement with emergency response agencies listed as first responders (Table 2) are solicited once per year. Copies of these letters are contained in Appendix E.

# 8. RECORDS AND REPORTS

## 8.1 Records of Incidents

All incidents which result in the activation of this Plan are documented. Documentation includes, as a minimum, the cause of the event, the date/time the event began/terminated, a physical damage and/or personnel injury report, radiation monitoring data, off-site assistance requested/received, off-site contacts record, corrective action taken, and re-entry/recovery plans. Additional description on incident record requirements is included in ISP-37 (see Appendix D).

## 8.2 Records of Preparedness Assurance

Records documenting facility preparedness are maintained for a three (3) year period following the activity date of record. These records include, as a minimum, attendance records of training and re-training, lesson plans, annual Plan review and update records, records of drill and exercise critiques, audit findings, and letters of agreement with off-site response organizations.

# 9. RECOVERY AND PLANT RESTORATION

Recovery from an emergency involves re-entering the AMS facility, restoration of the facility, and the resumption of normal operations. These activities are conducted in such a way as to minimize personnel exposures and radioactivity releases.

## 9.1 Re-entry

The decision to re-enter the facility is based on an evaluation by the Emergency Manager. The evaluation must reveal that emergency conditions have terminated or have stabilized before re-entry will be permitted. Re-entry personnel will then assess the extent of contamination and damage, and provide the information necessary to guide facility restoration.

## 9.2 Plant Restoration

During plant restoration, all personnel exposures will be maintained as low as reasonably achievable. The Emergency Manager is responsible for ensuring that plant restoration operations are performed according to the provisions of the ISP manual and according to standard industry practices. The Emergency Manager ensures that:

- Contaminated areas have been defined and posted and decontamination operations are scheduled.
- Radiation detection equipment, especially survey meters, are functioning properly and all restoration parties are trained and equipped with these meters.
- All enclosures and shielding used to contain radioactivity are functional.
- Ventilation systems and their associated alarms are functional.
- Evacuation and fire alarms are functional.
- The contents of the emergency lockers have been replenished.
- Ancillary city services (e.g., secondary responders) are notified, as necessary, of the potential impacts of restoration activities and the need for their services during restoration activities.

Once the appropriate status of these items are confirmed, the Emergency Manager declares the facility to be restored.

### *9.3 Resumption of Operations*

Following plant restoration, routine operations may resume. However, in addition to normal activities, the RSO will conduct an investigation into the cause of the incident, and will identify preventative actions that should be taken to minimize the re-occurrence of the incident. For all accidents other than minor spills, radiation surveys and engineering checks of all process and support systems will be conducted.

# 10. COMPLIANCE WITH COMMUNITY RIGHT-TO-KNOW ACT

The "Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) contains four major components: emergency planning (Sections 301-303), emergency release notification (Section 304), community right-to-know reporting (Sections 311-312), and toxic chemical release inventory reporting (Section 313). In regard to Sections 301-303, AMS is exempt from emergency planning by virtue of not possessing any substances listed in the USEPA's "List of Extremely Hazardous Substances and Their Threshold Planning Quantities".[29] In regard to Sections 311-312, AMS is exempt from the community right-to-know reporting requirements since the facility does not meet the applicable requirements for reporting (e.g., AMS does not have an inventory of hazardous chemicals requiring Material Safety Data Sheets).[30,31] In regard to Section 313, AMS is exempt from toxic chemical release reporting because it does not meet the applicable facility requirements.[32] In regard to Section 304, AMS is in compliance with the requirements for emergency release notifications since appropriate notification actions to be taken in the event of a release of regulated materials are specified.[33]

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29 Title 40, Code of Federal Regulations, Part 355, Appendices A and B.

30 Title 40, Code of Federal Regulations, Section 370.20

31 While an MSDS is required if the facility possesses more than 1,000 pounds of the chemicals listed in 20 CFR 1910.1200, or more than 500 pounds of the extremely hazardous substances listed in the appendices to 40 CFR 355, AMS does not possess any of these materials at the London Road facility. An MSDS for items AMS uses for normal consumer purposes (i.e., copy toner, spray paint, bathroom cleaner, etc.) is not required pursuant to 29 CFR 1910.1200 (b) (6) (vii).

32 Title 40, Code of Federal Regulations, Section 372.22, "Covered Facilities for Toxic Chemical Release Reporting".

33 Notification requirements from Title 40, Code of Federal Regulations, Section 355.40 (b).

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

February 13, 1996

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

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

Dear Mr. Null:

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

- RSP-008, "Instrumentation and Surveillance"
- RSP-010", Exposure Control"
- RSP-018, "Operation of the Gamma Spectrometer"
- RSP-019, "Assessment of Radioactivity in Water Samples"

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

Because our renewal application was originally submitted more than thirty (30) days prior to the expiration date of License No. 34-19089-01, AMS assumes the license will remain in effect, under its existing provisions, until final action is taken on this revised application. Since AMS wishes to institute significant changes in our radiation protection program in order to improve its applicability and auditability, your prompt consideration of our revised

[1] RSP-001 and RSP-003 were transmitted as part of our October 30, 1995 license renewal application. RSP-001, RSP-003, RSP-005, RSP-007, RSP-009, RSP-011, RSP-012, RSP-013, RSP-014, RSP-015, RSP-016, and RSP-017 were forwarded to you under separate cover. RSP-006 is currently undergoing technical and administrative review. As soon as the reviews are complete, the final versions of this RSP will be immediately forwarded to the USNRC.

application would be greatly appreciated. If you have any questions, please contact me at (216) 692-3270.

Sincerely

Robert Meschter

Robert Meschter, R.S.O.

cc: D. Cesar (w/o attach.)
D. Miller, Esq. - Stavole & Miller (w/o attach.)
C. D. Berger, C.H.P. - IEM (w/o attach.)
M. Weber - USNRC Region III (w/o RSP-008 & RSP-010)

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## 1 PURPOSE

The purpose of this procedure is to provide instruction on the operation of the sodium-iodide-based gamma spectroscopy system at Advanced Medical Systems, Inc. (AMS).

## 2 SCOPE

This procedure applies to the routine operation of the gamma spectroscopy system in use at the London Road facility. Analysis of other than water or soil samples are exempt from the requirements of this RSP.

## 3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment".

3.2 American Society of Mechanical Engineers, ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"

3.3 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

## 4 DEFINITIONS

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

## 5 PROCEDURE

5.1 Determine Energy Response and Regions of Interest

5.1.1 Energy response and regions of interest shall be determined daily, immediately prior to acquisition of background data.

5.1.2 Place either $^{60}Co$ calibration source over the detector.

5.1.3 Adjust amplifier gain and/or high voltage so that the two primary photopeaks fall in channels 155 (1.17 MeV peak) and 176 (1.33 MeV).

5.1.4 Acquire data until approximately 4,000 counts appear in Channel 176, then stop data acquisition.

5.1.5 Determine the regions of interest.

5.1.5.1 Place the left cursor to the left of channel 155 at the location where the peak tail reaches the continuum.

5.1.5.2 Place the right cursor to the right of channel 176 at the location where the peak tail reaches the continuum.

5.1.6 Record the left and right channel numbers on Attachment 1

5.2 Determination of Water Background

5.2.1 Background count rates in the regions of interest shall be determined daily, at the end of each shift.

5.2.2 Place a Marinelli Beaker containing deionized water over the detector.

5.2.3 Acquire data for a minimum of 28,800 seconds (eight hours).

5.2.4 Determine the number of counts in the Region (from Attachment 1).

5.2.5 Record the counts in the Region on Attachment 2

5.2.6 Determine $R_B$ and $\sigma_B$ as shown on Attachment 2.

5.3 Determination of Soil Background

5.3.1 Background count rates in the regions of interest shall be determined daily, at the end of each shift.

5.3.2 Place a Marinelli Beaker containing dry, cobalt-free soil collected from the AMS property over the detector.

5.3.3 Acquire data for a minimum of 28,800 seconds (eight hours).

5.3.4 Determine the number of counts in the Region (from Attachment 1).

5.3.5 Record the counts in the Region on Attachment 3

5.3.6 Determine $R_B$ and $\sigma_B$ as shown on Attachment 3.

5.4 Determine Efficiency for Water

5.4.1 Detection efficiency for water shall be determined daily, at the start of each shift.

5.4.2 Place the water-equivalent calibration source (Source No. A3082) over the detector.

5.4.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 526.3\ e^{\frac{-0.693\ \times\ t\ (days\ since\ March\ 1,\ 1995)}{1923.92}}$$

5.4.4 Record corrected activity on Attachment 4 (Item A).

5.4.5 Acquire data for 600 seconds.

5.4.6 Determine the number of counts in the Region (from Attachment 1).

5.4.7 Record counts on Attachment 5.

5.4.8 Determine $\epsilon_{water}$

5.5 Determine Efficiency for Soil

5.5.1 Detection efficiencies for soil shall be determined daily, at the start of each shift.

5.5.2 Place the soil-equivalent calibration source (Source No. A3083) over the detector.

5.5.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 587.6\ e^{\frac{0.693\ \times\ t\ (days\ since\ March\ 1,\ 1995)}{1923.92}}$$

5.5.4 Record corrected activity on Attachment 5 (Item A).

5.5.5 Acquire data for 600 seconds.

5.5.6 Determine the number of counts in the Region (from Attachment 1).

5.5.7 Record counts on Attachment 5.

5.5.8 Determine $\epsilon_{soil}$

5.6 Data Acquisition and Analysis

5.6.1 Collect a <u>full</u> Marinelli beaker of sample.

5.6.2 Label the sample by S-xxxxxx-yy or W-xxxxxx-yy, where S = Soil, W = Water, xxxxxx = today's date (e.g., 030195 for March 1, 1995), and yy = a unique sequential identifier that repeats at the start of each day (e.g., 01, 02, etc.).

5.6.3 Seal the sample container

5.6.4 If the sample is a soil sample, determine the sample mass in grams.

5.6.4.1 Weigh the empty Marinelli beaker (E)

5.6.4.2 Weigh the full Marinelli beaker (F)

5.6.4.3 Calculate the sample mass by F minus E

5.6.5 If the sample is a water sample, the volume is assumed to be "one liter"

5.6.6 Confirm that the outside of the sample container is free of contamination by smearing the outside of the container and ensuring that the smear count is less than "2x background". (If contaminated, place the container in a thin-walled plastic bag prior to placement on the detector.)

5.6.7 Place the sample over the detector

5.6.8 Acquire data for a minimum of 14,400 seconds (four hours) for water samples and 7,200 seconds (two hours) for soil samples.

5.6.9 Determine the number of counts in the Region (from Attachment 1).

5.6.10 Record counts on Attachment 6 of the sample is water or Attachment 7 if the sample is soil.

5.6.11 Determine $R_S$ using the most recent value of $R_B$ from Attachment 2 (for water) or 3 (for soil), and record on Attachment 6 or 7, as applicable.

5.6.12 Determine the Concentration and Minimum Detectable Activity and record on Attachment 6 or 7, as applicable.

5.6.13 Remove and archive the sample.

5.6.14 Confirm that the detector canning is free of contamination by smearing the outside of the canning and ensuring that the smear count is less than "2x background".

5.7 Confirmatory Analysis

5.7.1 Enclose the sealed Marinelli beaker inside of <u>two</u> zip-lock baggies.

5.7.2 Log the sample number and other pertinent information onto a Chain of Custody form (example follows Attachment 6).

5.7.2.1 The analysis to be requested for water samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 30 pCi/l"

5.7.2.2 The analysis to be requested for soil samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 5 pCi/g"

5.7.3 Forward the sample and the Chain of Custody form to a pre-selected analytical laboratory by overnight mail carrier (Federal Express or equivalent)

5.7.4 Maintain a copy of the Chain of Custody form and the airbill as the chain of custody record.

5.7.5 When results for water samples are received, record them on Attachment 6 and retain the Certificates of Analysis.

5.7.6 When the results for soil samples are received, record them on Attachment 7 and retain the Certificates of Analysis.

## 6 EXEMPTION PROVISIONS

Variances and exceptions to the requirements of this procedure shall be permitted pursuant to the written authorization of the RSO and the Radiation Safety Committee.

## 7 DOCUMENTATION

Records shall be maintained pursuant to RSP-004, "Radiation Protection Records"

## 8 ATTACHMENTS

8.1 Attachment 1 - Daily Energy Response and Regions of Interest

8.2 Attachment 2 - Daily Water Background Data

8.3 Attachment 3 - Daily Soil Background Data

8.4 Attachment 4 - Efficiency Determination for Water Samples

8.5 Attachment 5 - Efficiency Determination for Soil Samples

8.6 Attachment 6 - Analysis of Water Samples

8.7 Attachment 7 - Analysis of Soil Samples

Instrument Number__________________

## ATTACHMENT 1

## [illegible]Y ENERGY RESPONSE AND REGIONS OF [illegible]ST

| Date/Initials | Confirm Peaks are in Channels 155 and 176 | Channel to the left of Channel 155 Where Peak Meets Continuum (Channel A)<br>(Item A) | Channel to the right of Channel 176 Where Peak Meets Continuum (Channel B)<br>(Item B) |
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| | ☐ yes ☐ no | | |
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| | ☐ yes ☐ no | | |

Instrument Number_____

**ATTACHMENT 2**
**DAILY WATER BACKGROUND DATA**

| Initials | Start Date/Time | Stop Date/Time | Duration in seconds (Item A) | Number of Counts in Region (Item B) | Background Count Rate ($R_B$) in cps B ÷ A | $\sqrt{B}$ (Item C) | Background Standard Deviation ($\sigma_B$) in cps C ÷ A |
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Instrument Number_____

**ATTACHMENT 3**
**DAILY SOIL BACKGROUND DATA**

| Initials | Start Date/Time | Stop Date/Time | Duration in seconds (Item A) | Number of Counts in Region (Item B) | Background Count Rate ($R_B$) in cps B ÷ A | $\sqrt{B}$ (Item C) | Background Standard Deviation ($\sigma_B$) in cps C ÷ A |
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Instrument Number_____

ATTACHMENT 4
FICIENCY DETERMINATION - WATER SA

Source Number A3082, Activity of 526.3 nCi at 0300 March 1, 1995

| Initials | Date | Source Activity (nCi) Corrected for Half-life (Item A) | Counts in Region (Item B) | Count rate in cps B ÷ 600 (Item C) | Efficiency ($\epsilon_{water}$) in dps C ÷ (A x 37) |
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Instrument Number_____

ATTACHMENT 5
EFFICIENCY DETERMINATION - SOIL SA

Source Number A3083, Activity of 587.6 nCi at 0300 March 1, 1995

| Initials | Date | Source Activity (nCi) Corrected for Half-life (Item A) | Counts in Region (Item B) | Count rate in dps B ÷ 600 (Item C) | Efficiency ($\epsilon_{soil}$) in dps C ÷ (A x 37) |
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Instrument Number_____

**ATTACHMENT 6**
**ANALYSIS OF WATER SAMPLES**

| Initials | Date/Time | Sample No. | Count Time in seconds (Item A) | Counts in Region (Item B) | Sample count rate ($R_{s+b}$) in cps B + A (Item C) | Background count rate ($R_b$) from Attachment 2 (Item D) | $\sigma_s$ $\frac{\sqrt{B}}{A}$ (Item E) | Efficiency ($\epsilon_{wmat}$) in dps from Attachment 4 (Item F) | Concentration in pCi/l $\frac{C - D}{F \times 0.037}$ | MDA in pCi/l $\frac{4.66 \times E}{F \times 0.037}$ | Confirmatory Result |
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Instrument Number_____

# ATTACHMENT 7
## ANALYSIS OF SOIL SAMPLES

| Initials | Date/Time | Sample No. | Count Time in Seconds (Item A) | Sample Weight in grams (Item B) | Counts in Region (Item C) | Sample count rate in seconds ($R_{s+b}$) C + A (ItemDF) | Background count rate ($R_b$) from Attach-ment 3 (Item E) | $\sigma_s$ $\frac{\sqrt{C}}{A}$ (Item F) | Efficiency ($\epsilon_{mb}$) in dps from Attachment5 (Item G) | Concentration in pCi/g $\frac{D - E}{G \times B \times 0.037}$ | MDA in pCi/g $\frac{4.66 \times F}{G \times B \times 0.037}$ | Confirmatory Result |
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# ADVANCED MEDICAL SYSTEMS, INC.
# ANALYSIS REQUEST AND
# CHAIN OF CUSTODY RECORD

Reference No. _____



| | | |
|---|---|---|
| (1) Client Name | (7) Samples Shipment Date | (5) Bill to: |
| (2) Sample Team Leader | (8) Lab Destination | |
| (3) Task No. | (9) Lab Contact | |
| (4) Project Manager | (12) Technical Contact/Phone | (10) Report to: |
| (6) Purchase Order No. | (13) Carrier/Waybill No. | |
| (11) Required Report Date | | |

## ONE CONTAINER PER LINE

| (14) Sample Number | (15) Sample Description/Type | (16) Date/Time Collected | (17) Container Type | (18) Sample Volume | (19) Preservative | (20) Requested Testing Program |
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(23) Special Instructions

(24) Possible Hazard Identification
Non-hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐

(25) Sample Disposal
Return to Client ☐ Disposal by Lab ☐ Archive _____ months

(26) Turnaround Time Required: Normal ☐ Rush ☐

(27) QC Level: I ☐ II ☐ III ☐ Project Specific _____

| | |
|---|---|
| (28) Relinquished by: (signature, date, time): | Received by: (signature, date, time) |
| Relinquished by: (signature, date, time): | Received by: (signature, date, time) |
| Relinquished by: (signature, date, time): | Received by: (signature, date, time) |

(See Reverse for Instructions)

# INSTRUCTIONS FOR COMPLETING THIS FORM

1. **Client Name:** Record the name of the client (AMS)

2. **Sample Team Leader:** List the name of the team taking these samples.

3. **Task No.:** Indicate the AMS task number, if applicable.

4. **Project Manager:** Record the project manager's name.

6. **Purchase Order No.:** Non-AMS personnel should use this space to record the purchase order number authorizing the analysis of these samples. AMS and AMS subcontractors should leave this space blank if a project number has been given for billing.

7. **Samples Shipment Date:** Indicate the date these samples are shipped to the laboratory.

8. **Lab Destination:** Indicate the laboratory designated for sample shipment. Do not list more than one lab on this form. Be certain before sending samples that the laboratory you are designating is aware of the shipment and is capable of accepting these sample types and has available capacity.

9. **Lab Contact:** Give the name of the laboratory contact (typically the lab's project manager).

10. **Report to:** Give the name, address and phone number of the person to receive the data report for these samples.

11. **Required Report Date:** Record the date which you and the laboratory contact have determined the results will be reported (include verbal [illegible] report as appropriate).

12. **Technical Contact/Phone:** Indicate the name of the person to be contacted in case of any questions regarding these samples and the phone number where the contact may be reached the day the samples arrive in the laboratory.

13. **Carrier/Waybill Number:** If you are sending the samples by a commercial carrier such as Airborne or Federal Express, record the courier company name and the waybill or airbill number under which these samples will be shipped (Example - Fed-Ex/#513631771).

14. **Sample Number:** List the complete, unique identification number of each sample. These numbers must correspond with the identification numbers on the sample containers and the field sample collection document(s).

15. **Sample Description/Type:** Provide a short physical description of the sample and the sample type such as soil, sediment, sludge, water, wipe, air, concentrated waste or bulk.

16. **Date/Time Collected:** Record date and exact time each sample was collected. Use a 24-hour clock; i.e., 1645 not 4:45 p.m.

17. **Container Type:** Indicate the volume, color and type of the sample container used (Example - 1 gallon amber glass, 1 liter clear plastic, 4[illegible]illiliter clear glass).

18. **Sample Volume:** Estimate the amount of sample in the container. For air samples, indicate the volume of air sampled.

19. **Preservative:** Indicate what type of preservative, if any, has been used for the samples (Example - ice to 4°C nitric acid, hydrochloric acid).

20. **Requested Testing Program:** List the analyses to be performed on each sample <u>by method number or quotation number</u>.

23. **Special Instructions:** Use this space to record any special instructions to the lab regarding the processing of these samples.

24. **Possible Hazard Identification:** Indicate all hazard classes associated with the sample(s).

25. **Sample Disposal:** Indicate how the samples should be disposed of following analysis. The lab may charge for packing, additional archiving and disposal.

26. **Turnaround Time Required:** Check "Normal" or "Rush" as determined by the Technical Contact and the Lab Contact. Rush samples are subject to a surcharge.

27. **QC Level:** These should be specific to the analytical laboratory and should not be confused with USEPA Analytical Levels. Project Specific should reference a quotation number or other specifications that have been submitted to the laboratory before beginning work.

28 **Signatures:** When releasing custody of these samples, use the "Relinquished By" space to sign your full legal name, date and time of release. After verifying that all samples are present, the person receiving the samples must sign the "Received By" space to take custody of the samples.

## TABLE OF CONTENTS



**CONTROLLED COPY NO. : _____**

## 1 PURPOSE

The purpose of this procedure is to provide instruction on analyzing water samples for the presence of $^{60}Co$, and the criteria for discharge of water into the sanitary sewer system.

## 2 SCOPE

This procedure applies to the routine analysis of water samples at the London Road facility of Advanced Medical Systems, Inc. (AMS).

## 3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment".

3.2 American Society of Mechanical Engineers, ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"

3.3 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

3.4 American Public Health Association, Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

3.5 U. S. Environmental Protection Agency, Gamma Emitting Radionuclides in Drinking Water, Method 901.1, Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA 600/4-30-032.

3.6 U. S. Department of Energy, Gamma, Section 4.5.2.3, EML Procedures Manual, HASL-300, Environmental Measurements Laboratory.

3.7 U. S. Nuclear Regulatory Commission, NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20".

3.8 U. S. Nuclear Regulatory Commission, Communication from J. A. Grobe (Chief, Nuclear Materials Inspection Section 2) to D. Cesar (Treasurer, Advanced Medical Systems), February 1, 1995.

3.9 Advanced Medical Systems, Inc., RSP-018, "Operation of the Gamma Spectrometer".

## 4 DEFINITIONS

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

## 5 PROCEDURE

### 5.1 Responsibilities

5.1.1 Sample collection and analysis pursuant to RSP-018 shall be performed by a radiation surveyor.

5.1.2 The RSO should select and pre-qualify the commercial analytical laboratory used to perform confirmatory analyses.

5.1.3 Water shall be discharged only upon authorization by the RSO.

### 5.2 Data Acquisition

5.2.1 Water samples shall be placed into a one-liter Marinelli beaker.

5.2.2 Samples shall be analyzed pursuant to RSP-018.

5.2.3 Samples may be forwarded to a commercial analytical laboratory for confirmatory analysis.

### 5.3 Solubility Determination

5.3.1 Samples that contain detectable $^{60}Co$ shall be drawn (by vacuum pump) through a 0.45 micrometer filter.

5.3.2 The filtered sample shall be re-analyzed pursuant to RSP-018.

### 5.4 Confirmatory Analysis

5.4.1 The sample container shall be enclosed inside of <u>two</u> zip-lock baggies, labeled, and a Chain of Custody Form shall be completed as described in RSP-018.

5.4.2 The sample, with its Chain of Custody form, shall be shipped to the commercial analytical laboratory.

5.4.3 The samples shall be analyzed by gamma spectroscopy for Cobalt-60 pursuant to EPA Method 901.1 or HASL-300, with a nominal LLD of no greater than 30 pCi/l.

5.4.3.1 Analytical results that are less than the MDA or greater than 200 pCi/liter shall be forwarded to the RSO and no additional analyses are necessary.

5.4.3.2 Analytical results that are greater than the MDA but less than 200 pCi/liter shall be analyzed for suspended gross alpha and gross beta radioactivity pursuant to American Public Health Association Method 7110.

5.4.4 When results from the analytical laboratory are received, they shall be recorded and retained as described in RSP-018.

5.5 Discharge of Water (See Attachment 1)

5.5.1 Discharges of sampled water shall not exceed 40,000 liters (10,000 gallons) in a 24-hour period.

5.5.2 Water that contains greater than 200 pCi/l of $^{60}Co$ as determined from the sampling and analysis effort described herein shall not be discharged.

5.5.3 Water than contains no detectable $^{60}Co$ (e.g., less than the MDA) as determined from the sampling and analysis effort described herein may be discharged.

5.5.4 Water that exhibits <u>both</u> of the following may be discharged:

5.5.4.1 Less than 200 pCi/l of $^{60}Co$ and

5.5.4.2 From 5.3, the count rate of the filtered water is statistically similar to the count rate of the unfiltered water pursuant to

$$\frac{C_f}{t_f} \pm \frac{2\sqrt{C_f}}{t_f} = \frac{C_u}{t_u} \pm \frac{2\sqrt{C_u}}{t_u},$$

where $C_f$ = the net counts in the spectral region(s) of interest for the filtered water, $C_u$ = the net counts in the spectral region(s) of interest for the unfiltered water, $t_f$ = the count time for the filtered water and $t_u$ = the count time for the unfiltered water.

## 6 EXEMPTION PROVISIONS

Variances and exceptions to the requirements of this procedure shall be permitted pursuant to the written authorization of the RSO and the RSC.

## 7 DOCUMENTATION

7.1 Records to be maintained shall include:

7.1.1 Forms generated pursuant to RSP-018.

7.1.2 Chain of Custody documentation (forms, airbills, etc.)

7.1.3 Requests for analysis

7.1.4 Certificates of Analysis

7.1.5 Discharge logs/records

## 8 ATTACHMENTS

Attachment 1 - Technical Basis for Water Discharge Criteria

## ATTACHMENT 1
## TECHNICAL BASIS FOR WATER DISCHARGE CRITERIA

The objective of the water sampling and discharge program at Advanced Medical Systems, Inc. (AMS) is to ensure compliance with applicable regulations, as well as the radiological health and safety of employees and members of the general public. To ensure that these objectives are met, there must be clear instruction on how to interpret the results of sampling and analysis. These instructions are that a maximum of 10,000 gallons of water may be discharged over a single day. In addition, that water must be sampled and confirmed to contain less than 200 pCi/l of $^{60}$Co. However, any detectable $^{60}$Co in the sample must be deemed "soluble" in water.

These instructions were not selected arbitrarily. Instead, they were based upon regulatory and technical constraints and requirements. The following is a listing of the pertinent requirement and constraints:

- In Title 10, Code of Federal Regulations, Part 20, the USNRC authorizes discharge of licensed material into the sanitary sewage provided the material is readily soluble (or is readily dispersible biological material) in water, and the concentration of licensed material does not exceed that listed in Table 3 of Appendix B to 10 CFR 20.1001-20.2401. For $^{60}$Co, that concentration is 30,000 pCi/l. Therefore, AMS discharge concentrations must be less than 30,000 pCi/l of soluble $^{60}$Co.

- The USNRC has set a release limit for $^{60}$Co in soils of 8 pCi/g. Therefore, in order to ensure that the waste ash produced at the sewage treatment plant that services AMS remains exempt from regulation, AMS must not discharge <u>insoluble</u> $^{60}$Co in concentrations that exceed 1,362 pCi/liter. This number was derived from the assumption that every atom of $^{60}$Co discharged from AMS is transported to the ash, that 10,000 gallons of cobalt-bearing waste are discharged per day, and that the sewage treatment plant produces 7.5 tons of ash per day. The following is the calculation that was performed:

$$10000\ \frac{gal}{day} \times 4\ \frac{\ell}{gallon} \times X\ \frac{pCi}{\ell} \times \frac{day}{7.5\ tons} \times \frac{ton}{2000\ lb} \times \frac{lb}{454\ grams} = 8\ \frac{pCi}{gram}$$

$$X = 1362\ \frac{pCi}{\ell}$$

  Therefore, to ensure that there are no adverse radiological impacts on the local sewage treatment plant, and remain consistent with the USNRC's requirements, the discharge concentration from AMS must be less than 1392 pCi/l of $^{60}$Co.

- The USEPA, in Title 40, Code of Federal Regulations, Part 141.16, establishes maximum contaminant levels for radionuclides in drinking water. For $^{60}$Co, that level is based upon assuring that the contaminant does not produce an annual dose equivalent to the total body or any internal organ of more than 4 millirem in a year. This dose limit is equivalent to a concentration of about 280 pCi/liter. However, no solubility criteria are given in 40 CFR 141.16. Therefore, in order to demonstrate compliance with the drinking water standards, the USNRC's requirements and ensure no adverse impacts on the local sewage treatment plant, the discharge concentration from AMS must be less than 280 pCi/l of soluble $^{60}$Co, even though the discharge will not enter a drinking water supply directly.

- In a letter to AMS,[1] the USNRC specified that discharges to the sanitary sewage system of soluble $^{60}$Co in concentrations less than 200 pCi/liter were acceptable. The USNRC felt, upon issue of this letter,

[1] Grobe, J. A. USNRC, written communication to D. Cesar, AMS, February 1, 1995.

that the nominal concentration of 200 pCi/liter provides a comfortable margin of safety with respect to sewage sludge concentrations in relation to the USNRC release criteria.

- The USNRC's criteria for solubility are defined in USNRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20". This document lists the acceptable methods for demonstrating compliance with the solubility requirements. One of these is the American Public Health Association (APHA), Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

- APHA Method 7110 contains an analytical procedure for determining the quantity of suspended gross beta activity in water samples. However, water typically contains significant gross beta activity from isotopes such as uranium and daughters, radium and daughters, thorium and daughters, and $^{40}K$. The standard does not provide guidance on how much suspended gross beta activity indicates an insoluble material.

- The USEPA recognizes the presence of naturally-occurring radioactivity in water. Consequently, 40 CFR 141 indicates that if the average annual concentration of gross beta activity in water is less than 50 pCi/liter, no further analyses are required. Concentrations greater than 50 pCi/l may still be acceptable for a drinking water supply, but isotope-specific analyses are required before the decision is made.

- A nominal detection sensitivity for $^{60}Co$ in water by the methodology of gamma spectroscopy, when performed at a commercial analytical laboratory, ranges from 20 to 30 pCi/liter in a one-hour count time, depending upon the quantity of naturally-occurring radionuclides present in the sample. At AMS, the nominal detection sensitivity for a four-hour count time ranges from 20 to 50 pCi/l, again depending upon the quantity of naturally-occurring radionuclides that are present in the sample.

In light of the aforementioned requirements and constraints, the maximum concentration of $^{60}Co$ that can be released into the sewer system or drinking water supplies is 200 pCi/liter. In addition, any detectable (e.g., greater than MDA) activity must meet the USNRC's criteria for solubility pursuant to APHA Method 7710.

Since naturally-occurring beta activity is readily detected by these methods, the maximum concentration of suspended (i.e., insoluble) gross beta activity that might be released into the sewer system based upon the results obtained from a commercial analytical laboratory is 50 pCi/liter. For samples analyzed at AMS pursuant to RSP-018, "Operation of the Gamma Spectrometer" and RSP-019, "Assessment of Radioactivity in Water Samples", the maximum concentration of suspended $^{60}Co$ activity that might be released into the sewer system, yet remain unquantifiable, is approximately 35 pCi/liter. In either case, there no adverse radiological impact on the public water supply or the local sewage treatment plan will result.

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

FEB 28 1996

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

Dear Mr. Cesar:

We have completed our review of your Emergency Plan submitted under letter dated September 21, 1995, and request that you provide clarification and/or additional information on the following topics:

1. AMS Staffing Levels and Offsite Response Personnel

Your response to our previous comment I.A of our June 7, 1995 letter did not provide an assessment of how current staffing levels will be able to fulfill the functions and responsibilities described in the plan, especially during nonworking hours. The following issues should be addressed in the plan:

a. It appears that the onsite emergency organization is comprised of three individuals during working hours, and the absence of one or more individuals could severely impact the licensee's capability to promptly notify offsite response organizations and coordinate the response to an emergency. The licensee is required by 10 CFR 30.32(i)(3)(viii) to plan the notification and coordination so that unavailability of some personnel will not prevent notification and coordination. The plan should describe how the licensee will compensate for the functions assigned to an absent member of the emergency organization.

b. Section 4.2 of the plan should clearly state the order in which AMS staff members assume the role of Emergency Manager if the Radiation Safety Officer (RSO) is not available (see previous comment V.C).

c. It is still difficult to determine which personnel are assigned to each of the functional areas specified in Section 4.2.2 of Regulatory Guide 3.67 (see previous comment V.D). It would be helpful if these functional responsibilities were all specified in one place such as Figure 7.

d. During nonworking hours, it is unclear whether a fire or other emergency situation will be detected promptly if power lines or phone lines are down. The plan should describe how the alarm system signal is transmitted to ADT Security Systems and how ADT

would detect a loss of contact with the alarm system. Any difference in the response to a loss of contact versus an alarm signal should be described also.

e. During nonworking hours, it appears that local fire or police units could arrive before AMS staff and it is unclear whether there are adequate provisions to alert offsite response personnel to radiological hazards if no AMS personnel are there to meet them. The plan should describe arrangements with fire, police and rescue personnel regarding how they will fight fires and respond to alarms if AMS personnel are not present when they arrive at the site. The plan should also describe signs and other provisions to prevent offsite response personnel from unknowingly entering areas with elevated radiation levels.

2. Engineers Opinion Report

In response to our request for an engineering analysis of the facility structure, the emergency plan refers to an Engineers Opinion Report issued by Neff and Associates dated September 1995. We obtained a faxed copy of the report dated September 22, 1995 (after the date of the emergency plan). We noted a number of deficiencies in the report and a general failure to provide an adequate technical basis to support its conclusions. Most of our concerns regarding the structural integrity of your facility will be addressed in Inspection Report No. 030-16055/95006 which will be transmitted under separate cover. With respect to the emergency plan, the Engineer's Opinion Report does not provide an adequate analysis of the worst case earthquake. The report states that the structure can "withstand seismic forces as great as 5.2 Richter" and "a seismic event greater than 5.2 Richter in this region is highly improbable." Since the Richter scale is a method of classifying the energy released by an earthquake without defining other parameters such as epicentral distance, the statement fails to define the associated seismic forces on the structure. An adequate analysis should state, in appropriate units, the ground acceleration, velocity, and displacement that the worst case earthquake could impose on the structure. The analysis should evaluate how well the various existing structural systems in the building would withstand these seismic effects.

3. Facility Description

a. Section 1.1 contains a brief description of activities formerly conducted at the site, but there is no description of the activities currently authorized or conducted. The plan should describe the current activities.

b. Section 1.1 and Table 1 describe the amount of licensed material possessed on September 21, 1995. This inventory is subject to change and could increase up to the possession limits stated in

the license. The plan should state the total quantity of radioactive material authorized by the license. Typical quantities possessed at one time may be noted also.

c. Section 1.1 states that there are over 60,000 curies of cobalt-60 and 2200 kilograms of depleted uranium in the facility, but it is unclear where this material is typically located. Sections 1.2 through 1.2.12 only identify the location of approximately 34,000 curies of cobalt-60. The typical storage locations for the remaining material authorized by the license should be identified.

d. The plan still lacks a detailed site drawing showing the exterior features of the building and property described in Section 1.2 of Regulatory Guide 3.67 (see previous comment II.B). A detailed drawing of the exterior features of the site must be provided in addition to the interior floor plans. In addition to detailed information about the licensee's property, the drawing should show the pump house on Mandalay Avenue, the rail line that runs past the facility, and the nearest residents in each direction.

e. The terminology used to describe areas in the facility is still inconsistent (see previous comment II.D). Section 1.2 refers to a shielded work room on the main floor, but this term does not appear in the following sections or on Figure 3/Appendix B. Section 1.2 refers to a mechanical equipment room and a ventilation system equipment room on the second floor, but these areas are labeled as the clean equipment room and HEPA equipment room in the following sections and Figure 4/Appendix B. Section 1.2 refers to a source storage area and irradiation facility in the basement, but Section 1.2.3 discusses a source garden, and Figure 2/Appendix B does not identify any of these areas in the basement. Consistent terminology should be used and all areas discussed in the text should be indicated on the drawings.

f. Section 1.2.3 states that there is an L-shaped shield of sand-filled vaults on two sides of the source garden in the basement, but the floor plan in Figure 2/Appendix B does not show the shield. Significant safety features such as the sand shield, the emergency generator, fire pull stations, and storage locations of emergency response kits should be shown on the floor plans. The floor plans should also identify where electrical and natural gas services enter the building.

g. Section 1.3 states that Figure 5 identifies the facility and its proximity to near-site structures. It states that Figure 5 shows the location of schools, hospitals and fire stations also. Figure 5 appears to be a poor quality copy of a street map and neither the licensee's building nor any structures within 1 mile of the site are clearly identified. Figure 1 does not provide an

adequate picture of the area near the site either. The plan should contain a reasonably detailed drawing of the site area as described in Section 1.3 of Regulatory Guide 3.67 (see previous comment II.F). The plan should also contain a U.S. Geological Survey topographical map (7.5 minute series).

4. Types of Accidents

a. The discussion on page 2-2 refers to guidance issued by the International Commission on Radiological Protection (ICRP). This guidance is not directly applicable to facilities in the United States. The guidance applicable to protecting the public in this country is contained in the "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" issued by the U.S. Environmental Protection Agency (EPA 400-R-92-001). The plan should refer to this guidance regarding offsite protective action recommendations.

b. We have a number of concerns regarding the analysis in Section 2.1.1 and Appendix C of potential doses from a fire (see previous comment IV.A). Appendix C states that the source term for the worst case fire was assumed to be 40.4 curies, but the basis for that number is not provided. This does not appear to be a conservative assumption because the revised AMS license application dated October 30, 1995 requests a possession limit of 50 curies for packaged waste and surface contamination, and there is no explanation why the source term should not include bulk quantities of cobalt-60 from containers ruptured by one of the accidents postulated in Chapter 2 such a gas line explosion, train derailment, or earthquake.

In addition, we disagree with the statement in footnote 40 that a 10-meter release height is a conservative assumption. A ground level release with no plume rise would maximize the offsite dose estimate.

We note that the CAP88-PC computer code is not intended to estimate short term doses resulting from an unplanned release during an emergency. Using a 40-curie source term, we estimated an inhalation dose at 100 meters of 7.7 millirem using the hand calculation in Section 2.1.3 of NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," January 1988. This estimate is over an order of magnitude greater than the 0.2 millirem dose estimated by the CAP88-PC code. A more detailed and conservative analysis using more appropriate calculational methods should be provided.

c. Section 2.1.2 and Appendix C state that an earthquake could create a 100 millirem/hour dose rate 20 feet beyond the outside wall of the source garden. The plan should state the distance at which the dose rate would drop below 2 millirem/hour and whether that location is in an area accessible to the public. In addition, we attempted to run the Microshield code using the assumptions stated in Appendix C but we could not duplicate the results stated in the plan. The input parameters and assumptions should be described in enough detail to permit us to duplicate and evaluate the calculation.

d. Section 2.1.3 states that a tornado would not compromise the structural integrity of restricted areas and references the Engineers Opinion Report issued by Neff & Associates. Although this report states that portions of the building contained within the bunker-type construction would not sustain any appreciable distress, it also states "that it is scientifically certain that a tornado passing over this facility would impose significant structural damage" to other parts of the building. Restricted areas on the second floor and in the warehouse areas of the first floor could be completely demolished by a tornado releasing radioactive materials in those areas. Section 2.1.3 should provide a more accurate description of the potential damage from a tornado, and postulate the maximum amount of radioactive material that could be in these areas as a result of routine storage, preparation for shipments, or other operations.

5. Classification and Notification

a. Section 3.2 is still inconsistent with the notification requirements in the regulations (see previous comment III.A). Pursuant to 10 CFR 30.32(i)(3)(viii), the plan must contain a clear commitment to notify appropriate offsite response organizations promptly after declaring an Alert or Site Area Emergency (SAE). The plan should not differentiate between these classifications or give the impression that the licensee can needlessly wait a full hour before notifying offsite officials of an Alert declaration. In addition, the plan must clearly state that the licensee shall notify NRC immediately after notification of local and State authorities. Simply stating that NRC will be notified within one hour is not sufficient.

b. Several of the emergency action levels (EALs) in Attachment 1 of Appendix D are defined in terms of potential exposure rates or actual exposures. It is unclear how the Emergency Manager will be able to identify these conditions in a timely manner. It is unacceptable to wait for survey results if it will take more than 15 minutes to get them. EALs must be defined in terms of conditions that are apparent within the first few minutes of an

emergency. This is especially important during nonworking hours. If an alarm goes off and the condition cannot be verified within 15 minutes, the Emergency Manager should act conservatively by declaring an emergency and initiating notification of offsite response organizations. The EALs should be redefined.

c. The offsite response organizations listed in Attachment 1 of Appendix D to receive a notification vary depending on the event. Each of the organizations identified as a "first responder" should be notified every time an Alert or Site Area Emergency is declared. In addition, all NRC notifications should be made to the NRC Operations Center. The Operations Center coordinates event reports with regional staff.

d. The plan does not establish the initial recommendations for offsite protective actions that will be included in the initial SAE notification to offsite organizations (see previous comment III.B). If an accident has the potential to require road blocks or other protective actions offsite, the licensee should act conservatively and make initial recommendations to offsite officials until the scope of the accident can be verified. This would include recommendations to stop traffic on the rail line or rope off potentially contaminated areas. Protective action recommendations should be addressed in Sections 3.1.4 and 3.3, and Appendix D.

e. Section 3.3 should specify the minimum frequency of updates to offsite response organizations after the initial notification (see previous comment IX.B). The response to our previous comment states that Section 8.3 was being modified to include the information, but the revision does not include this information.

6. <u>Responsibilities</u>

a. Section 4.2 states that an environmental consulting firm and a certified health physicist have been retained to assist in all matters relating to radiation safety and environmental issues. Figure 7 only shows the environmental consultant as part of the AMS emergency organization and it is unclear what function either of these parties would perform during an emergency. The roles of the environmental consultant and the certified health physicist should be clarified.

b. The response to our previous comment V.E states that letters from the hospital, fire department, and police department will be included in the plan. Section 4.3 states that Appendix E contains letters of agreement from "applicable first responders" listed in Table 2 along with information on the agreed upon means of communication and notification with these agencies. Contrary to

these statements, Appendix E only contains letters from the fire department and two State agencies and there is almost no information about methods of communication. Complete documentation that offsite response agencies are aware of, and have agreed to their roles as specified in the plan should be provided.

c. The response to our previous comment V.G concerning the capabilities of offsite organizations and rumor control arrangements stated that the plan would be modified to address these items. The plan does not include this information. In addition to other capabilities, Section 4.4 should specifically address whether local fire or police personnel have the capability to conduct radiation surveys.

d. Section 4.4 fails to describe some of the organizations listed in Table 2. A description of the responsibilities and capabilities of each of these organizations should be provided.

e. In Table 2, the organizations do not appear to be listed in the order they would be called. The NRC Operations Center should be notified immediately after appropriate local and State organizations. Table 2 and Attachments 2 and 3 of Appendix D should be revised to prevent confusion.

7. Response Measures

a. The terms used for accidents are still inconsistent (see previous comment IV.B). The plan should establish the terms for accidents in Chapter 2 and these terms should be used consistently throughout the rest of the plan. The terms we found are listed below:

| Chapter 2 | Chapter 5 | Appendix D |
|---|---|---|
| Fire | Fire | Loss or Theft |
| Earthquake | Natural Phenomenon | Unauthorized Entry |
| Tornado | Tornado | Power Failure |
| Vandalism | Vandalism | Minor Spill or Release |
| Flood | Flood | Major Spill or Release |
| Industrial Facility Impact | | Minor Fire |
| Underground Gas Line Explosion | | Significant Exposure |
| Transportation Accident | | Fire, Explosion or Other Major Emergency |

b. We disagree with the statement in Section 5.3 that no actions can be taken to mitigate the consequences of a tornado or flood. When there is advance warning of severe weather conditions, we would expect the licensee to take reasonable steps to secure the facility and minimize releases. If a tornado warning is issued for the site area, we would expect the licensee to declare an alert and take immediate steps to secure licensed materials especially in the warehouse portions of the facility. Section 5.3 and Appendix D should address the mitigating actions that will be taken if a severe weather warning is issued.

c. Section 5.4.1 states that evacuated personnel will assemble at the designated muster area, however the location of the muster area is not specified and it is not shown on any of the drawings. The location of the muster area should be identified.

d. Section 5.4.1 does not describe provisions for search and rescue operations if the RSO cannot account for all personnel. This issue should be addressed.

e. Section 5.3 states that licensee staff will assist the fire department by conducting surveys during fire fighting efforts. Footnote 25 on page 5-2 states that in the event of a fire, only self-contained breathing apparatus (SCBA) should be worn, and full- or half-face respirators are not permitted. Section 6.4 states that respirators are maintained in the building and Table 3 indicates that a respirator is maintained at the pump house. Please indicate what types of respirators are maintained in the building and the pump house. SCBAs should be available in the building and the pump house to respond to a fire.

f. Section 5.5 still does not address informed consent (see previous comment VI.A). The plan should describe how the Emergency Manager will verify that a volunteer is aware of the health risks before authorizing emergency exposures exceeding 25 rem.

g. Issuing dosimeters to firemen is not addressed in section 5.11 of Appendix D. This issue should be addressed in the implementing procedure.

h. Section 5.5 states that personnel will be monitored for contamination, but there is no description of the procedures for decontaminating personnel if contamination is found. This issue should be addressed.

i. Section 5.6 states that the Cleveland Emergency Medical Service personnel receive annual training, but it is unclear who conducts this training. In addition, there is no letter of agreement confirming that this organization has agreed to transport contaminated individuals. The training issue should be clarified and a letter of agreement should be provided.

j. Sections 5.6 and 5.7 state that the University Hospital of Cleveland is capable of diagnosing and treating radiation injuries, and has a Radiation Safety Officer who will perform surveys and control contamination. There is no letter of agreement from the hospital verifying its capabilities and confirming its agreement with these statements (see previous comment VI.D). A letter of agreement should be provided.

8. Equipment and Facilities

a. Section 6.2 does not describe any communications capability at the alternate command center (the pump house). Both the primary and alternate command center should have a telephone or other means of communication with offsite organizations.

b. Section 6.4 states that dosimeters and survey meters are stored in the "instrument calibration room" shown in Figure 3, and that protective clothing and respirators are stored "in the locker room or storage room." There is no instrument calibration room indicated on Figure 3 and the storage location for the protective clothing is too vague. It is unclear whether these locations would be accessible during postulated accidents. Section 6.4 should use terminology that is consistent with the labels on the drawings. It would be helpful if the command center, equipment storage locations, first aid kits, emergency generator and other features related to emergency response were specifically indicated on the drawings.

c. Section 6.4 and Table 3 only list pocket dosimeters. While pocket dosimeters are useful for real-time dose assessment, they are not very accurate. The licensee should provide more accurate dosimeters (e.g., film badges or TLDs) that can be used to verify personnel exposures after an emergency is brought under control.

d. Table 3 indicates that only one respirator and two pocket dosimeters are maintained at the pump house. This does not appear to be sufficient to equip the licensee's staff and offsite rescue personnel that may need to enter the building. The pump house should contain enough respirators and dosimeters to equip the licensee's emergency staff, and enough additional dosimeters to monitor hose crews, search and rescue teams, or other offsite rescue personnel.

e. Table 3 indicates that only one frisker and one survey meter are maintained at the pump house. We believe that at least one additional survey meter should be provided at this location for backup. The range of the survey meters should be specified also.

9. Maintaining Emergency Capabilities

a. Section 7.2 should specifically state that the risks of emergency doses will be covered in the training of offsite rescue personnel so they can decide in advance what risks they would be willing to accept during lifesaving operations. Numerical estimates of health risks are provided in the EPA Manual of Protective Action Guides.

b. Section 7.3 should state that the exercise objectives and scenario shall be provided to NRC in advance (typically 60 days) to allow NRC to review and comment on the exercise.

c. Sections 7.4 and 7.5 should specify who is responsible for tracking findings from critiques and audits, and verifying that the findings are closed out.

d. Section 7.5 states that there will be periodic audits. The plan should clearly state that there will be annual audits.

e. Section 7.6 should state that the shelf-life of protective clothing and other degradable materials shall be tracked and changed out on a regular basis. In addition, provisions for calibration of the stack monitor and testing of the emergency generator should be described.

10. Records

Section 8.1 should specify that records of incidents shall be permanently retained with the licensee's decommissioning records.

11. Format

a. The plan still does not have a list of effective pages that a reader can use to verify his copy is complete and up-to-date (see previous comment XII). A list of effective pages should be provided.

b. Although Figures 2, 3, 4, and 5, and Appendix B have cover pages that are numbered, the actual drawings are not numbered or identified as part of the emergency plan. The drawings can be removed from the plan without creating any gaps in the page numbers. Every page of the plan, including the drawings, must be identified with a page number and a revision number/date.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 98538.

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

Sincerely,

John R. Madera, Chief
Nuclear Materials Licensing Branch

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

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

March 12, 1996

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

SUBJECT: NRC INSPECTION REPORT NO. 030-16055/95006(DNMS)

Dear Mr. Meschter:

This refers to the special inspection conducted by Robert E. Shewmaker, Engineering and Geoscience Branch, Division of Waste Management, Office of Nuclear Materials Safety and Safeguards. The on-site inspection was conducted on October 11-12, 1994, February 1-2, 1995, and July 20-21, 1995, at Advanced Medical Systems' London Road, Cleveland, Ohio facility. The inspection's purpose was to evaluate (1) the impact of the basement flooding on the facility's structural integrity and (2) the facility's structural integrity relative to the containment and protection of the radioactive material stored there. The enclosed report discusses information obtained during the inspection.

Based on observations made during the inspection we have concluded that the 1994-1995 basement flooding had no observable impact on the 1958 building's structural integrity. The 1958 building includes all areas, with the exception of the isotope warehouse, where radioactive materials are used and/or stored. We have also concluded that the building's structural integrity appears adequate at this time to contain the radioactive material in AMS' possession; however, some questions regarding the structure's condition were identified.

Indications of structural distress in limited areas were evident. The impact of those indications on the structure's long term integrity and seismic stability were not assessed in the report. However, those indications of structural distress appear to conflict with the conclusions of your Emergency Plan's "Engineers Opinion Report." In order to complete our review of your Emergency Plan, and to ensure an integrated assessment of your facility's integrity, you will need to address our report's findings, and the questions regarding seismic stability in our February 27, 1996 letter. The assessment should address the facility's ability to provide protective confinement of the radioactive materials over the facility's intended utilization period. The assessment should include sufficient engineering detail to support its conclusions and plans, if necessary, for structural remediation. Plans for

structural remediation, if identified, should include schedules with estimated completion dates for each action requiring remediation. The following items, discussed in the inspection report, should specifically be addressed:

1. The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the load-bearing masonry wall in the 1958 building's southeast corner. Associated distress that could limit the facility's ability to continue to provide protective confinement of the radioactive materials should also be assessed and corrective actions identified as necessary.

2. The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the 1958 building's north bay of the east masonry filler/curtain wall. Associated distress, caused by the introduction of moisture and other waterborne contaminants, that could limit the facility's ability to continue to provide protective confinement should also be assessed and corrective actions identified as necessary.

3. The precast concrete roof panels that in several areas exhibit corrosion products on the visible surface.

4. The second floor concrete slab in the area where it forms the ceiling of the hallway in front of the hot cell and the radiography room, and exhibits the effects of previous fluid penetration through the slab from above.

5. The need to periodically inspect and evaluate the building's ability to perform its defined functions over the utilization period. If a program is deemed appropriate, it should include inspection frequencies and evaluation activities.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Please provide your plans and schedule for completing the assessment within 30 days of this letter's date. In your response to this letter, include an evaluation of the impact of the assessment described above, as well as an evaluation of the impact of any plans and schedules for structural remediation, on the long term priority plans you submitted in your letter of October 11, 1995.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Geoffrey C. Wright, Acting Deputy Director
Division of Nuclear Materials Safety

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

Enclosure: Inspection Report
No. 030-16055/95006(DNMS)

See Attached Distribution

Distribution

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Marian Zobler
U.S. Nuclear Regulatory Commission
Rockville, MD 20555

December 20, 1995

U.S. NUCLEAR REGULATORY COMMISSION
HEADQUARTERS

Report No. 030-16055/95006(DNMS)

License No. 34-19089-01 (Current) Priority I Category B
License No. 34-07225-09 (Former)

Docket No. 030-16055 (Current); None Specified (Former)

Licensees: Advanced Medical Systems, Inc (Current)
Picker Corporation (Former)

Facility: 1020 London Road
Cleveland, OH 44110

Site Inspection and Interviews Conducted: October 11, 1994 through July 21, 1995

Inspector: Robert E. Shewmaker, PE
Senior Structural Engineer
12/21/95
Date

Accompanying Personnel: Wayne Slawinski
Senior Radiation Specialist
RIII

Reviewed By: Richard Weller, Section Leader
Engineering and Materials Section
12/22/95
Date

Approved By: Michael J. Bell, Chief
Engineering and Geosciences Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards
12/22/95
Date


Inspection Summary:

Inspections during the period of October 11, 1994 through July 21, 1995 (Report No. 030-16055/95006(DNMS))
Areas Reviewed: This series of special inspections consisted of three separate inspections relative to assessing the current and future structural integrity of certain specific areas within the Advanced Medical Systems, Inc.

(AMS) facility at 1020 London Road, Cleveland, Ohio. Areas of main focus were the hot cell, the waste hold-up tank (WHUT) room, the original radiography room (now known as the "high level" waste storage room), the source room, the front and back basements and the HEPA filter equipment room. In addition, the impact on the structural integrity of a water back-up condition that occurred in the basement areas of the facility was also assessed.

Results: One area of distress in a load-bearing masonry wall, supporting the roof structural steel framing in conjunction with the wall of the HEPA filter equipment room, was identified. This area also exhibited a breech in the building's waterproof envelope, leaving structural components exposed to a more rapid degradation rate than if protection were intact. One other area was found where the waterproof building envelope was not intact, however, any future structural distress resulting from this would not impact stored radioactive materials or wastes. Evidence of degradation in the form of rust on the exterior of concrete elements that had formed over the current service life of the structures was also found. It was concluded that with repairs and continued monitoring, the structural integrity of the 1958 building could be maintained consistent with the original design conditions with monitoring on a 10-year cycle.

## DETAILS

1. Persons Contacted

Mary Bennett, Administrative Assistant, Division of Building and Housing, City of Cleveland

Carol Berger, Project Manager, Integrated Environmental Management, Inc. (IEM), AMS consultant

David Ceasar, Treasurer and Chief Financial Officer, AMS

John W. Denega, Project Engineer, Neff and Associates, AMS consultant

Donald Jones, President, Quality Environmental Solutions, Inc. (QES), AMS consultant

Evans Matiatos, Environmental Chemist, Quality Environmental Solutions (QES), AMS consultant

Robert Meschter, Radiation Safety Officer, AMS

William J. Muniak, Attorney, Arter and Hadden, legal counsel for AMS

Vince Rocco, former Health Physics Technician, AMS

2. Purpose and Scope of Inspection

This was a series of limited scope special inspections related to the structural integrity of the physical building facility at 1020 London Road in Cleveland, Ohio, including the specific elements such as the hot cell, the waste hold-up tank (WHUT) room, the original radiography room (now known as the "high level" waste storage room), the source garden, the front and back basements and the HEPA filter equipment room. The structural integrity of the building facility with areas of contamination, waste storage or source material storage needs to be assured for the expected future time period over which the radioactivity should be controlled, that includes during events that are addressed in the emergency response plan for the facility. Depending on various decisions that may be made by AMS management, this time period may extend as much as an additional 25 to 30 years or more beyond the current time. The original inspection scope was later expanded in the late fall and early winter of 1994/1995 to include the assessment of any impact on structural integrity caused by basement flooding that resulted from the deliberate plugging of the outfall lateral line of the combined sanitary and storm sewers by the Northeast Ohio Regional Sewer District at the street trunk line.

On-site inspections were conducted three times during this period based on the changing conditions at the facility and the gradual discovery and flow of

factual information related to the facility, the life of which to date has spanned nearly a forty-year period, with portions spanning over 60 years. The first site inspection was conducted from October 11 through October 13, 1994, addressing the general facility configuration, general construction materials, general facility conditions, and the usage of the facility. The second site inspection was conducted on February 2, 1995, during the time when there was water in the basement of the facility in order to observe any potential damage to the facility. The third site inspection was conducted from July 19 through July 21, 1995, in order to complete additional detailed observations and review of existing conditions of the building structures of the facility and to observe the corrective actions being made in the subsurface drainage system.

## 3. Background on the Development of the Facility

The 1958 design, development and construction of the building facility for Phase I of the Picker X-Ray Corporation, that was subsequently acquired by AMS, encompassed the integration of a then existing warehouse/industrial building, with masonry load bearing walls and steel trusses as the roof framing steel, into the facility. That original building dating to at least 1934 (based on a City of Cleveland, Record of Permits Issued with an entry under "Electrical" and dated 12/3/34) was approximately 60 feet by 100 feet and 30 feet high. The 60 foot wide front portion of the warehouse/industrial building was enveloped by the construction of a new building with a front dimension of approximately 130 feet in width. Of that 130 foot east wall building front, approximately 107.5 feet of it is load bearing masonry and 22.5 feet of it is a masonry curtain wall surrounded by a structural steel bay of framing at the north end for the lobby-stairwell area. The south and exterior west walls of the facility are also load bearing masonry. The north wall is a masonry curtain wall within the structural steel frame of the lobby-stairwell area. Phase II consisted of a two-story addition of classrooms, completed in 1963.

It should be noted that a relatively complete set of design drawings are available for the facility at 1020 London Road for those portions built in 1958 and 1963 and these were used in the inspection and evaluation process. A listing of the design drawings used in the inspection and review process is attached as Appendix A. Other portions of the facility's building complex used by the licensee for handling radioactive materials, namely the isotope warehouse, were not included in any of the drawings or other records available at the site.

During the inspection and review process, the City of Cleveland, Division of Building and Housing, was contacted in order to review the records of permits associated with the 1020 London Road address. Appendix B lists the relevant permits issued against the address beginning with site clearing for the 1958 building construction. From these records it was determined that the building permit for the 1958 building was issued on 4/18/58 as Permit Number J46366 for the "Phase I Addition to Existing Brick and Block Warehouse." The permit for the addition that is known as the isotope warehouse was issued 5/4/62, under Permit Number K30250, for the L-shaped storage building

addition. A single sheet drawing was on file with the City of Cleveland for this structure which contained minimal information.

4. Design Bases of Building Facilities

There has been no general building code reference found on any of the documents, including the drawings, so the City of Cleveland was contacted to ascertain what building code was in effect when the building permit was issued. It was learned that the City of Cleveland had adopted its own building code in 1951 that was in effect in the 1958 time frame when the building permit was issued. Archival copies of that document and the relevant revisions are available for review at the Cleveland City Hall, but the document has not been reviewed.

The results of six (6) soil borings, made prior to the 1958 building construction for the foundation investigation, were summarized on the Site Development Plan (Dwg. SD-1) and indicated that the footings for the reinforced concrete (R/C) core of the 1958 building were founded in a grey to grey-brown shale above the normal water table. The Foundation Plan & Details (Dwg. F-1) indicated that the allowable bearing stress for those footings that were located below Elevation 640 feet was 5 T/sq. ft. Individual column footings for the interior steel frame portions of the 1958 building were founded in a hard, grey-brown shaley clay with Dwg. F-1 indicating an allowable bearing stress of 3 T/sq. ft. from Elevation 640 to 647 feet.

The design loadings for the 1958 building as specified on the concrete drawings for the R/C core were as indicated below, but no specific codes or standards related to reinforced concrete (R/C) or masonry design were cited. The general code for the design of reinforced concrete in effect at the time was the American Concrete Institute (ACI) Building Code for Concrete (ACI 318-56), dated 1956.

First floor of R/C core: Live Load(LL) = 500psf; Dead Load(DL) = 175psf

Second floor of R/C core: LL = 150psf DL = 90psf

The surrounding portion of the 1958 building's structural system is composed of a hybrid system containing load-bearing masonry walls, structural steel and reinforced concrete elements. The portions of the building envelope or exterior skin that are not formed as part of the structural system are masonry filler walls that act as curtain walls. The design loadings as specified on the structural steel drawings were as indicated below with a reference to the Specification for the Design, Fabrication and Erection of Structural Steel for Buildings, American Institute of Steel Construction (AISC), with no specific reference to the edition being used for the project. The particular edition of AISC in effect during this time frame was the 1949 edition.

First floor of remainder of bldg.: Ground supported slab

Second floor of remainder of bldg.: LL = 150psf DL = 70psf

Roof for entire complex : LL= 30psf DL= 30psf with 2.5K hanger load at center of purlins and beams

All of the loadings identified on the drawings, as noted above, include only vertical gravity loadings, with no indication of considerations made for lateral loads from wind, tornado, seismic events, or other events creating differential pressures or other loadings on the facility.

The specifications for materials used in the structural system were, in general, not available in the documents that were used in the inspection and evaluation process. Dwg. F-1 indicated that the concrete for the foundation was to be 3000 psi concrete at 28 days, but no information was provided on the properties of the reinforcing steel. Other materials used in the structural system were not identified by ASTM standards or by other numerical methods such as the identification of grade, strength or other specified properties.

## 5. Field Observations and Structural Evaluation

Based on experience in the design and construction of various types of facilities and structures with the various materials used in the civil engineering/building field, a general survey of the building's structural framing was performed. From this general survey critical areas of the structural system were reviewed and any areas of potential distress were identified.

In general, the reinforced concrete core structure of the 1958 building that forms the hot cell, the WHUT room, the original radiography room, the source garden and the front and back basements was found to be in good condition based on a visual survey of the exposed externally visible surfaces, with the exception of one questionable area. In this area there is evidence of considerable amounts of water or other fluid apparently having penetrated on the second floor of the facility. The floor in that area is a 6-inch thick reinforced concrete slab. The underside of the second floor slab in this area forms the ceiling of the first floor. Evidence of the fluid that penetrated exists on the ceiling adjacent to the hot cell and in front of the radiography room and around the corner of the radiography room into a hallway at the north side of the radiography room. It is not known what the source of this fluid was, but it could have been a source such as a ruptured pipe from freezing conditions or from the failure and leakage of exterior roof surfaces over the second floor. At the roof level in this general vicinity is the interface between the pre-1935 old warehouse building and the 1958 building. These interfaces are typically a source of leakage of roof water. Evidence of significant roof leakage can be seen on the suspended ceiling of the second floor in several areas of the building, but the period of time over which water was allowed to penetrate the building's originally waterproof envelope is unknown. In several areas such as in the southeast corner of the building and along the east front wall, there is evidence of water penetration of the roof deck structure. This structure is made up of haydite (lightweight) precast concrete roof panels, that exhibit corrosion products from the embedded reinforcing steel. The roof leakage apparently continued until

October of 1994 when some major roof repairs were made. It was noted during the inspection of the roof that the sprayed foam coating appeared to be holding considerable moisture. No information was available on the material so it is unknown whether or not under freezing conditions there would be expansive forces created that would rupture the waterproof roof envelop again.

Distress in the form of significant cracking in the southeast corner of the load-bearing masonry wall of the east front, near the second floor level, was identified as well as significant cracking in the north bay of the east masonry filler/curtain wall above the second floor elevation. Both these elements of the 1958 building serve to form part of the building envelope. The source garden, housed in the basement with access from the first floor, is located in the southwest corner of the 1958 building and is completely surrounded by reinforced concrete structural elements. This portion of the 1958 building appears to be in a condition that is adequate to meet the original design conditions although the visible portions of walls directly surrounding the source material are very limited.

The two areas of significant distress tend to indicate that the visible damage arose from the response of the structural system to a lateral load component that was parallel to the east wall which the structure was apparently not designed to resist. The most significant lateral load that could be identified that the building has experienced is the January 31, 1986, magnitude 5.2 earthquake that occurred in northeast Ohio although the observed distress and this event have not been clearly linked.

The distress at the southeast corner of the building associated with the east 3-wythe load-bearing brick masonry wall can be characterized as a saw-tooth crack extending horizontally 12 to 13-feet from the south building face and extending over approximately 4 feet vertically. The open crack, representing permanent displacement, indicates approximately a 5/8-inch horizontal differential displacement in the once continuous load bearing masonry wall that is 12 and 1/2-inches thick (Dwgs A-10 and P-2). The depth of the cracking into the 3-wythe wall is not known since the back side (inside the building) of the wall surface was not readily accessible. The face brick wythe is bonded to the two inner wythes with a header course each six courses of brick. Whether or not the wall was constructed with a mortared collar joint is unknown, but it is assumed the wall was constructed as a solid masonry bearing wall. The crack then appears to trace downward at the vertical joint between the corner stone return on the southeast corner and the east wall. The crack then shows as a fracture in the stone ledge of the east wall at the corner. Originally, the sections of stone were pinned together with brass dowels and the joints were mortared. At some of these joints there has been rotation and translation with rupture and mortar loss. Above the distressed region, the load-bearing wall supports the southern most roof structural steel purlin (P2) in a wall beam pocket on a 3/8" x 7" x 8" steel bearing plate. The purlin span is over 26-feet. On the inside of the 1958 building at this purlin bearing there is evidence of movement between the bearing wall and the purlin in the longitudinal direction of the purlin. It is not known at this time which structural element remains with the permanent movement; the east wall in the perpendicular direction or the purlin in its longitudinal direction. In addition to the cracking of the east wall,

evidence of lateral loading was found at a point about 17-feet from the east wall in an area along the south wall that the purlin runs parallel to with its 26-foot span. At this area the purlin penetrates an interior non-load bearing concrete block masonry wall (Dwg P-3) that is perpendicular to the south wall. Rupture of the joints of this wall where the masonry was fit around the purlin has occurred and there is a permanent opening of over 1-inch between the non-load bearing wall and the load bearing brick south wall indicating permanent differential movement.

The distress of the east wall near the northeast corner of the 1958 building is associated with a rupture type failure that is evident on the inside of the building as a cracked and displaced concrete block filler or curtain wall. This wall section is within the region above the lobby area where the structural elements are steel framing as opposed to a load bearing type masonry wall. The rupture line is most pronounced in a vertical direction just adjacent to the northeast steel column of the building within the area from the second floor level to the roof. The rupture line extends over approximately 12-feet of the 14-foot story height and has approximately a 1 and 1/4-inch displacement out of plane at the maximum offset. This rupture surface is generally through every other course of concrete block and does not follow a saw-tooth pattern along the mortar joints. The concrete block in this curtain wall appears to be nominal 4-inch thick block (half block) that was made into a wall in which the concrete block portion is confined between the webs of the two columns (F1 and D1, Dwgs. S-1, A-7 and A-10), the second floor concrete slab surface and the underside of the flange of the structural steel roof beam (RB3). It is possible to see through the ruptured concrete block of the inner wythe of the wall to the brick, but it was not possible to determine the bond mechanism between the inner wythe of concrete block and the two outer wythes of brick. The outer two wythes of brick are supported between the columns (F1 and D1) by a lintel beam (C1), at approximately 4'9" below the level of the second floor, that is part of the lobby entrance structural steel framing in this bay. The existing design drawings do not provide any information on the details of this wall section, but it is assumed the 3-wythe wall was intended to be bonded construction. At a level approximately two courses of concrete block above the second floor level, the rupture line turns horizontal and runs along the mortar joint between courses. Approaching the next column (D1) along this joint rupture, the rupture becomes a crack that then becomes invisible to the unaided eye. The interface between the top of this wall and the structural steel framing is along a non-bonded, but tight joint on the underside of the bottom flange of structural steel roof beam (RB3). At the rupture surface intersection with this joint there is a 1 to 1 and 1/4-inch displacement of the top of the wall outward from under the beam flange. This offset continues toward the next column (D1) that is approximately 22 feet away. The offset is not visible at the next column. This distressed area represents an approximately 12'x 20' area of curtain wall (inner wythe) that is now free or ruptured on three of the four edges representing an "inner flap" in the wall. An inspection of the outer surface of this wall did not reveal any cracking when viewed from ground level. It did reveal that an outward bulge of the brick wall in the area directly opposite the "inner flap" now exists. In addition, the stone corner and stone return at this northeast corner of the 1958 building show displacement and rotation at the corner with failed joints. The distress was also reflected in

the displacement of the stone coping at the top of the walls as they intersect at this northeast corner of the building. Differential movement of 2-1/2 to 3 inches was found at this corner between the coping and the walls. Sighting horizontally along the line formed by the corner of the coping stone on top of the east wall as well as vertically upward along the corner of the stone return at the north east corner of the building, it is obvious that there is a level of distress remaining in the elements described.
The building permit for Phase II was issued 4/22/63 for an addition to the north of Phase I and consisted of a steel-frame building approximately 160' in the N-S direction and 175' in the E-W direction. This was to be used as classrooms. No extensive inspection or evaluation efforts were made on this addition since no known contamination exists in that addition and there are no known plans to allow storage of radioactive waste or source material in the Phase II addition.

Based on the observations of the areas of distress of the two ends of the east front wall of the 1958 building, the interface of the 1963 Phase II building and the 1958 building was an area that needed to be examined. This was based on the fact that under seismic loading the front portion of the 1958 building would be expected to respond as a much stiffer building element in the structure than the 1963 structural steel building frame that did not appear to be a braced frame nor a rigid frame type design. The possibility exists that the 1963 building could be more flexible, thus exhibiting a larger deflection than the 1958 building and could have actually transferred additional lateral load into the 1958 building than would have occurred without the 1963 building. It was noted in the review of the drawings for the 1963 building that revisions had apparently been made in the framing of the 1963 building at the interface with the 1958 building along the original 1958 building north wall. Drawings S-1 and S-2 in the preliminary versions showed the structural steel roof framing system purlins, designated P1, as framing into beam pockets cut into the masonry wall and seated on bearing plates, BP1, or as second floor structural steel framing system beams, designated B1, framing into similar beam pockets with bearing plates, BP2. The as-constructed conditions found in the field during the inspection revealed that the beam pockets in the masonry wall of the 1958 building had not been used to support the structural steel framing of the roof and second floor framing, but additional columns and beams had been erected. Drawing F-1, Revision 1, for the Phase II 1963 building indicated the addition of Footing M on Column Line 2 as part of the changes made in the framing system. This deliberate separation of the primary structural elements may have been as a result of the recognition of the possibility of the different connecting phases of the building phases responding to loads over time in a different manner. Whether the concern was over what would be considered a more normal concern, related to differential vertical movement, since the foundations were separate, rather than over lateral loads is not known since no design calculations were available. In the actual configuration, both the precast concrete roof panels as well as the cast-in-place concrete slab on the steel frame of the second floor represent a stiff diaphragm capable of transmitting considerable lateral load. Only a 1/2 inch premolded expansion joint separated the two structures, probably insufficient rattle space for the dynamic lateral response of the two buildings. Such a loading could explain the observed distress.

As is discussed in Section 6 of this report, the basement slab underwent some uplift loading as a result of differential water pressures, so that once the basement was drained and dry, it was necessary to inspect the concrete structural elements to determine whether or not the basement flooding event had any impact on the structural integrity of the 1958 building. Cracks that were observed in the basement floor slab were judged by an NRC inspector to be cracks that probably existed previously, but which opened an additional amount during the basement flooding and allowed additional flow to occur into the basement. No additional signs of distress were noted by the inspector who had inspected the facility before and after the flooding event. While it is possible that contaminants that could increase the rate of corrosion of the reinforcing steel in the submerged reinforced concrete elements, could have been transported and deposited so as to attack the steel, at present, there is no visible evidence of such degradation. Therefore, it is concluded that there was no observable significant impact on the structural integrity of the 1958 building as a result of the basement flooding event.

At this time, the design basis and condition of the isotope warehouse, built in 1962, has not been fully assessed regarding its ability to protect stored source material. Source material contained in a certified shipping cask would potentially resist the collapse of the one story warehouse building. The only record found to exist for this 1962 addition that also modified the area identified as the air lock was located in the public records maintained by the City of Cleveland. These records were related to the issuance of the building permit for the modification and addition. The record consists of a single drawing providing some information on the addition. The structure is a combination of structural steel columns, structural steel beams, open-web bar joists, and load-bearing concrete block masonry walls. The drawing provides the geometry of the facility and the necessary details for the steel elements, but provides no information on the load-bearing concrete block walls regarding the block type, reinforcing and other construction details. No information was found relative to the original design criteria for this addition.

## 6. Background on Subsurface Drainage

Another known condition that the facility has been subjected to is an artificially high water level outside the basement of the facility as a result of the deliberate closure of the combined sanitary and stormwater sewer system at the lateral discharge point into the public sanitary district mainline. This resulted in the eventual backup flooding of the basement to a depth of over four feet with a portion of the initial quantity of water entering through an open 32-inch high standpipe and the remainder apparently entering via seepage paths.

During the period when the basement of the facility was covered with water as a result of the non-functioning subsurface drainage system, an inspection was performed on February 2, 1995. The main focus was the integrity of the basement floor slab under the uplift forces created by the differential water head between the inside and outside of the basement. Once the initial charge of water was introduced through a 32-inch high open standpipe, the water level in the basement continued to rise based on the head differential to the

outside of the basement. No specific leakage paths had been found, but indications of some cracks in the floor slab had been noted through the water. It was not possible to determine whether the cracks were new cracks or old cracks that may have opened some additional amount as a result of the uplift pressure loads. During this time period some restrictions were placed on the differential water pressure to minimize the uplift on the floor slab. The differential pressure could be controlled by pumping the basement water into storage tanks.

In a letter dated March 22, 1995, AMS addressed, in Item #3, the re-connection of the foundation underdrain system to a new manhole and lateral and then to the main sewer line. As a result of issues raised related to this subject, NRC sent a letter to AMS dated June 14, 1995. The AMS response was contained in a letter that was discussed on a telephone conference call on July 18, 1995 between NRC and AMS. At the time of that telephone conference call, AMS had made a sketch available to NRC, that presented in plan view, the status of the work at the facility as of July 18, 1995. It was indicated on the sketch that the excavation and removal of the foundation drainage system perforated clay tile in front of the facility had been completed and a new PVC perforated drainage pipe had been completed in that same location. This system discharged in a new connector line to the new manhole. As of July 18, 1995, the new manhole had not been connected to the NEORSD mainline and no outfall or discharge was available from the new manhole. It was noted that the wye connection between the piping of the foundation drainage system and the 4-inch diameter sanitary sewer line coming from the building under the east wall footing as shown on the drawings was not found. The 4-inch diameter sanitary line had been cut and apparently the cut upstream end grouted closed. The sketch indicated the same work had been completed around the SE corner of the facility and along the south wall to near the re-entrant corner at the south stairwell. The open end of the new foundation drain pipe during the construction process was shown at the end of the backfilled zone of the excavated trench. The open excavation of the trench continued around the perimeter of the building and around the SE corner of the rear stairwell toward the SW corner of the building. The open trench extended only partially along the south wall of the stairwell since AMS had decided not to excavate in the vicinity of the source garden that is directly inside the basement walls at the SW corner of the 1958 building. In this region the sketch indicated that the existing foundation drain would be abandoned and a slurry wall installed around the abandoned pipe and the unexcavated soil mass. The slurry wall would continue around the SW corner of the building and past the northern extent of the source garden along the west wall and be continued to an area under the airlock slab and end adjacent to the west wall of the basement. The base of the slurry wall was to be cut into the very impervious shale material into which the building footings were founded. An impervious membrane cover was shown on the sketch that would then be attached to the exterior wall of the building and extended over the soil mass inside the slurry wall and then carried down to the top of the slurry wall and over its outside top corner so as to "shed" all precipitation outside the encircled volume. The new foundation drainage system would then be extended around the outside of the slurry wall. The remainder of the excavated trench was shown on the sketch as beginning against the west wall at a point just north of the northern extent of the source garden and the gas meter cover shed and continuing under the air

lock structure. It was also noted on the sketch that the existing foundation drainage pipe on the west side in this area had been removed and a tee connection had been found with a 4-inch sanitary pipe that penetrated the west wall footing and flowed to the east, under the basement floor. It was noted that the 4-inch diameter line at the outflow end of the tee from the old foundation perimeter drain (upstream end of 4-inch line going through the footing) was to be grouted closed.

7. Field Observations of Reconstructed Subsurface Drainage

Upon arrival at the site on the morning of July 19, 1995, the status of construction was as had been indicated in the sketch of July 18, 1995, except for the work that was underway that morning. Some additional trenching along the west wall, representing the trench for the slurry wall as it curved away from the northwest corner of the source garden area and the gas meter cover shed extending to the SW corner of the building, had been completed that morning. Work was underway in the trench by AMS contractors related to testing for contamination of soil/gravel and foundation material samples in the area along the west wall and under the airlock where the old existing foundation drainage system had ended and where the old foundation drain pipe had been removed.

On July 20, 1995, an AMS letter, dated July 19, 1995, was hand delivered at the site to an NRC inspector that summarized the July 18, 1995, telephone conference call and provided the status of the site as of July 18, 1995. AMS indicated that the 4-inch line the foundation drain system discharged into at the west wall would be grouted closed throughout the entire length (all under the building from the rear west wall to the front east wall). The material to be used in the pipe grouting procedure was identified in Attachment 2 of the submittal as AV-118 Duriflex, made by Avanti International, that is an acrylic resin based chemical grout. It is transferred to the grout location in a water solution prior to the time of catalyst reaction to form the gel state. Included with the letter as Attachment 1 was the sketch of the plan view that had been the subject of the July 18, 1995, telephone conference call. In addition, Attachment 3 presented a cross-section view through the proposed reconstruction zone adjacent to the source garden. This indicated a slurry wall was to be formed on one side that would be 6-inches thick and approximately 4-feet high within a 30-inch wide trench with no indication at what elevation the wall would begin or end with respect to the building footings except to indicate a bottom depth of 15-feet. The wall was apparently to be constructed with a grout material that had been recommended by the NEORSD in a July 3, 1995, letter to AMS. The grout would be a 50/50 cementitious material of Type I cement/Class F flyash with a local sand using an intrusion aid additive under the trade name of Mearl Foam. The grout formulation was to produce a 500 psi minimum strength material. The new 4-inch diameter perforated PVC foundation drainage system pipe was shown with gravel backfill, topped with a geotextile to act as a filter for the retention of fined-grained trench backfill soil material. A 20-mil geomembrane to perform as an impervious membrane was indicated for placement on the ground surface with a 6-inch thick free draining protective material topping.

AMS provided technical information from the manufacturers of the two grouting materials in the July 19, 1995 letter and an NRC inspector, after a review of the submitted information, concluded that if used properly, the materials should perform as intended by the consultants in this application.

As work continued on July 20, 1995, to complete the excavation of the trench for the slurry wall around the SW corner of the building at a distance outside the south wall of the stairwell and to the intersection with the trench extended from alongside the east wall of the stairway, the AMS contractors discussed how the formed slurry wall would be constructed. The AMS site personnel and the contractors then proposed the construction of the wall without forming and placing normal ready-mix concrete into the full trench width, thus avoiding any formwork except for bulkheads in the trench at the end of wall placements, therefore, avoiding placement of personnel in the deep trench. The 4-inch diameter foundation drain pipe would then be placed in another trench excavated outside the slurry wall after the wall has been constructed. NRC inspectors agreed that this proposal was an acceptable alternative to the approach presented in the July 19, 1995, letter. A revised Attachment 3 to the letter was provided to the inspectors at the site on July 20, 1995.

On July 21, 1995, work on the construction of the slurry wall continued in the morning while the inspectors were on site. It was pointed out by the inspectors that the loose shale material left in the bottom of the trench would prevent obtaining a "good seal" for water cutoff at the bottom of the slurry wall and the shale material. The AMS personnel and the contractors were informed of this observation so that corrective action could be taken prior to the placement of the concrete wall.

Since there was no direct observation of the backfilling of the foundation perimeter drainage system, discussions with AMS and the contractors indicated that no geotextile filter cloth was utilized along any of the new drainpipe and there was no placement of new, controlled gradation gravel around the foundation perimeter drainage system. Over the long term, it will be prudent to monitor the discharge from this system into the new manhole during periods where there is water infiltration into the ground and flow in the system in order to assure that migration of fines with clogging of the foundation drainage system does not occur.

## 8. Conclusions and Recommendations

As a result of the review, inspection and evaluation activities, it is concluded that the subsurface drainage conditions that resulted from the action to block the combined storm and sanitary systems, had no significant impact on the structural integrity of the 1958 built facility. While the structural integrity of the 1958 building system is probably at this time sufficient to withstand the original design loads (which apparently did not include any significant lateral loads), the building's waterproof envelope is not at this time intact as a result of the cracking and open joints in the building's exterior. This can lead to more rapid degradation rates of the structural system than would be expected if the waterproof envelope were

intact. The cracked bearing wall and the ruptured inside of a curtain wall section with the resulting outside distress that was induced, leaves the ends of the east (front) wall vulnerable to more rapid degradation with the entrance of water and freezing temperatures. Loss of the bearing wall which supports the roof system in the vicinity of the HEPA filter room could impact that contaminated enclosure on the second floor level. Loss of the curtain wall would not have any impact on radioactive material storage areas or contaminated areas. The hot cell, the WHUT room, the original radiography room, the source garden and the front and back basements, and the HEPA filter room, except as noted above, should maintain their structural integrity relative to the original design conditions. It is recommended that if these structural elements are to be relied on in the future, that an inspection and evaluation program be put into place. An interval of no more than ten years between structural integrity inspections/evaluations and after major loading events should be provided for in the program.

Based on the distress that has been identified from a limited visual inspection that focussed on obvious areas needing an evaluation, it is likely that the structure has undergone a loading event outside the original design envelope. This has left isolated portions of the building in a damaged condition. Action needs to be taken to restore the building's waterproof envelope that is violated in the damaged areas and restore the local integrity of the structural system.

The replacement of the subsurface drainage system based on the observations made by an NRC inspector and the information provided by the licensee, appears to be acceptable, but until a new connection is made to the public sewer system, the drainage system will not function without active pumping.

Without additional investigation and evaluation by the licensee, including repairs of the areas of distress discussed in this report, one could not conclude that the facility would remain intact for an additional 25 years. Without repairs it is likely that sections of the exterior curtain wall could collapse due to degrading conditions. It is recommended that an assessment of the structural integrity of the facility be made by the licensee prior to the development of any repair program to address the distressed areas observed in this inspection so that if additional areas of distress are discovered they can be considered, if necessary, for incorporation to the repair program. The precast concrete roof panels in several areas exhibit corrosion products on the visible surfaces indicating the attack of the embedded reinforcing steel. Also a closer examination of the area of the underside of the second floor concrete slab in the area of the original radiography laboratory should be undertaken.

A loading condition that departs from the design conditions, such as may have occurred in the past, could also cause damage that could be considered to raise the level of concern about the structural integrity of the facility since the damage may be clearly visible. It should be noted that it may also become necessary to consider new loading conditions if the useful life is to be extended or credible events for the emergency plan are outside the original design envelope of the structures.

APPENDIX A

# REFERENCE DESIGN DRAWINGS

1958 Building

1. SD-1, Site Development Plan
2. F-1, Foundation Plan and Details
3. A-7, Elevations
4. A-10, Wall Sections 3-3 Thru 6-6
5. S-1, Roof Steel Framing Plan
6. S-2, Second Floor Steel Framing Plan
7. P-2, First and Second Floor Plumbing
8. P-3, First Floor Toilets, Showers and Riser Diagrams

1963 Building

9. F-1, Foundation Plan
10. S-1, Roof Framing Plan
11. S-2, Second Floor Framing Plan

CONSTRUCTION SEQUENCE
AMS FACILITY
1020 LONDON ROAD
CLEVELAND, OHIO

APPENDIX B

December 15, 1995

| CITY OF CLEVELAND BLDG PERMIT NUMBER | DATE | AMS CONTRACT NUMBER | PROJECT DESCRIPTION |
|---|---|---|---|
| J45739 | 3/24/58 | 635 | Demolition of Frame Office Bldg |
| J46366 | 4/18/58 | 635 | Phase I-Addition to Existing Brick and Block Warehouse (The 1958 Building) |
| | | 678 | Completion of 2nd Floor (The 1958 Building) |
| K30250 | 5/4/62 | | Addition to Office and Lab of One Story L-Shaped Storage Bldg, 82'x 32.25' and 38'x 18' (Isotope Warehouse) |
| K40211 | 4/22/63 | 801 | Phase II-Addition of Classrooms (The 1963 Building) |
| | | 846 | Office Remodelling |
| L2485 | 5/12/67 | | One Story Masonry Storage Bldg, 16'x 16' (Small add-on by Truck Bay) |
| L28739 | 3/26/70 | | Addition for Storage |

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

March 13, 1996

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

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

Dear Mr. Null:

In response to your letter dated December 5, 1995 wherein you requested the opportunity to review the Radiation Safety Procedures (RSPs) that were referenced in our license renewal application dated October 30, 1995, enclosed is RSP-006, "Training and Qualifications of Radiation Protection Personnel". With this submission, Advanced Medical Systems, Inc. (AMS) has provided all of the procedures that were referenced our Radiation Protection Program Plan.[1]

With the exception of RSP-001 and RSP-003, these procedures were submitted to you as supplemental information only, to assist in your review of our renewal application. They are not to be considered part of the application package or incorporated as license conditions. However, your comments on these RSPs, which have been reviewed and approved by the AMS Radiation Safety Committee, are welcome.

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

Sincerely

Robert Meschter, R.S.O.

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

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[1] RSP-001 and RSP-003 were transmitted as part of our October 30, 1995 license renewal application. RSP-002, RSP-003, RSP-005, RSP-007, RSP-008, RSP-009, RSP-010, RSP-011, RSP-012, RSP-013, RSP-014, RSP-015, RSP-016, and RSP-017 were forwarded to you under separate cover.

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## 1 PURPOSE

This procedure details the knowledge, skills, abilities, and training that are necessary to ensure that radiation protection personnel at the Advanced Medical Systems, Inc.(AMS) London Road facility and at field service sites are able to provide effective services.

## 2 SCOPE

This Radiation Safety Procedure (RSP) applies to all AMS personnel performing radiation protection functions at the London Road facility or during work performed by AMS at field service locations. Personnel performing functions that do not pertain to implementation of the Radiation Protection Program Plan are exempt from the requirements of this RSP.

## 3 REFERENCES

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

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

3.3 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19809-01.

3.4 U. S. Nuclear Regulatory Commission, Regulatory Guide 1.8, "Qualifications and Training of Personnel for Nuclear Power Plants", 1975

3.5 U. S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-0008, "Applications for the Use of Sealed Sources in Portable Gauging Devices", May, 1995.

3.6 U. S. Nuclear Regulatory Commission, Draft Regulatory Guide and Value/Impact Statement, Division 10, Task FC 411-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Servicing Preregistered Gauges, Measuring Devices, and Sealed Sources Used in Such Devices", June, 1985.

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

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

3.9 Advanced Medical Systems, Inc. "Radiation Protection Technician Training Manual".

3.10 Advanced Medical Systems, Inc. "Authorized User Training Manual".

3.11 Advanced Medical Systems, Inc. "Field Service Technician Training Manual".

## 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 Qualifications of the RSO

5.1.1 The RSO should have an Associate's degree (or equivalent) in the physical or biological sciences, and shall have completed course work and/or have experience with the following:

5.1.1.1 Principles and practices of radiation protection;

5.1.1.2 Radioactivity measurements, monitoring techniques, and the use of instruments;

5.1.1.3 Mathematics and calculations basic to the use and measurement of radioactivity;

5.1.1.4 Biological effects of radiation;

5.1.1.5 Safety practices applicable to protection from the radiation, chemical toxicity, and other properties of the radioactive materials in use at AMS facilities;

5.1.1.6 Conducting radiological surveys and evaluating results;

5.1.1.7 Evaluating radioactive material processing facilities for proper operations from a radiological safety standpoint; and

5.1.1.8 Applicable USNRC, USEPA, and OSHA regulations, as well as the terms and conditions of any licenses and permits issued to AMS by these agencies.

5.2 Qualifications of the ARSO

5.2.1 The ARSO should have an Associate's degree in the physical or biological sciences (or equivalent).

5.2.2 The ARSO shall perform work under the direct supervision of the RSO until such time as the ARSO meets the qualifications of the RSO.

5.3 Refresher Training of the RSO and ARSO

5.3.1 The RSO and ARSO should participate in a minimum of 20 hours of refresher training on an annual basis.

5.3.2 Refresher training may consist of a combination of:

5.3.2.1 Attendance at seminars or training courses on radiation protection issues

5.3.2.2 Self development through review of books and literature on radiation protection issues

5.3.2.3 Attendance at scientific meetings where radiation protection issues are discussed

5.3.2.4 Formal education in physics, health physics, statistics, meteorology, radiation biology, industrial hygiene and data base management.

5.3.3 Refresher training shall be documented on a "Refresher Training Documentation" form (Attachment 1).

5.4 Training of Radiation Protection Technicians

5.4.1 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Radiation Protection Technician Training Manual".

5.4.2 The duration of training shall be 40 hours of classroom instruction, practical demonstration of RSPs, and on-the-job training in the duties of a Radiation Protection Technician.

5.4.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Radiation Protection Technicians (Attachment 2).

5.4.4 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

**Note: The evaluation may be in the form of oral and/or written evaluations.**

5.4.5 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 2).

5.4.6 Unless under the direct supervision of the RSO, personnel shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.4.7 Personnel shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.4.8 Refresher training:

5.4.8.1 Should be conducted:

5.4.8.1.1 A minimum of once a year, and more frequently if a need is identified.

5.4.8.1.2 Whenever major changes are made in operational procedures

5.4.8.1.3 When regulations which affect the radiological aspects of the work take effect

5.4.8.2 Shall include a review of:

5.4.8.2.1 RSPs

5.4.8.2.2 Protection methods (Area 2 of Attachment 2)

5.4.8.2.3 Changes in applicable regulations or license conditions;

5.4.8.2.4 Deficiencies identified during the performance of radiation safety program audits.

5.4.8.3 Shall be documented (Attachment 1 and 6)

5.5 Training of Authorized Users

5.5.1 Authorized Users shall be qualified as Radiation Protection Technicians.

5.5.2 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Authorized User Training Manual".

5.5.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Authorized Users (Attachment 3).

5.5.4 The duration of training shall be 40 hours of classroom instruction, practical demonstration of Isotope Shop Procedures, and on-the-job training in the duties of an Authorized User.

5.5.5 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

**Note: The evaluation may be in the form of oral and/or written evaluations.**

5.5.6 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 3).

5.5.7 Unless under the direct supervision of the RSO, Authorized Users shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.5.8 Authorized Users shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.5.9 Refresher training:

5.5.9.1 Should be conducted:

5.5.9.1.1 A minimum of once a year, and more frequently if a need is identified.

5.5.9.1.2 Whenever major changes are made in operational procedures

5.5.9.1.3 When regulations which affect the radiological aspects of the work take effect

5.5.9.2 Shall include a review of:

5.5.9.2.1 Changes in applicable regulations or license conditions;

5.5.9.2.2 Deficiencies identified during the performance of radiation safety program audits.

5.5.9.3 Shall be documented (Attachment 1)

5.6 Training of Field Service Technicians

5.6.1 Field Service Technicians shall be qualified as Authorized Users.

5.6.2 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Field Service Technician Training Manual".

5.6.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Field Service Technicians (Attachment 4).

5.6.4 The duration of training shall be 40 hours of classroom instruction, practical demonstration of field service procedures, and on-the-job training in field service duties as listed on the "Teletherapy Unit Five Year Inspection & Preventative Maintenance Report" (Attachment 5)

5.6.5 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

**Note: The evaluation may be in the form of oral and/or written evaluations.**

5.6.6 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 4).

5.6.7 Unless under the direct supervision of the RSO, Field Service Technicians shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.6.8 Field Service Technicians shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.6.9 Refresher training:

5.6.9.1 Should be conducted:

5.6.9.1.1 A minimum of once a year, and more frequently if a need is identified.

5.6.9.1.2 Whenever major changes are made in operational procedures

5.6.9.1.3 When regulations which affect the radiological aspects of the work take effect.

5.6.9.2 Shall include a review of:

5.6.9.2.1 Basic knowledge (Area 2, Attachment 4)

5.6.9.2.2 Emergency service (Area 8, Attachment 4)

5.6.9.3 Shall be documented (Attachment 1).

5.7 Training and Qualifications of RSC

5.7.1 RSC members shall be drawn from those departments and positions that can provide insights into decision-making on radiological issues at the London Road facility.

5.7.2 RSC members shall receive introductory-level training in:

5.7.2.1 Radiation and radioactivity

5.7.2.2 Instrumentation

5.7.2.3 Radiation protection program management

5.7.2.4 Regulations and license requirements

5.7.3 Refresher training shall be conducted a minimum of once per calendar year.

## 6 EXEMPTION PROVISIONS

6.1 A waiver of training/qualifications requirements for the RSO shall require the approval of the Vice President and the RSC.

6.2 A waiver of training/qualifications of the ARSO shall require the approval of the RSO, the Vice President, and the RSC.

6.3 A waiver of training for Radiation Protection Technicians shall require the approval of the RSO (see Attachment 7).

6.4 A waiver of training for Authorized Users and Field Service Technicians shall require the approval of the RSO, the Vice President, the Director of Engineering and the RSC (see Attachment 7).

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

## 7 DOCUMENTATION

7.1 All records associated with implementation of this procedure shall be maintained pursuant to RSP-004.

7.2 Completed Performance Verification Sheets shall be maintained by the RSO.

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

7.4 Memoranda detailing waivers (Attachment 7) or exceptions to qualifications stated in this procedure shall be maintained in the individual's training file.

7.5 The qualifications of those individuals whose signature appears as an approval authority on a PVS shall be maintained by the RSO.

## 8 ATTACHMENTS

8.1 Attachment 1: "Refresher Training Documentation"

8.2 Attachment 2: "Performance Verification Sheet for Radiation Protection Technicians"

8.3 Attachment 3: "Performance Verification Sheet for Authorized Users"

8.4 Attachment 4: "Performance Verification Sheet for Field Service Technicians"

8.5 Attachment 5: "Teletherapy Unit Five Year Inspection & Preventative Maintenance Report"

8.6 Attachment 6: "Radiation Safety Procedure Review"

8.7 Attachment 7: "Waiver of Training"

## ATTACHMENT 1
REFRESHER TRAINING DOCUMENTATION

| Name (Print): | | | |
|---|---|---|---|
| Signature: | | | |
| **Description of Training** | **Location of Training** | **Date Completed** | **No. of Hours** |
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## ATTACHMENT 2
## PERFORMANCE VERIFICATION SHEET FOR RADIATION PROTECTION TECHNICIANS

**NAME OF RADIATION PROTECTION TECHNICIAN:**

| Performance Item | Item Required (Check) | Date of Qualification | Signature of RSO or Designee |
|---|---|---|---|
| **Area 1 - Basic Radiation Protection** | | | |
| Radiation Fundamentals (Science/math review; radioactivity; interactions, biological effects quantities and units) | | | |
| [illegible]surement Methods (survey instruments, external and [illegible]nal monitoring systems, environmental monitoring systems) | | | |
| Operational Aspects (Protection principles, surveys and inspections, waste management, emergencies) | | | |
| Regulations, Standards, Guidelines and Procedures | | | |
| Written Examination (Passing Level 80%) and Exam Review | | | |
| **Area 2 - Protection Methods** | | | |
| Describe basic radiation protection methods. | | | |
| Don and doff anti-C clothing. | | | |
| Perform a whole body frisk. | | | |
| [illegible]onstrate the procedure for entering and exiting a [illegible]amination area. | | | |
| Describe and demonstrate the procedure for personnel decontamination. | | | |
| Describe and demonstrate the procedure for surface decontamination. | | | |
| Identify and explain the meaning of all radiological postings at the facility. | | | |
| Describe and demonstrate respirator use | | | |
| Describe and demonstrate the use of breathing zone samplers | | | |
| Describe and demonstrate the use of personnel dosimeters | | | |

| NAME OF RADIATION PROTECTION TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| **Area 3 - Instrumentation Use** | | | |
| Describe the operational procedure of an exposure rate survey instrument. | | | |
| Describe the operational procedure of a contamination survey instrument. | | | |
| Describe the operational procedure of the smear (well) counter. | | | |
| Describe the operational procedure of the gamma spectrometer. | | | |
| **Area 4 - Performing Surveys** | | | |
| Perform a contact exposure rate survey and complete the required documentation. | | | |
| Perform an ambient exposure rate survey and complete the required documentation. | | | |
| Perform a contamination survey and complete the required documentation. | | | |
| State the surface contamination limits for AMS. | | | |
| Collect and analyze an air sample and complete the required documentation. | | | |
| Describe how items being shipped from AMS are surveyed, including documentation. | | | |
| Describe how items are received at AMS, including documentation. | | | |
| Identify and describe all restricted areas at AMS. | | | |
| Describe the procedure for handling and maintaining radiation survey records. | | | |
| **Area 5 - Radiation Safety Procedures** | | | |
| Perform the activities described in RSP-008, "Instrumentation and Surveillance". | | | |
| Perform the activities described in RSP-009, "Contamination Control" | | | |
| Perform the activities described in RSP-011, "Radiological Areas and Posting" | | | |

| NAME OF RADIATION PROTECTION TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Perform three (3) successful demonstrations of receiving radioactive materials as described in RSP-014, "Receipt, Handling and Identification of Radioactive Materials" | | | |
| Perform three (3) successful demonstrations of shipping radioactive materials as described in RSP-015, "Packaging and Transportation of Radioactive Materials" | | | |
| Perform the activities described in RSP-005, "ALARA Program". | | | |
| Perform the activities described in RSP-016, "Emergency Response and Notifications". | | | |
| Perform the activities described in RSP-012, "Control of Work" | | | |
| Perform the activities described in RSP-013, "Control of Radioactive Waste" | | | |
| Perform the activities described in RSP-017, "Stop Work Authority" | | | |
| Perform three (3) successful demonstrations of data acquisition as described in RSP-018, "Operation of the Gamma Spectrometer" | | | |
| Perform three (3) successful demonstrations of the activities described in RSP-019, "Assessment of Radioactivity in Water Samples" | | | |
| Perform three (3) successful demonstrations of the activities described in ISP-5.1, "Emergency Generator Test" | | | |
| Perform three successful demonstrations of the activities described in ISP-7, "Air Monitor System" | | | |
| Perform three successful demonstrations of the activities described in ISP-6, "Gamma Alarm Function" | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |

# ATTACHMENT 3

## PERFORMANCE VERIFICATION SHEET FOR AUTHORIZED USERS

**NAME OF AUTHORIZED USER:**

| *Performance Item* | *Item Required (Check)* | *Date of Qualification* | *Signature of RSO or Designee* |
|---|---|---|---|
| **Area 1 - Basic Nuclear Safety** | | | |
| Complete Radiation Protection Technician Training | | | |
| **Area 2 - Basic Knowledge** | | | |
| Review work authorization and RWP requirements. | | | |
| Review the use and operation of all emergency devices | | | |
| Review and demonstrate the Hot Cell Ventilation System | | | |
| Review and demonstrate the Safety Airlock System | | | |
| Demonstrate the use of the Source Garden and related equipment. | | | |
| Demonstrate the use of the hot cell and related equipment. | | | |
| Review and demonstrate Hot Cell maintenance. | | | |
| Written Examination (Passing level 80%) and Exam Review | | | |
| **Area 3 - Operational Procedures** | | | |
| Successfully leak-test three (3) active sources. | | | |
| Perform three (3) active source transfers into Hot Cell. | | | |
| Provide three (2) demonstrations of raising Hot Cell floor plug, removing active source, identifying source capsule, replacing source, and replacing floor plug. | | | |
| Provide two (2) demonstrations of raising and inserting the floor plug in Bulk Isotope Storage. | | | |
| Provide two (2) demonstrations of decontaminating the Hot Cell deck. | | | |
| Successfully demonstrate installation and removal of three (3) mock-up sources from machine heads and source exchange containers. | | | |
| Successfully demonstrate installation and removal of three (3) active sources from a machine head and source exchange container. | | | |

| NAME OF AUTHORIZED USER: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Prepare four (4) machine had and source exchange container shipping packages. | | | |
| Successfully demonstrate packaging of solid radioactive waste. | | | |
| Successfully demonstrate packaging of liquid radioactive waste. | | | |
| Provide three (3) successful demonstrations of radioactive materials shipments. | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |

# ATTACHMENT 4

## PERFORMANCE VERIFICATION SHEET FOR FIELD SERVICE TECHNICIANS

**NAME OF FIELD SERVICE TECHNICIAN:**

| Performance Item | Item Required (Check) | Date of Qualification | Signature of RSO or Designee |
|---|---|---|---|
| **Area 1 - Basic Nuclear Safety** | | | |
| Complete Radiation Protection Technician Training | | | |
| Complete Authorized User Training | | | |
| **Area 2 - Basic Knowledge** | | | |
| Review applicable regulations for foreign and domestic field service. | | | |
| Review transportation requirements (10 CFR 71.5, 49 CFR and IAEA Safety Series No. 6). | | | |
| Review the theory, operation and service manuals of the Model C-2222 teletherapy unit. | | | |
| Review the theory, operation and service manuals of the Model C-9 teletherapy unit. | | | |
| Review the theory, operation and service manuals of the Model V-9 teletherapy unit. | | | |
| Describe a unit installation (unpacking, assembly, adjustment, equipment/tools, radiation safety, acceptance criteria, documentation requirements, accessory installation/adjustment, laser alignment) | | | |
| Describe a unit tear down for shipment (packing, crating, marking, disassembly procedures, documentation) | | | |
| Demonstrate blueprint reading capability (mechanical & schematic) | | | |
| Describe quality assurance procedures and unit acceptance criteria. | | | |
| Describe basic troubleshooting steps for heads, units, tables and controls. | | | |
| Perform device Production/Assembly operations (Geneva facility) for a total of 200 hours. | | | |
| Written Examination (Passing level 80%) and Exam Review | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| **Area 3 - Installation of the Model C-9** | | | |
| Successfully perform three (3) room layouts (one time at a field site). | | | |
| Successfully erect three (3) stands (one time at a field site). | | | |
| Successfully install three (3) barriers (one time at a field site). | | | |
| Successfully install three (3) heads (one time at a field site) | | | |
| Successfully install three (3) bearing rings (one time at a field site). | | | |
| Successfully install three (3) collimator (one time at a field site). | | | |
| Successfully performing three (3) wirings and inspections (one time at a field site). | | | |
| Perform three (3) successful checkouts and adjustments (one time at a field site). | | | |
| Deliver three (3) operator training courses (two times at a field site). | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |

**NAME OF FIELD SERVICE TECHNICIAN:**

| Performance Item | Item Required (Check) | Date of Qualification | Signature of RSO or Designee |
|---|---|---|---|
| **Area 4 - Five-year Inspection and Preventative Maintenance for the Model C-9** | | | |
| Successfully demonstrate a source head check (Item I of Maintenance Report) | | | |
| Successfully evaluate the condition of a collimating device (e.g., calibrate field size indicators, calibrate distance localizer, check collimator accessories and take an x-ray film (Item II of Maintenance Report). | | | |
| Successfully determine the unit true isocenter (Item III.A of the Maintenance Report). | | | |
| Successfully evaluate the safety modifications (Item III.C of the Maintenance Report). | | | |
| Successfully evaluate the treatment timer operation (Item III.D of the Maintenance Report). | | | |
| Successfully determine the source transit time (Item III.E of the Maintenance Report). | | | |
| Successfully complete all operational tests on the collimator (Item III.F of the Maintenance Report). | | | |
| Successfully perform a collimator mechanical inspection (Item [illegible] of the Maintenance Report). | | | |
| Successfully perform an electrical inspection (Item III.H of the Maintenance Report). | | | |
| Successfully replace rocker switches on VG8 control (rotational units). | | | |
| Successfully perform a general safety inspection (Item III.J of the Maintenance Report). | | | |
| Successfully evaluate and adjust the table (Item IV of the Maintenance Report. | | | |
| Complete and document four (4) full inspections (two at a field site) | | | |
| Other (describe): | | | |
| Other (describe): | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| **Area 5 - Installation of the Model V-9** | | | |
| Successfully perform three (3) room layouts (one time at a field site). | | | |
| Successfully erect three (3) stands (one time at a field site). | | | |
| Successfully install three (3) counterweights (one time at a field site). | | | |
| Successfully install three (3) heads (one time at a field site) | | | |
| Successfully install three (3) bearing rings (one time at a field site). | | | |
| Successfully install three (3) collimator (one time at a field site). | | | |
| [illegible]cessfully performing three (3) wirings and inspections (one [illegible] at a field site). | | | |
| Perform three (3) successful checkouts and adjustments (one time at a field site). | | | |
| Deliver three (3) operator training courses (two times at a field site). | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| **Area 6 - Five-year Inspection and Preventative Maintenance for the Model V-9** | | | |
| Successfully demonstrate a source head check (Item I of Maintenance Report) | | | |
| Successfully evaluate the condition of a collimating device (e.g., calibrate field size indicators, calibrate distance localizer, check collimator accessories and take an x-ray film (Item II of Maintenance Report). | | | |
| Successfully determine the unit true isocenter (Item III.A of the Maintenance Report). | | | |
| Successfully evaluate the safety modifications (Item III.C of the Maintenance Report). | | | |
| Successfully evaluate the treatment timer operation (Item III.D of the Maintenance Report). | | | |
| Successfully determine the source transit time (Item III.E of the Maintenance Report). | | | |
| Successfully complete all operational tests on the collimator (Item III.F of the Maintenance Report). | | | |
| Successfully perform a collimator mechanical inspection (Item [illegible] of the Maintenance Report). | | | |
| Successfully perform an electrical inspection (Item III.H of the Maintenance Report). | | | |
| Successfully replace rocker switches on VG8 control (rotational units). | | | |
| Successfully perform a general safety inspection (Item III.J of the Maintenance Report). | | | |
| Successfully evaluate and adjust the table (Item IV of the Maintenance Report. | | | |
| Complete and document four (4) full inspections (two at a field site) | | | |
| Other (describe): | | | |
| Other (describe): | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| **Area 7 - Service for the Model C-1000, C-2000, C-3000, C-5000 and C-10000** | | | |
| Successfully demonstrate a source head check (Item I of Maintenance Report) | | | |
| Successfully disassemble and ship three (3) heads and units (one time at a field site). | | | |
| Successfully perform a general safety inspection (Item III.J of the Maintenance Report). | | | |
| Successfully perform source exchanges as described in Area 8. | | | |
| Complete and document four (4) full inspections (two at a field site) | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Area 8 - Source Exchange | | | |
| Describe the radiation safety checklist and the purpose for each item on the list. | | | |
| Describe and demonstrate a routine survey at a field site (maze and shield wall, top of machine head, leak test) | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Perform the activities described in ISP-23, "Source Installation and Exchange Procedures" | | | |
| Describe post-exchange actions (dose assessment, records, reports) | | | |
| Complete three (3) active source exchanges (two at a field site) | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |
| **Area 9 - Emergency Service** | | | |
| Describe and demonstrate pre-service procedures. | | | |
| Describe and demonstrate the procedure for closing a stuck shutter. | | | |
| Describe and demonstrate the procedure for responding to a radiation accident in the workplace. | | | |
| Describe and demonstrate the procedure for containing a leaking source. | | | |
| Describe incident reporting requirements. | | | |
| Describe and demonstrate post-service actions (dose assessment, records, reports and notifications) | | | |
| Complete and document two (2) emergency service calls involving a mock-up source. | | | |
| Complete and document two (2) emergency service calls involving an active source. | | | |
| Other (describe): | | | |
| Other (describe): | | | |

| NAME OF FIELD SERVICE TECHNICIAN: | | | |
|---|---|---|---|
| **Performance Item** | **Item Required (Check)** | **Date of Qualification** | **Signature of RSO or Designee** |
| Other (describe): | | | |
| Other (describe): | | | |
| Other (describe): | | | |

## ATTACHMENT 5

TELETHERAPY UNIT FIVE YEAR INSPECTION AND PREVENTATIVE MAINTENANCE REPORT

## ATTACHMENT 6
## RADIATION SAFETY PROCEDURE REVIEW

| **Name (Print):** | | | |
|---|---|---|---|
| **Signature:** | | | |
| **RSP Number** | **RSP Title** | **RSP Date** | **Date of Review** |
| RSP-001 | Radiation Protection Program Plan | | |
| RSP-002 | Definitions | | |
| [illegible]-003 | Control of Radiation Safety Procedures | | |
| RSP-004 | Radiation Protection Records | | |
| RSP-005 | ALARA Program | | |
| RSP-006 | Training and Qualifications of Radiation Protection Personnel | | |
| RSP-007 | Training in Radiation Protection" | | |
| RSP-008 | Instrumentation and Surveillance | | |
| RSP-009 | Contamination Control | | |
| RSP-010 | Exposure Control | | |
| RSP-011 | Radiological Areas and Posting | | |
| [illegible]P-012 | Control of Work | | |
| [illegible]-013 | Control of Radioactive Waste | | |
| RSP-014 | Receipt, Handling, and Identification of Radioactive Materials | | |
| RSP-015 | Packaging and Transportation of Radioactive Materials | | |
| RSP-016 | Emergency Response and Notifications | | |
| RSP-017 | Stop Work Authority | | |
| RSP-018 | Operation of the Gamma Spectrometer | | |
| RSP-019 | Assessment of Radioactivity in Water Samples | | |
| | | | |
| | | | |
| | | | |

## ATTACHMENT 7

# WAIVER OF TRAINING

Individual's Name (Print): _____

Individual's Signature: _____

Training being waived:

___ Radiation Protection Technician Training
___ Authorized User Training
___ Field Service Technicians Training
___ Classroom Training
___ Practical Demonstrations
___ Other (describe)_____

Reason for Waiver: _____

APPROVALS:

***Not all approval signatures are required in all instances. See RSP-006 for instructions.***

Radiation Safety Officer:_____
Signature and Date

Vice President:_____
Signature and Date

Chair, RSC:_____
Signature and Date

Director of Engineering:_____
Signature and Date