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June 10, 1996

Ms. Cynthia D. Pederson, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Application for Withholding of Proprietary Information Pursuant to 10CFR 2.790

Dear Ms. Pederson:

Accompanying this application from Advanced Medical Systems, Inc. (AMS) is a letter (dated June 10, 1996) and a report entitled, "Building Recovery Project" (Report No. 94009/G-6125, June 10, 1996). Pursuant to Title 10, Code of Federal Regulations, Section 2.790, AMS requests that Appendix B and Appendix C of the report be specifically exempted from public disclosure because they contain commercial financial information regarding both AMS and a low-level waste broker with whom AMS is undergoing contract negotiations.

Kindly call me at 216/466-8005 if you have any questions or if I can provide you with additional information.

Sincerely,

DAVID CESAR
Vice President and Treasurer

DC/cs

Attachments

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Appendix A - Task Descriptions for the Building Recovery Project

Task 1: Disposal of Sealed Sources and Bulk Cobalt

Purpose

There are approximately 55,000 curies of sealed sources and bulk ^{60}Co metal in the AMS inventory. Since October of 1995, AMS has attempted to identify a domestic or foreign market for these sources. Although a number of potential users have been identified, their needs are for sources with significantly greater activity than is present in the AMS inventory. Therefore, AMS has not met with success in transferring the inventory to other users.

Other than those that currently exist in device heads, the sealed sources at AMS are of no operational value in that they are not a necessary part of current operations. To reduce the liabilities associated with their possession (e.g., increased emergency plan, decommissioning funding, surveillance, security and licensing requirements), in light of the fact that a third-party transfer is unlikely, AMS pursued other solutions to the inventory reduction problem.

After many conversations and levels of negotiation, it was determined that the relatively small volume but high activity of the sealed source inventory could provide a cost-mitigating factor for conventional disposal. This fact placed conventional disposal of the sources into the realm of financial possibility, but only if AMS is permitted to "tap" funds that are currently held by the USNRC for decommissioning funding.

Approach

For Task 1, the current inventory of unpackaged sealed sources and bulk cobalt, with the exception of those sources in the hot cell stuck plug (see Task 7), will be stabilized with a disposal site stabilization agent that has been approved by the State of South Carolina.[11] This stabilization will be performed in the AMS hot cell by AMS and Chem Nuclear Systems, Inc. (CNSI) personnel inside of the shipping cask liners. Remote handling capabilities will be used to the greatest possible extent in order to minimize personnel exposures from handling and stabilization of the materials. Once the stabilization agent has cured adequately, the cask liner will be loaded by AMS and CNSI personnel into a lead shielded, Type B shipping cask(s) for shipment to the low-level radioactive material burial site in Barnwell, South Carolina.

AMS anticipates that the transfer will be accomplished in one or two shipments, based upon the type of Type B cask that is utilized. AMS also anticipates that the shipments will be highway route controlled, which will require notification of states through which they are transported.

Responsibilities

All permitting and licensing actions for this task will be handled by AMS or technical consultants to AMS, with the assistance of CNSI. CNSI will be responsible for "receiving" the stabilized materials, disposition of the sources in the transfer liner, overpacking the transfer liner, stabilization of sources in the liner, transport of sources to Barnwell, and off-loading the disposal liner into a Class "C" trench for disposal. AMS has assigned a project manager (R. Alan Duff, IEM) to coordinate the source loading/packaging. The movement of sources from storage areas into shipping containers will be performed by qualified AMS employees (S. Haddock and C. Reed). Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All CNSI shipments will be inspected and released by the

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[11] Materials that are already packaged in AMS shipping casks (e.g., the GE-500 and the "Blue" casks) will be transported and disposed of "as-is".

project manager prior to departure from the London Road facility. The radioactive materials inventory will be debited by the RSO. All documentation associated with this task will be maintained by the RSO.

CNSI will periodically forward invoices for services to AMS, who will forward a copy to the USNRC. AMS will then request that the USNRC release sufficient decommissioning funds to honor the invoice.

Deliverable

Once the sources are accepted at the Barnwell site, a Certificate of Disposal will be returned to AMS. The certificate will be maintained in the AMS record keeping system pursuant to RSP-004, "Radiation Protection Records".

Task 2: Disposal of Dry Solid Waste

Purpose

In addition to the sealed sources and the bulk cobalt, there are approximately 2,500 cubic feet of dry solid radioactive waste (containing approximately 25 curies of ^{60}Co at the London Road facility). Some of these materials are located in the facility basement, and others are contained within the high level waste storage area and the isotope shop warehouse. Like the sources and bulk cobalt, this material serves no purpose at AMS and, in fact, presents a number of operational disadvantages such as increased demands for surveillance and accountability actions, increased potential for facility contamination, and increased personnel exposures. Therefore, as part of the contract with CNSI, AMS has negotiated for disposal of the dry solid waste at the Barnwell facility. However, successful execution of this contract is dependent upon whether AMS is permitted to "tap" its resources currently held by the USNRC for decommissioning funding.

Approach

A final inventory of the materials to be disposed of (e.g., type, form, packaging, activity) will be prepared and forwarded to CNSI. Shortly before CNSI arrives at the London Road facility to effect the solid waste shipment, the packaged materials will be staged. All materials will be packaged in the appropriate shipping containers (Type A, Type B, or industrial packaging). Depending upon exposure rates, overpacks may be used. AMS intends to dispose of the low-level radioactive waste at the Barnwell facility.

It remains a possibility that not all of the low-level waste materials at the London Road facility can be properly characterized and/or packaged prior to CNSI's arrival on site. Therefore, some waste materials may be left on site for storage until other wastes can be consolidated with them. These wastes will be shipped for disposal at some future date.

Responsibilities

AMS has assigned a project manager to coordinate waste characterization, packaging and loading activities (A. Duff, IEM). An inventory of the materials to be disposed of will be prepared by AMS, and the waste will be packaged. Handling of the packaged waste between the AMS staging areas, the transport vehicle, and the Barnwell facility will be performed by CNSI. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All CNSI shipments will be inspected and released by the project manager prior to departure from the London Road facility. The radioactive materials inventory debited by the RSO shortly thereafter. All documentation associated with this task will be maintained by the RSO.

CNSI will periodically forward invoices for services to AMS, who will forward a copy to the USNRC. AMS will then request that the USNRC release sufficient decommissioning funds to honor the invoice.

Deliverable

Once the materials are accepted at the Barnwell site, the Certificate of Disposal will be returned to AMS. There it will be maintained in the AMS record keeping system pursuant to RSP-004, "Radiation Protection Records".

Task 3: Radiological Stabilization of Basement

Purpose

As a result of technically-indefensible legal action taken by the Northeast Ohio Regional Sewer District (NEORSD), the AMS facility on London Road does not have a direct connection between the building and the regional sewer system for the discharge of sanitary waste, rain water from the building's roof drains or storm water that surrounds the building. Even after completion of an extensive sewer remediation project that involved installation of a new foundation drainage system and a new manhole, the free-flow of water away from the building is still not possible for a variety of legal and regulatory reasons. As of the date of this proposal, AMS is bound by court order and USNRC license requirements to pump water from the foundation drains into hold-up tanks, sample the tanks for the presence of radioactivity, notify the NEORSD of pending discharge of each tank, and await the results of a NEORSD confirmatory sampling effort prior to discharge. As a result, a major portion of the daily activities performed by the AMS staff at the London Road facility involves water management.

As of the date of this letter, over 180,000 gallons of water have been pumped, sampled and discharged from the remediated foundation drainage system. To date, no detectable ^{60}Co has been identified. Furthermore, in an April 12, 1996 letter from Robert Meschter (AMS) to John Madera (USNRC Region III), AMS demonstrated that the soils upon which the London Road building was constructed have the same radiological character now as they did before the 1995 flood. Therefore, baring a failure in the function of the remediated foundation drainage system, the probability of contaminated water inadvertently entering the regional sewer system is remote, at best.

Because of the delay associated with discharge of each tank (e.g., typically five days), coupled with the increased precipitation AMS has experienced during the spring and early summer months, temporary limitations in tank storage capacity can occur. If a spring or summer storm should occur such that the tank or pumping capacity is exceeded, AMS has one of two options: (1) it must discharge the pumped water directly into the street without sampling and in violation of the court order, or (2) it must cease pumping the water out of the manhole. If pumping ceases, (e.g., if the foundation drainage system is rendered non-functional), the storm water that accumulates around the building will enter the building basement, come in contact with the contents of the WHUT Room and the stored waste, and become contaminated. This water cannot be discharged until the radioactivity is removed.

The financial and radiological impacts associated with foundation drain failure or impaired tank capacity would be similar to those suffered during the financially-devastating flood event of 1995. This occurrence forced AMS to implement an expensive water treatment and sewer remediation program, costing in excess of $1M, only to be forced to store the treated water on site.[12] It also drained the corporation of almost all of its cash reserves, rendering it unable to bear the cost of another water clean-up project if such an event should be required. Thus it is imperative that the basement of the London Road facility be converted into a radiologically benign environment such that potential water incursion will result in negligible regulatory or financial harm.

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[12] As of the date of this report, the treated water from the 1995 project continues to be stored in the AMS warehouse in collapsible storage tanks.

Approach

The basement of the AMS facility currently contains two primary sources of transferrable radioactivity. These are the basement itself, which exhibits removable activity of approximately 10,000 dpm per 100 cm^2, and the WHUT Room,[13] which is hydraulically-connected to the remainder of the basement and contains approximately 40 curies of ^{60}Co in the form of residual surface contamination, residual Hot Cell waste in the tanks, and contaminated water.[14] In order to ensure that a future water incursions into the basement does not produce a large volume of contaminated water, this step of Building Recovery Project is to decontaminate the basement to levels that are below the AMS release criteria, and to stabilize the WHUT Room such that no water may enter or exit.

A proposal from Pentek, Inc. (Coraopolis, Pennsylvania) has been received wherein a dustless decontamination methodology for the concrete floors and walls of the AMS basement will be used. Pentek will provide a decontamination crew of trained operators, and all equipment and accessories for decontamination of approximately 3,500 square feet of concrete surface. (The scabbling depth is anticipated to be less than 1/8-inch, however arrangements for additional effort at "hot spots" and slab anomalies has been included in the contract.) The release criteria for the basement will be: 1,000 dpm/100 cm^2 removable activity and 5,000 dpm/100 cm^2 total (fixed plus removable) activity.[15] The waste generated as part of this effort (e.g., approximately 10 drums of loose powder) will be incorporated into the WHUT Room stabilization effort, described as follows.

A proposal has been received from MS Technology, Inc. (Oak Ridge, Tennessee) to provide an engineering design for stabilization of the radioactive materials in the WHUT Room. The purpose of the project is to ensure that liquids do not enter or exit the WHUT Room for the duration of its safe storage period. The design must address any standing water or void spaces that currently exists in the WHUT Room and incorporation of the waste generated from the Pentek work. However, all stabilizing materials used for this task must be readily removable during eventual building decommissioning. The work for this sub-task will be performed under the supervision of a registered Professional Engineer (PE). Once the design has been received and reviewed by AMS, a copy will be forwarded to the USNRC for final approval.

Immediately after the basement has been decontaminated and the WHUT Room has been stabilized, a final status survey, pursuant to the methodologies described in NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination" will be performed and documented. A copy of the survey report will be provided to the USNRC.

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[13] The WHUT room, located directly beneath the Hot Cell, collected waste from the hot cell via a floor drain. It was designed to hold liquid wastes generated in the hot cell and in the isotope area. It contains a 100-gallon tank for waste water from a cell sink and floor drain; a 500-gallon tank for overflow from the smaller tank and liquid waste from the showers, sinks and drains in the laboratory, and a two-column ion exchange system. The surfaces of the WHUT Room are unpainted poured concrete. A small dike is located at its entrance to prevent the migration of liquids to other areas of the basement in the event of a spill. The various pipes and conduit that originally penetrated the walls have been removed and sealed with lead rope, lead wool, concrete and silicone. No light or power exists in the room, and there is no floor drain.

[14] Integrated Environmental Management Report No. 94009/G-3104, "Evaluation of the WHUT Room Source Term", June 16, 1995.

[15] U. S. Nuclear Regulatory Commission, Regulatory Guide 1.86.

Responsibilities

AMS will obtain the engineering design for the WHUT Room stabilization from a registered Professional Engineer and forward it to the USNRC for final approval. AMS will assign a project manager for the basement decontamination and the WHUT Room stabilization (R. Alan Duff, IEM). The WHUT Room stabilization and decontamination effort will be performed by AMS personnel and Pentek, with the assistance of a registered Professional Engineer. The final status survey of the basement will be performed by the project manager and AMS. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All documentation associated with this task will be maintained by the RSO.

Deliverable

At the completion of this task, the final status survey report will be generated. A copy of the survey will be forwarded to the USNRC, along with a request for performance of a confirmatory survey and release of the basement for unrestricted use.

Task 4: Hydrological Stabilization of Basement

Purpose

After the 1995 basement flood, questions were raised in regard to the structural integrity of the building. In subsequent inspections by the USNRC and a registered Professional Engineer under contract to AMS, it was determined that there was no apparent damage to the building or its ability to contain its inventory of licensed radioactive materials. However, there is no guarantee that a future flood event will have a similar outcome.

Task 3 (above) of the Building Recovery Project is to stabilize the radiological conditions in the basement of the AMS facility such that the radiological impact of water into the basement is minimized or eliminated. Task 4 then will ensure that the probability for water incursion is minimized.

Approach

For this task, AMS will submit to the USNRC a formal request to free-release ground/surface water from the foundation drains. This request will be based upon the volume of clean water that has been pumped to date from the new foundation drainage system, a statement of the radiological stability of the basement, the WHUT Room, the abandoned lateral connection from the building to the sewer interceptor, and the abandoned drain tile located in the vicinity of the source garden, and a proposal for periodic confirmatory measurements during an interim period of mutually-agreeable duration.

Since the regional sewer system is a combined sanitary/storm system, it is possible, even after the new connection has been made, that a major storm could cause basement flooding. Should this unlikely event occur, the radiological impacts will be minimal because the basement of the building will have been released for unrestricted use (see Task 3).

Responsibilities

The request to free-release foundation drainage water will be prepared by AMS. Once the amended license has been received, AMS and its legal counsel will pursue the legal authority to free release this water.

Deliverable

A request to permit free-release of foundation drainage water, along with all supporting documentation, will be submitted to the USNRC. A copy of the court order to permitting free-release of the water will be submitted to the USNRC. Confirmatory sampling results from the discharge system will be made available at the AMS facility for review by the USNRC during future inspections.

Task 5: Modify Conceptual Decommissioning Plan and Decommissioning Funding Plan

Purpose

As part of the license renewal process, and pursuant to 10 CFR 30.36, AMS must provide the USNRC with a decommissioning funding plan. The current basis for the funding plan is the Conceptual Decommissioning Plan for the London Road Facility (Revision 0) which was submitted to the USNRC on October 20, 1995. On March 20, 1996, AMS received comments on the Plan from the USNRC, responses to which were returned on April 12, 1996. To date, the USNRC has taken no additional action on this Plan.

The approach and cost estimate contained within Revision 0 of the Plan were designed to accommodate on-going possession of up to 93,100 curies of ^{60}Co in a building with a variety of radiologically-restricted areas and potentially-significant dispersible activity. Once the Building Recovery Project is complete, the abbreviated quantity of items to be decommissioned will demand lesser funds for eventual decommissioning. Therefore, a revision to the Plan will be required.

Because the USNRC has not yet made a decision as to the appropriate decommissioning methodology for the London Road Facility (e.g., DECON vs SAFSTOR), all applicable technologies will be evaluated in Revision 1 of the Plan. The goal will be to optimize cost, waste generated for eventual disposal, and the magnitude of personnel exposures. However, Revision 1 will also contain a clear description of the preferred methodology and a detailed cost estimate for implementing that methodology.

Once the USNRC has approved the Conceptual Decommissioning Plan, AMS will submit a revised Decommissioning Funding Plan wherein new decommissioning financial assurance instruments will be included. If, as anticipated, the net value of the current letter of credit is reduced, a new letter of credit will be submitted.

Approach

The key components of Revision 0 of the Conceptual Decommissioning Plan are the description of items to be decommissioned, the methodology by which decommissioning will be implemented at the time of license termination, and the decommissioning cost estimate. For the revised Plan, the only items remaining to be decommissioned after the Building Recovery Project is complete will be the Hot Cell, the stabilized WHUT Room, the Hot Cell ventilation system, a small section of abandoned drain tiles, and the abandoned lateral connection from the building to the regional sewer system. Thus, the "items to be decommissioned" section of the Plan will be modified accordingly in Revision 1.

Although an ALARA analysis will be presented for both the DECON and SAFSTOR decommissioning alternatives, AMS anticipates that the preferred decommissioning alternative in Revision 1 will remain SAFSTOR, since this alternative clearly satisfies the requirements for protecting the public while minimizing initial commitments of time, labor, money, occupational radiation exposure, and waste disposal.[16] Modifications to the facility would be limited to those which ensure the security of the building against intruders, and ensure containment of the licensed inventory. Finally, a revised cost estimate for the preferred alternative, presented in the same format as Appendix F of USNRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72" (June, 1990), will be prepared.

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[16] As a result of radioactive decay of this material, reductions in personnel exposure and simplifications in the complexity of operations will be achieved by deferring major decontamination efforts for 50 years. Also, because much of the residual radioactivity present in the facility will have decayed to background levels after the storage period, the volume of material that must be packaged for disposal, if any, will be significantly reduced.

Responsibilities
Revision 1 of the Conceptual Decommissioning Plan for the London Road Facility will be prepared by AMS and forwarded to the USNRC for review/comment. Once approved, the Plan will be funded by the corporation to the level of the decommissioning cost estimate shown therein.

Deliverable
AMS will submit to the USNRC Revision 1 of the Conceptual Decommissioning Plan for the London Road Facility, and a Decommissioning Funding Plan that contains a new letter of credit. The scheduled delivery date of these items is subject to timely USNRC approvals, but is anticipated within six (6) months after authorization to proceed on the Building Recovery Project is given.

Task 6: Free-release Remainder of Building

Purpose
Because only sealed sources will be handled at the AMS facility after the Building Recovery Project is complete, it is in the best interest of AMS to release the remainder of the building, with the exception of the Hot Cell and the WHUT Room, for unrestricted use. This action will reduce the cost of on-going surveillance and will ensure that personnel are not unnecessarily exposed to radioactive materials. Furthermore, full-facility decontamination will reduce/eliminate the potential for re-contamination of the basement and will permit the corporation to pursue other (non-radiological) uses for the building.

Approach
Prior to the start of work, a plan of action will be developed. This will begin with performing an initial "scoping" survey, using wide area detectors, for the purpose prioritizing activities and securing the necessary supplies and resources. It is likely that work will proceed from "least contaminated" to "most contaminated" areas of the facility. However, throughout the project, close attention will be paid to waste minimization since all waste generated during this task must be packaged for eventual off-site shipment.

Immediately after the remainder of the building has been decontaminated, a final status survey, pursuant to the methodologies described in NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination" will be performed and documented. A copy of the survey report will be provided to the USNRC, along with a request to release the building for unrestricted use.

Responsibilities
Project management, surveys, decontamination, and waste packaging will be performed by AMS personnel. The final status survey of the building will also be performed by AMS personnel. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All documentation associated with this task will be maintained by the RSO.

Deliverable
At the completion of this task, the final status survey report will be forwarded to the USNRC, along with a request for performance of a confirmatory survey and release of the building, with the exception of the WHUT Room, Hot Cell and ventilation system, for unrestricted use.

Task 7: Request Exemption from Physical Inventory Requirements

Purpose
Approximately 3,000 curies of ^{60}Co in the form of doubly-encapsulated sealed sources are currently located in a storage well in the Hot Cell. Because the well plug has become lodged in the well, these sources cannot be removed and included in the inventory reduction efforts (Task 1) without incurring significant damage to the Hot Cell's capabilities. Since the integrity of the Hot Cell is necessary to support on-going

licensed operations, the Building Recovery Project does not include removal of the "stuck plug" and extraction of the sources contained therein.[17]

Provision 14(c) of USNRC license No. 34-19089-01 states that "A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory". Since the physical inventory of the remaining sealed cannot be performed until the stuck plug is removed, AMS will submit an amendment application requesting deferral of the physical inventory requirement for these sources until after plug removal. Supporting information for this amendment will be a copy of the inventory log showing the disposition of all sealed sources between June 10, 1996 and the end of the Building Recovery Project, that were at the London Road facility, the number and location of sealed sources that remain at the London Road facility after the Building Recovery Project is complete, and documentation to show that additional sources *do not exist* in any other location of the building. This information will show that all sealed source (e.g., those that can be physically inventoried and those that are sealed within the stuck plug of the Hot Cell) are "accounted for" and under the control of the AMS Radiation Safety Officer.

Approach

Immediately after Tasks 1 through 4 of the Building Recovery Project are complete, AMS will submit an application to amend Provision 14(c) of License No. 34-19089-01 requesting an exemption from performing a physical inventory of the sources in the stuck plug until the plug is removed. Included in the application will be an accounting of the sealed source status for the year prior to the application, a summary of surveillance information confirming that "unaccounted for" sources do not exist at the facility, and a commitment to complete the physical inventory once the stuck plug is removed.

Responsibilities

The amendment application will be submitted by the AMS Radiation Safety Officer.

Deliverable

An application to amend License No. 34-19089-01, along with supporting documentation, will be forwarded to the USNRC.

Task 8: Request Exemption from Emergency Plan Requirements

Purpose

Title 10, Code of Federal Regulations, Section 30.32(i) requires submittal of an "Emergency Plan for Responding to a Release" if the possession limit at the licensee's facility exceeds 5,000 curies of ^{60}Co. As part of its license renewal efforts, an emergency plan was in fact, submitted by AMS to the USNRC for review and comment. On June 7, 1995, after initial USNRC review of the plan, a letter of deficiency was issued and additional information was requested. Because the magnitude of deficiencies was significant, a revised Plan was submitted on September 22, 1995. This revision was consistent with the guidance contained in USNRC Regulatory Guide 3.67 (1992), "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities". On February 28, 1996, the USNRC mailed comments on Revision 0 of the Emergency Plan. The AMS response to those comments was forwarded on March 22, 1996. To date, the USNRC has taken no additional action on this issue.

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[17] This task will eventually be completed. Therefore, it will be included in the long range strategic plan for the facility, submittal of which is addressed in Task 11 of the Project.

Included in the March 22, 1996 submittal were the AMS responses to comments received from the Ohio Environmental Protection Agency, the Ohio Emergency Management Agency, the Cuyahoga Emergency Management Assistance Center, the Ohio Department of Health, and the City of Cleveland Division of Fire. These agencies were listed in the AMS emergency plan as "first responders". However, many of these agencies were "less than cooperative" in providing a written commitment to respond and a listing of services they would/could provide to AMS in the event of an emergency.

Task 10 of the building Recovery Project is for AMS to submit an amendment application to reduce the maximum inventory to 10,000 curies. This limit will be sufficient for the sources contained within the stuck plug of the Hot Cell, and the sources that will be brought to the facility for calibration, loading and shipping to purchasers of teletherapy units. Without exception, the 10,000 curies will be comprised of only non-dispersible materials. Therefore, an exemption from the emergency planning requirement of 10 CFR 30.32 will be solicited after Task 10 is complete.

Approach

Even after completion of the Building Recovery Project, the AMS license limit will exceed the 5,000 curie exemption for submission of an emergency plan. However, as permitted in 10 CFR 30.32(i), AMS will submit an evaluation showing that the maximum dose to a person offsite in the event of an emergency will not exceed one (1) rem effective dose equivalent based upon the fact that the radioactive material inventory is not subject to release during an accident because of its physical form and the way in which it is packaged. The evaluation will contain sufficient hypothetical dose estimates to support the AMS position.

Responsibilities

The application for exemption from emergency plan requirements will be prepared by the AMS Radiation Safety Officer.

Deliverable

An application for exemption from emergency plan requirements, including an evaluation of the maximum dose to a person offsite in the event of an emergency, will be submitted to the USNRC.

Task 9: Request Extension of Safe Storage Period for WHUT Room

Purpose

In an October 20, 1988 letter from A. B. Davis (USNRC) to Dr. Seymour S. Stein (AMS), the USNRC concurred with AMS's February 8, 1988 and July 6, 1988 request to delay decontamination of the WHUT Room until personnel exposure rates are reduced significantly, stating that "isolation can be carried out safely with some benefit in the reduction in occupational exposure and waste requiring disposal" (see page 1 of the October 20, 1988 letter). AMS continues to maintain that effective decontamination of the WHUT Room will result in significant but unnecessary personnel exposures. Therefore, an extension of the safe storage period for the WHUT Room for an additional license term (e.g., five years) will be requested.

Approach

AMS will perform an ALARA analysis comparing two WHUT Room decontamination options. Option (1) will be immediate decontamination and option (2) will be delayed decontamination. The analysis will emphasize short- and long-term personnel exposures, waste volume considerations, and cost.

Responsibilities

The ALARA analysis will be performed by AMS. The report of findings, attached to a request to extend the safe storage period for the term of the license, will be submitted to the USNRC by the AMS Radiation Safety Officer.

Deliverable

The request to extend the WHUT Room safe storage period for an additional license term will be submitted to the USNRC. Included will be a detailed description of radiological conditions in the WHUT Room and the findings from the ALARA analysis, and a commitment to re-visit this issue during subsequent license renewals.

Task 10: Request Reduction in License Limit

Purpose

At the completion of the Building Recovery Project, approximately 3,000 curies of residual radioactivity will remain.[18] In addition, and as part of its routine operations, AMS may also bring up to 6,000 curies in the form of sealed sources to the facility for calibration, loading and shipping to purchasers of teletherapy units. So that the scope of License No. 34-19089 reflects actual site activities and conditions for the purpose of reducing regulatory liabilities, AMS will seek an amendment to License No. 34-19089-01 to reduce the maximum possession limit.

Approach

Pursuant to 10 CFR 30.32, AMS will submit an application to amend License No. 34-19089-01 to permit a maximum possession limit of 10,000 curies of ^{60}Co in the form of sealed sources and residual contamination in the Hot Cell, ventilation system and WHUT Room. Included will be a description of the intended use of the materials, and a copy of the AMS Radiation Protection Program Plan.

Responsibilities

The amendment application will be submitted by the AMS Radiation Safety Officer.

Deliverable

An application to amend the maximum license inventory to 10,000 curies of ^{60}Co, along with all supporting documentation and amendment fees, will be submitted to the USNRC.

Task 11: Submit Long-Range Strategic Plan

Purpose

After completion of the Building Recovery Project, limited personnel and financial resources will still render it impossible for AMS to complete the remaining activities in the "Strategic Plan for the London Road Facility" in a single campaign. Therefore, to avoid unnecessary and negative financial impacts on the company, yet ensure steady and well-managed progress toward completion, the remaining activities will be prioritized based upon an activity's ability to improve the implementability of other activities, AMS's ability to fund the activity in the near-, intermediate- and long-term, and on the cost/benefit associated with the activity's timely completion. In general, high priority items will be scheduled for completion within one year after the Building Recovery Project, intermediate priority items within one to three years, and lower priority items within three to five years.

Approach

To ensure steady progress toward completing the outstanding activities, a revision to the "Strategic Plan for the London Road Facility" will be prepared. As with the previous revisions, this document will contain AMS's commitment to and schedule for completing such remaining items as the physical inventory of sealed sources, WHUT Room decontamination, disposition of treated water in the collapsible storage tanks, audit/assessment of the Radiation Protection Program, upgrade of Standard Operating Procedures,

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[18] With the exception of the contents of the WHUT Room and surface contamination in the Hot Cell and its ventilation system, the physical form of these materials will be doubly-encapsulated sealed sources.

housekeeping improvements, community relations, reconnection of sewer system to London Road Interceptor, and any other items that may be identified by AMS or the USNRC.

Revision 0 of the Strategic Plan for the London Road Facility" was submitted to the USNRC on October 11, 1995. Included in Revision 0 was a commitment to provide quarterly updates on AMS's progress toward meeting its goals. The last quarterly report, Revision 3 of the Plan, was submitted to the USNRC on April 8, 1996. Therefore, Revision 4 of the Plan, due for submittal on July 15, 1996, will address, primarily, activities performed during the Building Recovery Project. Revision 5 of the Plan, due for submittal on October 15, 1996, will show the status of the Building Recovery Project, but will also address the long-range plans for the facility.

Responsibilities

Revisions 4 and 5 of the Strategic Plan for the London Road Facility will be prepared by the AMS Radiation Safety Officer.

Deliverable

Revisions 4 and 5 of the Strategic Plan for the London Road Facility will be submitted to the USNRC pursuant to the Revision 0 schedule (e.g., July 15, 1996 and October 15, 1996, respectively).

Task 12: Perform Routine Operations and Meet Regulatory Commitments

Purpose

As part of its continuing license obligations, AMS has committed to performing certain duties and implementing certain specific actions in response to USNRC requests. To ensure that the Building Resource Project does not inadvertently divert attention from timely response to previous regulatory demands, and to avoid the need to solicit extensions in meeting those commitments. AMS intends to track all outstanding regulatory and compliance issues along with the 11 tasks in the Building Recovery Project.

Approach

A task list for the Building Recovery Project, which includes the task description, responsible party(ies), due date, and current status, was developed on May 10, 1996. Included in the task list are specific regulatory commitments such as Radiation Safety Committee meetings, routine surveillance activities, and responses to USNRC requests for information (e.g., the Shewmaker inspection report, the December 6, 1995 Demand for Information Letter). The task list is updated on a daily basis.

Responsibilities

Commitment tracking throughout the Building Recovery Project will be performed by the AMS Radiation Safety Officer. Activities will be performed by specified individuals as shown on the task list for the Building Recovery Project.

Deliverable

None. However, the USNRC may wish to review the task list as part of its routine inspections of the AMS facility.

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

June 11, 1996

Geoffrey C. Wright
Acting Deputy Director
Division of Nuclear Material Safety
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

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

Dear Mr. Wright:

Advanced Medical Systems, Inc. (AMS) is in receipt of your letter dated May 31, 1996 wherein additional information on AMS Radiation Safety Procedure No. RSP-019, "Assessment of Radioactivity in Water Samples" was solicited. The purpose of this letter is to respond to that request.

As you will recall, the February 8, 1996 versions of RSP-018, "Operation of the Gamma Spectrometer" and RSP-019 were forwarded to Mr. Kevin G. Null in my letter dated February 13, 1996. However, subsequent to that submission, and after telephone conversations with you and others at Region III, AMS revised both procedures significantly. The March 11, 1996 versions were then approved by the AMS Radiation Safety Committee, and implemented shortly thereafter.

Enclosed are copies of the most recent versions of these two procedures, which address the issues raised in your May 31, 1996 letter. If additional information is required, please call me at (216) 692-3270.

Sincerely

Robert Meschter

Robert Meschter, R.S.O.

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

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Advanced Medical Systems, Inc.

OPERATION OF THE GAMMA SPECTROMETER	Procedure: RSP-018	Revision No.: 000
	Page: 1 of 20	Date: June 11, 1996
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

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 License No. 34-19089-01 (as amended).

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

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

3.4 U. S. Nuclear Regulatory Commission, NUREG-1507, "Minimum Detectable concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

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 a ^{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 intersects the continuum.

5.1.5.2 Place the right cursor to the right of channel 176 at the location where the peak tail intersects 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 should be determined at least once per work week, at the end of a 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 as shown on Attachment 2.

5.3 Determination of Soil Background

5.3.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a 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 as shown on Attachment 3.

5.4 Determination of Filter Background

5.4.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.4.2 Place the filter stand and an unused 90-mm diameter filter over the detector.

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

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

5.4.5 Record the counts in the Region on Attachment 4

5.4.6 Determine R_B as shown on Attachment 4.

5.5 Determine Efficiency for Water

5.5.1 Detection efficiency for water should be determined daily, at the start of each shift.

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

5.5.3 Perform decay correction on source activity by:

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

5.5.4 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 ϵ_{water}

5.6 Determine Efficiency for Soil

5.6.1 Detection efficiencies for soil should be determined daily, at the start of each shift.

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

5.6.3 Perform decay correction on source activity by:

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

5.6.4 Record corrected activity on Attachment 6 (Item A).

5.6.5 Acquire data for 600 seconds.

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

5.6.7 Record counts on Attachment 6.

5.6.8 Determine ϵ_{soil}

5.7 Determine Efficiency for Filter

5.7.1 Detection efficiencies for filters should be determined daily, at the start of each shift.

5.7.2 Place the disk calibration source (Source No. IPL-495-51) over the detector.

5.7.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 13.4\ e^{\frac{0.693 \times (\text{days since June 1, 1995})}{1923.92}}$$

5.7.4 Record corrected activity on Attachment 7 (Item A).

5.7.5 Acquire data for 600 seconds.

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

5.7.7 Record counts on Attachment 7.

5.7.8 Determine ϵ_{soil}

5.8 Data Acquisition and Analysis

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

5.8.2 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.).

5.8.3 Seal the sample container

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

5.8.4.1 Weigh the empty Marinelli beaker (E)

5.8.4.2 Weigh the full Marinelli beaker (F)

5.8.4.3 Calculate the sample mass by F minus E

5.8.5 If the sample is a water sample (filtered or unfiltered), the volume is assumed to be "one liter"

5.8.6 Confirm that the outside of the sample container (if the sample is soil or water) 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.)

5.8.7 As necessary, filter the water sample through a 0.45 micrometer filter pursuant to RSP-019.

5.8.8 Place the sample or filter over the detector

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

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

5.8.11 Record counts on Attachment 8 if the sample is water, Attachment 9 if the sample is soil, or Attachment 10 if the sample is a filter.

5.8.12 Determine R_S using the most recent value of R_B from Attachment 2 (for water), 3 (for soil) or 4 (for filters), and record on Attachment 8, 9 or 10, as applicable.

5.8.13 Determine the Concentration and record on Attachment 8, 9 or 10, as applicable.

Note: Both negative and positive results should be recorded.

5.8.14 Determine the Minimum Detectable Activity and record on Attachment 8, 9 or 10, as applicable.

Note: The Minimum Detectable Activity that will assure a 0.05 probability of a Type II error is determined by solving the following equation:

$$MDA = \frac{3 + 4.65 \times \sqrt{B_R \times t_s}}{t_s \times E_{water} \times 0.037}$$ RTM 6-13-96

where MDA = the minimum detectable activity (pCi/l), B_R = the background count rate, t_s = sample count time, E_{water} = the detector efficiency for ^{60}Co

Δ (sec) RTM 6-13-96

using a one-liter Marinelli beaker, and 0.037 is a conversion factor used to convert the results of the calculation into units of "pCi per liter".

5.8.15 Remove and archive the sample.

5.8.16 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".

5.9 Confirmatory Analysis for Water or Soil

5.9.1 Ensure the lid of the Marinelli beaker is securely closed.

Note: Filtered water samples cannot be forwarded for confirmatory analysis.

5.9.2 Log the sample number and other pertinent information onto a Chain of Custody form (Attachment 11).

5.9.2.1 The analysis to be requested for water samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 35 pCi/l"

5.9.2.2 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"

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

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

5.9.5 When results for water samples are received, record them on Attachment 8 and retain the Certificates of Analysis.

5.9.6 When the results for soil samples are received, record them on Attachment 9 and retain the Certificates of Analysis.

5.9.7 When the results for filtered water (if applicable) are received, record them on Attachment 10 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 - Daily Filter Background Data

8.5 Attachment 5 - Efficiency Determination for Water Samples

8.6 Attachment 6 - Efficiency Determination for Soil Samples

8.7 Attachment 7 - Efficiency Determination for Filters

8.8 Attachment 8 - Analysis of Water Samples

8.9 Attachment 9 - Analysis of Soil Samples

8.10 Attachment 10 - Analysis of Filters

8.11 Attachment 11 - Chain of Custody Form

Instrument Number ____________

ATTACHMENT 1
DAILY ENERGY RESPONSE AND REGIONS OF INTEREST

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

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 (Item C)

Instrument Number_____

ATTACHMENT 4
DAILY FILTER 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 (Item C)

Instrument Number _____

ATTACHMENT 5
EFFICIENCY DETERMINATION - WATER SAMPLES

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 (ϵ_{water}) in c/d C ÷ (A x 37)

Instrument Number_____

ATTACHMENT 6
EFFICIENCY DETERMINATION - SOIL SAMPLES

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 cps B ÷ 600 (Item C)	Efficiency (ϵ_{wd}) in c/d C ÷ (A x 37)

Instrument Number _____

ATTACHMENT 7
EFFICIENCY DETERMINATION - FILTERS

Source Number IPL-595-51, Activity of 13.4 nCi as of June 1, 1995

Initials	Date	Source Activity (nCl) Corrected for Half-life (Item A)	Counts in Region (Item B)	Count rate in cps B ÷ 600 (Item C)	Efficiency (ϵ_{wb}) in c/d C ÷ (A x 37) x 4

Instrument Number _____

ATTACHMENT 8
ANALYSIS OF WATER SAMPLES

RTH 6-19-96

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	Background count rate (R_b) from Attachment 2 (Item D)	σ_n $\sqrt{D \times A}$ (Item E)	Efficiency (ϵ_{water}) in dps from Attachment 5 (Item F)	Concentration in pCi/l $\frac{C - D}{F \times 0.037}$	MDA in pCi/l $\frac{3 + (4.65 \times E)}{A \times F \times 0.037}$	Confirmatory Result

Instrument Number ______________

ATTACHMENT 9
ANALYSIS OF SOIL SAMPLES

RTM 6-17-96

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 (Item D)	Background count rate (R_b) from Attachment 3 (Item E)	σ_b $\sqrt{E \times A}$ (Item F)	Efficiency (c_{cal}) in dps from Attachment 6 (Item G)	Concentration in pCi/g $\frac{D - E}{G \times B \times 0.037}$	MDA in pCi/g $\frac{3 + (4.65 \times F)}{A \times G \times B \times 0.037}$ (printed 2.71 struck out, 3 written in by hand)	Confirmatory Result

Instrument Number_______________

ATTACHMENT 10
ANALYSIS OF FILTERED WATER

RTM 6-17-96

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 4 (Item D)	σ_b $\sqrt{D \div A}$ (Item E)	Efficiency (ϵ_{water}) in dps from Attachment 7 (Item F)	Concentration in pCi/l $\frac{C - D}{F \times 0.037}$	MDA in pCi/l $\frac{3\ (\text{~~2.71~~}) + (4.65 \times E)}{A \times F \times 0.037}$	Confirmatory Result

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

(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 or final 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, 40 milliliter 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 by method number or quotation number.

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.

Advanced Medical Systems, Inc.

ASSESSMENT OF RADIOACTIVITY IN WATER SAMPLES	Procedure: RSP-019	Revision No.: 000
	Page: 1 of 9	Date: June 11, 1996
	Approved by (Vice President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

The purpose of this procedure is to provide instruction on collecting and analyzing tanked and free-flowing 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 collection and 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, NUREG-1507, "Minimum Detectable concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

3.8 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".

3.9 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.

3.10 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 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 the authorization of the RSO.

5.2 Sample Collection from a Hold-up Tank

5.2.1 Two re-circulation pumps (approximately 2,500 gph capacity each), or similar methodology, shall be activated within the hold-up tank staged for discharge.

5.2.2 Re-circulation shall continue for a minimum of two (2) tank volumes prior to sample collection to ensure adequate mixing.

Note: For example, if the hold-up tank volume is 3,000 gallons, the re-circulation pumps shall be activated 40 minutes prior to sample collection.

5.2.3 A sample of water shall be collected from the hold-up tank into a clean one-liter Marinelli beaker.

Note: Samples may be collected from any location of the hold-up tank.

5.2.4 The location, date and time of sample collection shall be documented.

5.2.5 No additional water shall be added to the hold-up tank after the sample has been collected.

5.2.6 The re-circulation pumps, or equivalent agitation device, shall remain in operation until the results of the analysis is received.

5.3 Sample Collection from a Free-flowing Source

5.3.1 A sample of water shall be collected from within the free-flowing source into a clean one-liter Marinelli beaker.

5.3.2 The location, date and time of sample collection shall be documented.

5.4 Data Acquisition

5.4.1 Water samples shall be analyzed by the methodologies described in RSP-018.

5.4.2 Counting conditions shall ensure a nominal detection limit of no greater than 70 pCi per liter using the following equation:

$$MDA = \frac{3 + (4.65 \times \sqrt{B_R \times t_s})}{t_s \times E_{water} \times 0.037}$$

RTCI 6-11-96

(SEC)

where MDA = the minimum detectable activity (pCi/l), B_R = the count rate from a "background" sample, t_s = sample count time, E_{water} = the detector efficiency for ^{60}Co using a one-liter Marinelli beaker, and 0.037 is a conversion factor used to convert the results of the calculation into units of "pCi per liter".

Note: This calculational methodology will ensure a 0.05 probability of a Type II error when comparing the sample result to the background result.

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

5.5 Solubility Determination

5.5.1 Samples that contain less than 100 pCi/liter of ^{60}Co shall be drawn (by vacuum pump) through a 0.45 micrometer filter.

Note: **The entire one (1) liter sample shall be drawn through the filter.**

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

5.5.3 Counting conditions shall ensure a nominal detection limit of no greater than 15 pCi per liter.

$$MDA = \frac{3 + (4.65 \times \sqrt{B_R \times t_s})}{t_s \times E_{filter} \times 0.037}$$

where MDA = the minimum detectable activity (pCi/l), B_R = the count rate from a "background" filter, t_s = sample count time, E_{filter} = the detector efficiency for ^{60}Co using a disk source, and 0.037 is a conversion factor used to convert the results of the calculation into units of "pCi per liter".

Note: This calculational methodology will ensure a 0.05 probability of a Type II error when comparing the sample result to the background result.

5.6 Confirmatory Analysis

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

Note: Filtered water samples cannot be forwarded for confirmatory analysis.

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

5.6.3 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 15 pCi/l.

5.6.3.1 Analytical results that are less than the MDA or greater than 100 pCi/liter shall be forwarded to the RSO and no additional analyses are necessary.

5.6.3.2 Analytical results that are greater than the MDA but less than 100 pCi/liter shall be analyzed for suspended gross alpha and gross beta radioactivity pursuant to American Public Health Association Method 7110.

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

5.7 Discharge of Water (See Attachment 1 for technical basis)

5.7.1 Discharges of sampled water shall not exceed 25,000 gallons in a 24-hour period.

5.7.2 Water that contains greater than 100 pCi/l of ^{60}Co as determined from the sampling and analysis effort described herein shall not be discharged.

5.7.3 Water than contains no detectable ^{60}Co activity (e.g., activity above the MDA) may be discharged.

5.7.4 Water that exhibits both of the following may be discharged:

5.7.4.1 Less than 100 pCi/l of ^{60}Co by direct counting and

5.7.4.2 No detectable ^{60}Co activity (e.g., activity above the MDA) on a 0.45 micrometer filter after filtration.

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

7.2 Records shall be maintained pursuant to RSP-004,

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 for the discharge of water into the sanitary sewer system, 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 were developed such that a maximum of 25,000 gallons of water may be discharged over a single day. Water to be discharged must be sampled and confirmed to contain less than 1[illegible] 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 analysis of a series of regulatory and technical constraints and requirements. The following is a listing of the pertinent requirement and constraints in regard to gross radioactivity that were considered in developing the water discharge criteria for AMS:

- 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 545 pCi/liter. This number was derived from the assumption that every atom of ^{60}Co discharged from AMS is transported to the ash, that 25,000 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:

$$\text{Discharge Limit (pCi/l)} = \frac{8\ pci/g}{\frac{1\times10^{5}\ l}{day} \times \frac{1\ day}{7.5\ ton} \times \frac{1\ ton}{1.1\times10^{-6}\ grams}}$$

  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 "X", or 545 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 United States District Court Order on Consent, the Northeast Ohio Regional Sewer District, who services the AMS facility, entered into a pre-treatment agreement with AMS in regard to radionuclide discharge limits.[1] This agreement stipulates that "water proposed for discharge from the foundation footer drain system that shows the presence of Cobalt 60 in a concentration of 100 picocuries/liter or less, may be discharged".

The following is a listing of the pertinent requirement and constraints in regard to insoluble radioactivity that were considered in developing the water discharge criteria for AMS:

- 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 insoluble 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 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.

[1] United States District Court, Northern District of Ohio, Eastern Division, Order on Consent, Case No. 1:94 CV 2555, December 22, 1995.

The following is a listing of the pertinent constraints in regard to detection limits that were considered in developing the water discharge criteria for AMS:

- A nominal detection sensitivity for ^{60}Co in water by the methodology of gamma spectroscopy, when performed at a commercial analytical laboratory, is approximately 20 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.

- A nominal detection sensitivity for ^{60}Co on a filter by the methodology of gamma spectroscopy, when performed at a commercial analytical laboratory, is approximately five (5) pCi/filter 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 eight (8) to 15 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, and to ensure an element of conservatism in its discharge practices, the maximum concentration of ^{60}Co that may be released into the sewer system or drinking water supplies by AMS is 100 pCi/liter, as determined by gamma spectroscopy. However, any detectable activity (e.g., greater than MDA) must meet the USNRC's criteria for solubility pursuant to APHA Method 7710.

For samples analyzed for solubility at AMS pursuant to RSP-018, "Operation of the Gamma Spectrometer" and RSP-019, "Assessment of Radioactivity in Water Samples", the maximum concentration of insoluble ^{60}Co activity that might remain undetectable, is approximately 15 pCi/liter. Since discharges at this concentration will clearly impose no radiological impact on the public water supply or the local sewage treatment plant, an AMS discharge of up to 15 pCi/liter of insoluble ^{60}Co, at total daily volumes of less than 25,000 gallons, is considered to be "below concern".

June 12, 1996

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

SUBJECT: NOTICE OF VIOLATION DATED MAY 21, 1996

Dear Mr. Meschter:

This acknowledges receipt of your letter dated May 24, 1996, in response to our letter dated May 21, 1996, transmitting a Notice of Violation.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original signed by
Kevin G. Null for
John R. Madera, Chief
Nuclear Materials Licensing Branch

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

See Attached Distribution

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