U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-16055/93002(DRSS)

License No. 34-19089-01 Priority I Category B

Docket No. 030-16055

Licensee: Advanced Medical Systems, Inc. (AMS)
1020 London Road
Cleveland, OH 44110

Site Inspections Conducted: April 19, 1993 and May 24-28, 1993

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Inspection Summary:

Inspections on April 19, 1993 and May 24-28, 1993
(Report No. 030-16055/93002(DRSS))
Areas Inspected: Special, announced, limited scope safety inspections to evaluate the licensee's: (1) physical inventory and pre-inventory hot cell decontamination projects; and (2) effluent management and control program. The inspection included a review of: organization, management control and staffing; radiological controls implemented during the hot cell decontamination and physical inventory projects, including external and internal exposure controls and monitoring; physical inventory progress and problems; effluent release pathways and control mechanisms; sanitary sewer and airborne effluent discharges, monitoring and analysis, including previous unresolved items associated with the stack monitoring system; and portions of the licensee's facility survey program. The inspection team analyzed several samples collected from various restricted and unrestricted areas on the licensee's property, both within and outside the licensee's facility, and conducted extensive surveys of the licensee's facility and property.
Results: One violation of regulatory requirements and several other concerns were identified. In addition, unresolved items associated with the adequacy of your sanitary sewer liquid radwaste release procedure and the application of facility water usage data to determine liquid effluent release concentrations are being evaluated further by the staff. The inspection found the radiological controls implemented during the hot cell decontamination and physical inventory projects to be generally good with one exception. This exception is described in Section 5(b). The concerns identified during the inspections are listed below.

- Reliability of the removable compression plug in the basement floor drain (Section 6(a)).

- Potential for floods or other uncontrolled entries of water into the facility and ability to obtain a representative sample of these liquid radwastes (Section 6(a)).

- Area survey program weaknesses (Sections 7 and 8(b)).

- Identification and control of potentially contaminated floor mop wash water (Section 8(a)).

DETAILS

1. Persons Contacted

Steven Haddock, Isotope Technician
Norman Kelbley, Former Radiation Safety Officer
*Mark Loeser, Radiation Safety Officer
Steven McDermott, Former Radiation Safety Officer
*Sherry Stein, Director, Regulatory Affairs
Edward Svigel, Engineering Manager

The inspectors also contacted and were assisted in surveying the sanitary sewer system by representatives from the Northeast Ohio Regional Sewer District and City of Cleveland. Additionally, an Ohio Department of Health representative assisted the inspectors in conducting site area surveys.

A public exit meeting was held on May 28, 1993 and attended by state and local government officials, media representatives and local residents.

*Denotes those present at the site (licensee) exit meeting on May 27, 1993.

2. Purpose and Scope of Inspection

These limited scope special safety inspections were conducted to review primarily two areas of the licensee's program. The licensee's physical inventory and pre-inventory hot cell decontamination projects; and its radioactive effluent management and control program, including a historical review of effluent discharges to the environment.

The effluent management and control program was reviewed to gather information to assist the NRC staff in evaluating a 10 CFR 2.206 petition from the Northeast Ohio Regional Sewer District. The petition requests that the NRC require AMS to: (1) assume all costs resulting from the offsite release of cobalt-60 that has been deposited at the Sewer District's Southerly Treatment Center and (2) decontaminate the sewer connecting AMS' London Road facility with the public sewer at London Road and continue downstream to the extent sampling indicates is necessary.

The inspection team analyzed several samples collected from the licensee's site, including soil and sanitary sewer sludge/sediment samples, and performed surveys both inside the licensee's facility and outside the facility within the site boundary. Surveys outside the facility's site boundary and in the sewer system were conducted in response to Cleveland City Council concerns about the radiological environment in the neighborhood surrounding the licensee's London Road facility.

3. Organization, Management Controls and Staffing

The licensee's organization and management control system remains essentially as previously described (Inspection Reports No. 030-1055/90001(DRSS) and No. 030-16055/92001(DRSS)).

As reported in Inspection Report No. 030-16055/92001(DRSS), the licensee experienced significant turnover in radiation safety officer and health physics personnel in the last several years. The licensee employed five different RSOs between 1987 and 1992. The sole isotope handler (i.e. source fabricator) also terminated employment a couple years ago and a replacement has not been obtained. As a result of significant turnover of radiation safety management and health physics personnel, the licensee has lacked continuity and oversight of certain licensed operations and has been slow in implementing necessary improvements to its program. The current radiation safety officer (RSO) was hired by the licensee and subsequently approved by the NRC in Amendment No. 23, dated March 13, 1992. At the same time, an isotope technician was also hired and authorized to conduct sealed source handling operations. One of the licensee's two authorized teletherapy service engineers terminated employment in 1993. The licensee has no immediate plans to fill the vacated engineer position. The London Road facility is normally staffed only by the RSO and isotope technician. Other licensee staff frequent the London Road facility as deemed necessary. The remainder of the licensee's staff maintain offices at its Geneva, Ohio facility.

The licensee's current health physics staff has limited hot cell operational and sealed source manufacturing experience. Consequently, license authorization is currently limited to the conduct of teletherapy service operations and routine health physics activities at the London Road facility.

For the last several months, the licensee has focused its time toward completing its initial physical inventory and transferring sealed sources to authorized recipients in an effort to reduce its overall inventory of licensed material. These activities are further described in Section 5.

4. Hot Cell Decontamination

a. Overview

For approximately one month beginning in late January 1993, the licensee performed a general decontamination of its hot cell. The decontamination was necessary to improve the cell's radiological condition, and thereby enable physical inventory activities to be conducted safely. (An historical perspective of the physical inventory issue is provided in Section 5). To accomplish the physical inventory, sealed sources must be transferred into the hot cell for examination and identification purposes.

Consequently, prior to inventory initiation, solid radwastes had to be removed from the cell and the cell's contamination levels reduced.

The inspectors discussed the decontamination project with the licensee and reviewed relevant health physics records. Inspector findings are presented below.

b. Staffing

The decontamination was performed by four members of the licensee's staff. The RSO planned the job and provided health physics supervision, the isotope technician was responsible for manipulator operations and two service engineers from the licensee's Geneva, Ohio office fulfilled various health physics and decontamination tasks. All involved personnel possessed previous health physics experience and received job specific instructions from the RSO both initially and as the job progressed.

c. Radiological Controls

The decontamination job was performed remotely using the hot cell's manipulators. This reduced the degree of radiological controls required to accomplish the task safely. The principal health physics concerns were contamination control and external dose from waste and other materials removed from the cell.

To control contamination, the licensee fabricated a plastic containment around the cell's transfer chute. Routine contamination smear surveys of the containment structure and surrounding isotope shop floor areas were made each time materials were removed from the cell. Protective clothing (PCs) consisting of gloves, booties and coveralls were worn by those working near the containment structure in the isotope shop. Radiation Work Permits (RWPs) were developed and described the necessary radiological controls. Contamination control effectiveness was evaluated through continuous air sampling of the work environment in the isotope shop. The air samples were taken in a manner to represent the worker's breathing zone. Highly contaminated paper and other solid wastes which littered the cell were removed and loose cobalt-60 pellets were collected, placed in bulk capsules and stored in one of the cell's storage plugs. A magnetic sweep tool was used to collect the loose pellets. Decontamination foam and paper towels were used to reduce smearable contamination levels on the cell's tabletop.

The inspectors reviewed the licensee's air sample analysis and maximum permissible concentration (MPC) assignment methods and results; no problems were noted. No individual involved in the decontamination project was exposed to significant airborne concentrations, nor approached the 40 - hour control level of 10

CFR 20.103(b)(2). The licensee reported that the containment structure maintained its integrity and controlled contamination as intended.

External exposure control methods included assessment of external radiological conditions in the work area and use of shielding. All individuals involved in the project were provided whole body and wrist film and thermoluminescent dosimeter (TLD) ring badges supplied and analyzed by R. S. Landauer Jr., and Company, and licensee supplied high and low range self-reading dosimeters. The TLD extremity monitors were worn by those involved in cell waste removal. Dosimeters were read and dose recorded at least daily. Whole body film badges were exchanged weekly and extremity badges monthly. Whole body and extremity monitoring results were reviewed by the inspectors for the first quarter of 1993, for all individuals involved in the project. Maximum quarterly whole body and extremity exposures were 1035 mrem and 5870 mrem, respectively. These exposures are 35% and 31% of 10 CFR 20.101 whole body and extremity quarterly limits.

During the decontamination project, the licensee increased the frequency of its hot cell stack air sample analysis from monthly to weekly. The frequency was increased at the NRC's request to better evaluate short term increases in airborne effluent concentrations that normally occur during hot cell activities. Licensee records show that the maximum weekly concentration of cobalt-60 effluent released to the environment during the decontamination project was 7 E-12 uCi/ml. This concentration is less than 3% of the 10 CFR 20.106 limit.

Approximately two cubic feet of radioactive waste was generated during the decontamination project. This waste is currently stored onsite pending disposal.

No violations of regulatory requirements were identified.

5. Physical Inventory Project

a. Historical Overview/Progress and Problems

License Condition 14 of Amendment No. 8, which became effective in June 1986, required that the licensee conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under its license. An NRC inspection conducted in January 1990 disclosed that physical inventories had not been conducted for several years, and likely not conducted since inception of the requirement in 1986. In July 1990, the NRC issued a violation to the licensee for failure to conduct physical inventories.

The licensee accepted inventory records from the previous owner of the facility, equipment and sources, Picker Corporation. The licensee stated that they did not verify that the licensed material listed on its predecessor's inventory record was actually present and accounted for. Rather than an inventory to physically account for all material possessed at a given time, the licensee conducted a semi-annual records review to account for material receipt/transfer. Additionally, the licensee's inventory records documented uncertainties in the location of several sources.

The licensee initiated a physical inventory shortly after the January 1990 inspection, but suspended further inventory efforts in September 1990, due to the resignation of its RSO. A replacement RSO was not hired and authorized on the NRC license until May 1991. Between May 1991 and early 1992, the newly appointed RSO was involved with training, hot cell ventilation system replacement, and the preparation of a Decommissioning Funding Plan cost estimate which is required by 10 CFR 30.35. Consequently, little time was devoted to the completion of the required physical inventory. A new ventilation system was installed for the hot cell, to replace an existing temporary system that was installed during an NRC ordered facility decontamination. ("Order Modifying License, Effective Immediately, and Demand For Information", dated July 23, 1987). However, the newly installed ventilation system subsequently leaked and its design, fire protection safety features and operability testing were found to be deficient by the NRC staff (Inspection Report No. 030-16055/91002(DRSS).

In early 1992, the RSO left the employ of the licensee. On March 13, 1992, AMS amended its NRC license to add another new RSO. Again, the physical inventory was postponed due to the training requirements for the new RSO and completion of the hot cell ventilation system redesign and replacement project. To avoid previous similar problems, the ventilation system was redesigned with contractor assistance and evaluated and approved by the NRC prior to its construction.

Condition 14 of the AMS license was amended on May 8, 1992, to outline a schedule of activities required to be accomplished in order to complete the inventory in a timely manner. License Condition 14 required a properly designed, constructed, installed and tested ventilation system to be completed by August 31, 1992. The physical inventory was required by License Condition to be completed on or before March 31, 1993.

An appropriate hot cell ventilation system was installed, tested and declared operable by the licensee to satisfy the August 31, 1992 deadline. Shortly thereafter, the radiological conditions in the hot cell were found to be unacceptable to allow the inventory to recommence safely, as described in Inspection Report

No. 030-16055/92002 (DRSS). Consequently, the decontamination of the hot cell described in Section 4 was undertaken by the licensee.

The physical inventory was started in March 1993. By early April 1993, the licensee had completed about 75% of the inventory, including an inventory of its principal sealed source storage area, the source garden. At this time, only the two hot cell storage plugs (wells) remained to be inventoried. However, the licensee discovered that one of the two hot cell storage plugs was stuck, its lifting bracket severed and could not be repaired without personnel entry into the cell. As a result, the licensee was unable to gain access to the radioactive material stored in the front storage well, despite several varied attempts to remove the storage plug remotely. Although the cell was previously decontaminated to allow the inventory to resume, the cell was not sufficiently clean to permit safe personnel entry. On April 19, 1993, License Condition 14 was again amended, extending the required inventory completion date from March 31 to June 1, 1993.

In April and May 1993, the licensee completed the inventory of the licensed material in the rear hot cell storage plug and transferred several cesium-137 and cobalt-60 sources to authorized recipients. However, the licensee's attempts to open the cell's stuck front plug continued to be unsuccessful. In a letter dated May 17, 1993, the licensee outlined three actions that must be completed prior to personnel entry into the cell to remove the front plug. First, the cobalt-60 sources in the source garden must be removed or rearranged to allow space for the sources from the cell's rear plug. Second, the sources in the rear plug must be placed in the garden. Third, the decontamination room and hot cell must be decontaminated to allow safe personnel entry. Techniques must also be devised and evaluated to determine the best methods for removal of the front plug. The letter further stated that the hot cell and decontamination room cleanup would not be completed until at least July 31, 1993.

As of June 1, 1993, the physical inventory of licensed material in the hot cell's front plug has not been initiated. The licensee does not anticipate inventory completion until late August or September 1993. Consequently, the licensee is in violation of License Condition 14., which requires that a physical inventory of all radioactive material possessed under the license be completed by June 1, 1993.

b. Radiological Controls

To conduct the physical inventory, sealed sources stored in the licensee's source garden, need to be individually transferred into the hot cell for identification. The "transfer monster", a large shielded cask, is used to make the transfer of sources from garden to hot cell. In addition, sealed sources and bulk (unsealed) material stored in source capsules within the hot cell's two storage plugs must be removed from their storage wells and inventoried.

Prior to the inventory project, the licensee was generally aware of both the external and internal exposure control problems which could be encountered. This included monitoring and controlling external dose to the lower extremities while using the transfer monster and monitoring for contamination upon source removal from the hot cell after identification is complete. However, as discussed later in this section, the licensee did not fully recognize all the potential contamination problems associated with externally contaminated or potentially leaking sealed sources transferred from its source garden, and was also somewhat hampered because it did not possess more sophisticated air monitoring equipment. The inspectors review of the radiological controls used by the licensee during the inventory project are discussed below.

(1) External Exposure Control and Monitoring

Prior to inventory initiation, the two licensee personnel involved in the inventory work discussed the inventory methods, familiarized themselves with transfer monster operations and conducted dry runs of the transfer process. Basic time, distance and shielding principles were utilized during the inventory process to reduce external exposure. RWPs were developed to prescribe the necessary radiological controls.

With the exception of wrist badges, the personnel monitoring equipment described in Section 4(c) was provided to the two workers involved. Additionally, a TLD and self-reading dosimeter (SRD) was worn on the ankle of one worker to assess lower extremity dose that occurred when sources are raised from the source garden into the transfer monster and later returned to the garden. About 70 mrem per week was received by the lower extremities during the source garden inventory in March 1993. The whole body and upper extremity doses incurred by licensee staff in the first quarter of 1993 are provided in Section 4(c). Although the licensee did not differentiate between dose that was accrued during the hot cell decontamination versus physical inventory projects, based on SRD data, the majority of dose accumulated during the first calendar quarter of 1993 did not result from physical inventory activities.

The external exposure control methods, practices and personnel dosimetry programs utilized by the licensee during the inventory project appear adequate.

(2) <u>Contamination and Internal Exposure Control and Monitoring</u>

All sources stored in the source garden were known to be sealed sources; consequently, the licensee did not anticipate significant contamination control problems in transferring them to the hot cell. However, since the physical condition of some of the older sources in the storage garden was unknown, the potential existed for a leaking and/or externally contaminated source. To evaluate this potential problem, the licensee continuously collected air samples from two fixed locations in the isotope shop. (The isotope shop is the area where the transfer process from source garden to hot cell took place.) Also, worker breathing zone samples were collected during insertion and removal of sources into the hot cell. However, since the licensee did not possess a portable continuous air monitoring system providing real time air concentration data, work environment airborne concentrations were not known until samples were analyzed subsequent to the work activity. The hot cell's transfer chute was contamination smear surveyed each time a source was removed from the cell, as an immediate indication of a potential contamination problem. Transfer chute surveys were not conducted, however, after insertion of sources into the cell. The licensee would perform personnel surveys (frisks) if contamination was suspected during the course of the day and upon egress from the radiologically controlled area (RCA). Full PCs minus head protection were worn by involved personnel.

Despite the contamination control measures described above, both workers discovered contamination on their heads and necks upon egress from the RCA at the end of work activities on Friday March 12, 1993. Frisks with a portable survey instrument identified about 300,000 disintegrations per minute (dpm) on the head of one worker and about 6500 dpm on a nasal smear. Contamination on the face and neck of the other worker was significantly less. Multiple sources were transferred from the source garden to hot cell and inventoried on that afternoon between personnel surveys; therefore, the licensee was unable to pinpoint the cause of the contamination event at the time.

Both workers were immediately decontaminated and arrangements were made for whole body count bioassays to take place the next work day at the University of Pittsburgh. Based on the magnitude and duration of the skin contamination, the maximum cobalt-60 beta skin dose to the head of one worker was determined by the NRC to be about 100 mrad. The gamma (deep) dose to the worker's head from the contamination was less than the skin dose. Whole body counts at the University of Pittsburgh on Monday, March 15, 1993, revealed a maximum intake of about 3 nanocuries of cobalt-60. No isotopes other than natural occurring potassium-40 were identified by the whole body counts. This maximum cobalt-60 intake equates to an airborne concentration less than 10% of the 40-hour control level of 10 CFR 20.103(b)(2).

The licensee learned after the event, that depleted uranium was used as shielding/encapsulation for certain competitor cobalt-60 sealed sources that it possessed, and that the depleted uranium readily oxidized over time. The oxidized depleted uranium was reported to appear as a black sooty material, which was observed in the hot cell by the licensee when a competitor's sealed source was inventoried on March 11 and another was inventoried late in the day on March 12, 1993. According to the licensee, the March 12, 1993 contamination event was likely caused by the source inventoried late in the day on March 12, which was externally contaminated with depleted uranium. However, based on the whole body count results, only cobalt-60 was involved in the contamination event and not depleted uranium. Also, the magnitude of the contamination identified on the workers was greater than what would be expected from oxidation of depleted uranium on the external surfaces of a source. Therefore, the NRC concludes that the source of the contamination problem remains unknown. The problem was more likely caused by a sealed source that was externally contaminated with cobalt-60 from its long term storage in the source garden, or became contaminated with cobalt when introduced into the hot cell. Although not confirmed through the performance of a leak test, source leakage may also have caused or contributed to the contamination event. The suspect competitor source was returned to the source garden after it was inventoried on March 12, 1993, where it continues to reside. The suspect source does not pose any further radiological hazard, provided it remains stored in the source garden.

To minimize the probability of similar contamination problems, the licensee expanded its contamination surveys and on March 16, 1993, began conducting hot cell transfer chute contamination smear surveys after each source transfer both into and out of the hot cell. The licensee also began wearing PCs with hoods. These additional control measures appeared to be effective since no additional contamination control problems reportedly occurred during [illegible]pletion of the source garden inventory.

One violation of regulatory requirements was identified.

6. Effluent Release Pathways, Mechanisms and Discharges

The inspectors evaluated the licensee's radioactive effluent management program, including an evaluation of release pathways, mechanisms and procedures, and a review of effluent discharge records. The licensee's operations generate two types of radioactive effluent: liquid effluent (radwaste) released to the sanitary sewer system and airborne particulate effluent released to the environment through the hot cell ventilation system stack.

Results of inspector review of these two effluent release pathways is provided below.

a. Liquid Effluent

The London Road facility and its equipment was purchased by AMS from Picker Corporation in 1979. No significant changes were made to the facility's design by AMS upon its purchase, including those portions of the facility used for collecting and processing liquid radwastes.

AMS obtained an NRC license to possess radioactive material and began facility operations in November 1979. From 1979 through mid to late 1988, liquid radioactive waste was collected in two stainless steel holdup (settling) tanks located in the waste holdup tank room (WHUT) in the basement of the facility directly beneath the hot cell. The tanks have a total capacity of 600 gallons. A 500-gallon tank received waste water from the decontamination showers and sinks in the isotope shop locker room change area, an isotope shop sink and a washing machine used to launder protective clothing. A 100-gallon tank received waste water from the hot cell sink and floor drains, the decontamination room sink and floor drain and the isotope shop floor trench. Although not shown on facility plumbing blueprints, the current RSO believes that the hot cell sink drain connects to the floor drain discharge line. Documents which describe the AMS facility indicate that the tanks were interconnected so that the 100-gallon tank drained into the 500-gallon tank, if overfilled.

Based on the licensee's ISP-1 Procedure Manual, the WHUT room has no floor drains and the room is diked (curbed) to contain a capacity of approximately 2400-gallons of liquid. The floor drain and dike information was confirmed in a February 8, 1988 WHUT room decontamination plan, compiled by a licensee health physics contractor, Nuclear Support Services, Inc. (NSS). ISP-1 also states that all drains to the WHUT room tanks have screen filters, preventing solids of 1 mm or larger from passing into the tanks.

One of the licensee's previous RSOs stated that when the WHUT room was in use, waste water was pumped from the two WHUT room tanks into a 55-gallon steel batch tank (drum) located just outside the WHUT room in the back basement. The contents of the batch tank were mixed and a small sample drawn and analyzed for compliance with regulatory limits, prior to discharge of the tank's contents through the back basement floor drain and into the sanitary sewer system.

Licensee sewer discharge logs indicate that on April 16, 1986, use of the 55-gallon batch tank was discontinued and replaced by a new 200-gallon plastic tank. The 200-gallon tank was and continues to be positioned in the front basement just outside the WHUT room. Although a previous RSO recalled that the 55-gallon batch tank was still positioned in the back basement in early 1988, it does not appear that it was used for batch releases to the sanitary sewer system since April 1986. The same RSO indicated that the 55-gallon tank was physically removed from its radwaste processing position sometime later in 1988.

In October 1988, as part of a major decontamination project at the facility, the NRC approved interim entombment of the WHUT room in lieu of decontamination at that time. The entombment was approved until December 31, 1994, to coincide with the next renewal of the AMS license. In mid-1988, the licensee began isolation of the WHUT room and completed its entombment in early 1989. The isolation and entombment was conducted pursuant to the aforementioned NSS Plan. A February 13, 1989 facility decontamination status report to the NRC stated that the WHUT room entombment had been completed. According to the February 8, 1988 NSS plan, all pipes, conduits and ductwork leading into the WHUT room were severed on the outside of the room and interior pieces were pushed into the room. Room penetrations were then sealed with concrete and silicon sealants. The access door to the WHUT room was sealed with brick and concrete blocks mortared together on the outside of the room and sprayed with epoxy sealants. Based on January 1988 NSS survey data and taking into account radioactive decay, the WHUT room and its tanks currently contain about 200-300 curies of cobalt-60 in the form of sediment. The tanks also likely contain liquids. There is no indication that the WHUT room floor was treated with sealant to provide a watertight seal or whether water remained in the room at that time or exists in the room today.

One of the licensee's previous RSOs indicated that during the WHUT room isolation process in 1988, discharge lines from the isotope shop sink and locker room change area showers, sinks and washing machine were re-routed into the 200-gallon plastic tank, rather than the 500-gallon WHUT room tank. The time frame recalled by the previous RSO appears fairly accurate since a licensee letter to the NRC dated February 8, 1988, states that discharges from the locker room change area were re-routed from the WHUT room. Also, during WHUT room isolation, discharge lines from the isotope shop floor trench and decontamination room sink and floor drain were disconnected and removed, eliminating further discharges into the 100 gallon WHUT room tank from these sources. The decontamination room sink has been physically removed. However, the current RSO indicated that both the hot cell sink and floor drains remain unplugged and should the hot cell sink be used, the water could drain into the WHUT room. The cell plug and drain configurations could not be physically verified by the inspectors during the inspection.

Sometime during or shortly before WHUT room isolation, the licensee discontinued its use of water in the hot cell, decontamination room, and isotope shop and reverted to use of decontamination foam and paper toweling as its decontamination agent. The washing machine was physically removed after the licensee switched from cloth to plastic disposable PCs several years ago. Although the water supply to the hot cell sink is currently double valved closed and the licensee has no immediate plans for use of water in the cell, the potential exists for future liquid discharges into the WHUT room. To address this potential problem, the licensee agreed to maintain the water supply line valves closed and tag the valves to alert others to maintain them isolated. Other than use of the hot cell sink, the only other potential source of liquid radwaste that could result from facility operations is from the isotope shop sink or locker room change area showers or sinks, and those liquids drain to the 200-gallon tank in the front basement.

Since radioactive waste discharge lines were severed, removed and/or re-routed during WHUT room isolation, the 200-gallon plastic tank served as both a holdup tank, replacing the WHUT room tanks, and sanitary sewer batch release tank. Liquid radwastes from both the 55-gallon batch tank and later the 200-gallon batch/holdup tank were released to floor drains in the facility basement; the 55-gallon tank to the back basement floor drain and the 200-gallon tank to the front basement drain. Both drains are linked to a common line which discharges into the sanitary sewer system through the manhole on AMS property in front of the building.

The discharge pipe from the 200-gallon plastic tank is epoxied into the floor drain in the front basement, sealing the drain from other inputs. To prevent potentially contaminated water from inadvertently discharging to the sanitary sewer system through the back basement floor drain, the licensee installed a removable compression type plug in the floor drain. The primary function of the plug is to contain flood waters in the basement from flowing to the sewer system until sampled and analyzed by the licensee. Similarly, the license requires in Procedure Manual ISP-1 that the basement floor drain be temporarily plugged when the basement floor is washed (decontaminated), and the wash water vacuumed up and placed into the WHUT room holdup tanks. An August 1986 licensee contractor health physics survey report (Rad Services, Inc.) states that the basement floor drain was plugged at the time of their visit. As described later in this Section, a city sewer backup in 1989 flooded the facility basement and the floor drain plug held the flood waters from back flowing into the city sewer system; however, the NRC is concerned that the existing removable compression plug could be inadvertently removed or may loosen and fail to function as intended. Consequently, the licensee should investigate options to replace the existing plug with one that ensures more reliability.

The licensee's London Road facility was constructed with two liquid effluent discharge lines which transfer effluent into the municipal sanitary sewer system. A four inch diameter discharge line used to convey radioactive liquid effluent from the front and back basement floor drains, and a fifteen inch line designed for discharge of clean (non-radioactive) liquids from all other sinks, toilets and drains in the facility. The two discharge lines meet at a common manhole just outside the entrance to the licensee's facility. Also joining that manhole is a connection from the building foundation drains and storm water drains. From there, the lines connect into the sewer below London Road. The details of the underground drain system were verified through review of the facility's original plumbing blue prints. To further verify liquid effluent discharge routes, during the inspection, a dye was placed into the facility's loading dock catch basin and visually verified that it drained to the London Road sewer and not one of the side street interceptors.

Based on licensee statements and discharge log records, no liquid radwaste has been generated or released to the sanitary sewer system since May 1989. Also, the licensee has stated that it does not plan to produce liquid radwaste in the future since water is no longer used in source manufacturing operations or in facility decontamination activities. Furthermore, the revised 10 CFR 20 prohibits discharges of licensed material to the sanitary sewer system that is not readily soluble (or dispersible biological material) in water. Due to the form of the cobalt-60 used, liquid radwastes generated by the licensee would not meet the new 10 CFR 20 criteria. Consequently, effective January 1, 1994, the licensee would no longer be authorized to release liquid radwastes containing cobalt-60 to the sanitary sewer system.

When the licensee purchased the London Road facility from Picker Corporation and obtained an NRC license in 1979, the Picker facility operating procedures were subsumed and incorporated into the AMS license. One of these procedures is ISP-12, "Release Of Liquid Waste Into Sanitary Sewerage System", governing release of liquid radwaste to the municipal sewer system. Another procedure, ISP-1, the facility procedure manual, requires that waste be pumped off the top of the WHUT room holding tanks, passed through a cloth filter to remove solids, and placed in the 55 gallon batch tank. ISP-1 has not been revised, however, to address the 200 gallon batch tank, in use since 1986. The inspectors were unable to verify if liquids pumped from the WHUT room tanks to the batch tank were filtered in any way.

ISP-12 currently requires the licensee to use actual facility water usage data from water bills, updated on a quarterly basis, to determine daily and monthly sewer discharge limits and demonstrate compliance with 10 CFR 20.303. Prior to each release to the sewer system, ISP-12 specifies that the batch tank's contents be mixed for five minutes, using a motor driven agitator (propeller) positioned near the bottom of the batch tank. After mixing, a sample is drawn using a water column sampling probe and discharged into a beaker. A 5 ml subsample is then required to be withdrawn from the beaker and analyzed using a well counter system. A 5 ml liquid cobalt-60 reference standard is used to determine well counter efficiency. An earlier (1983) version of ISP-12 required that the batch tank sample be drawn through the tank's sample valve. A schematic diagram of the batch tank in ISP-1 continues to show a sample drain valve near the bottom of the tank. Whether a water column sample probe or the sample drain valve was used for batch tank sampling was not resolved during the inspection. ISP-12 further indicates that if the product of the sample concentration and volume of liquid in the batch tank, divided by the facility's average daily water use is less than applicable 10 CFR 20.303 concentration limits, the tank's contents could be released to the sanitary sewer system. The licensee's discharge logs show that the licensee would also verify that the total cumulative activity discharged for the calendar year was less than the one curie limit of 10 CFR 20.303, prior to the discharge.

Inspector review of ISP-12 revealed several issues which are considered unresolved at this time. The filtering, mixing and sampling practices need to be further examined. The mixing practices and sampling techniques could introduce significant uncertainties into the quantities of licensed material reportedly released to the sewer system. While the current ISP-12 procedure appears adequate, until reviewed further, technical aspects associated with actual batch tank mixing/sampling are unknown.

During the inspection, the NRC and licensee split a sample of contaminated water for independent analysis and comparison. The NRC analyzed its sample using the gamma spectroscopy system in the mobile laboratory (described in Section 9) and the licensee used its well counter. NRC/licensee analysis results were comparable, differing by less than 5%. Based on the split sample analysis, the licensee has the capability to accurately determine the concentration of cobalt-60 in a liquid sample.

Inspector review of the licensee's sanitary sewer discharge log book disclosed that the licensee typically determined its facility's average daily water usage based on annual water bill use records, not quarterly data as required by the current (1987) version of ISP-12. It is unclear if and when quarterly water usage data was applied to sanitary sewer discharges. The 1983 revision to ISP-12 required that average facility water usage be computed based on annual water bills. Until reviewed further, this matter also remains unresolved. Had quarterly water usage data been used to determine average daily use rates for the facility, the concentrations reported by the licensee as released to the sewer may have been underestimated during certain low water use periods. This was particularly true in the second quarter of 1983, where the licensee listed its water usage to be only 1000 cubic feet (i.e. 84 gallons per day average). However, this small volume of water reported to have been used is unlikely to be accurate, considering the size of the licensee's staff at the time, and appears to be an error in the licensee's water usage record. The licensee's facility used about 25,000 - 50,000 cubic feet of water in a typical calendar quarter in the 1980's. The NRC does not have specific requirements regarding the method for determining average daily and monthly water usage.

The inspectors reviewed batch tank analysis methods, resultant data and sewer disposal logs maintained by the licensee. Logs were available and reviewed for the period May 1980 to May 1989. Quarterly facility water usage information listed by the licensee for the period June 1981 to date was also reviewed and verified with water billing records, when available. The licensee's records showed that 121 batch tank releases were made to the sanitary sewer system, totaling 225 millicuries (mCi) of cobalt-60, from May 1980 through 1989. Specifically, ten batch tank releases were made to the sanitary sewer system in 1980, 5 in 1981, 4 in 1982, 37 in 1983, 8 each in 1984 and 1985, 20 in 1986, 12 in 1987, 16 in 1988 and one in 1989.

Additionally, records showed that the licensee released 3.2 mCi of cobalt-60 in a volume of about 5300 gallons of liquid to the sewer in May 1989, when a sewer backup flooded the basement of the licensee's facility. There is likely considerable uncertainty regarding the total quantity of licensed material released from the 1989 sewer backup, due to the problems in accurately calculating the volume involved and ensuring a representative sample was obtained for the analysis process. This issue will also be pursued further by the NRC. Records showed the May 1989 release to be the last discharge of liquid radwaste to the sanitary sewer system. Based on the licensee's records, the cumulative quantities of liquid effluent released to the sanitary sewer system in calendar years 1980-1989, satisfied 10 CFR 20.303 annual limits. However, based on the uncertainties and unresolved issues discussed above, the accuracy of the release data is uncertain and continues to be reviewed by the NRC. Annual release data obtained from licensee logs is graphically depicted in Figure I (attached).

Due to the potential for producing a large volume of liquid radwaste should a flood or other uncontrolled release of water into the facility basement occur, and the problem associated with obtaining a representative sample of liquids containing metallic cobalt-60, the NRC plans to split sample and independently analyze all future radwaste effluent to the sanitary sewer system prior to its release.

b. Airborne Particulate Effluent

The licensee's ventilation system maintains restricted area air flow negative with respect to surrounding unrestricted areas. Normal air flow with the ventilation system operable is from unrestricted areas, into the isotope shop, decontamination room and hot cell, up through the cell's high efficiency particulate air (HEPA) filtration system and subsequently released through the stack located atop the roof of the London Road facility. The hot cell ventilation system was redesigned by the licensee and a consultant, and a new improved system was installed and tested within the past year.

Stack effluent is monitored and sampled continuously by a system consisting of an MD-1, 1.4 mg/cm^2 end window geiger mueller (G.M.) probe linked to a Ludlum Model 177 ratemeter and strip chart recorder. Particulate samples are continuously collected on a filter paper which is changed and analyzed by the licensee at least monthly. The current stack monitoring and sampling system was designed, installed and its operating parameters analyzed in 1986 by one of the licensee's previous RSOs, with assistance from a consultant health physics group. System design parameters, specifications and current operating data were re-evaluated during this inspection, including the unresolved items previously identified in Inspection Reports No. 030-16055/90001(DRSS) and No. 030-16055/91002(DRSS). The inspectors determined the stack sampling system to be isokinetic, in that the velocity of air entering the sampling probe is equivalent to the actual stack flow (about 900 linear feet/minute). The inspectors also determined that sampling system line losses were not significant, based on ANSI N13.1-1969 criteria. Dioctyl phthalate (DOP) tests of the hot cell's HEPA filtration system in September 1992 showed filtration efficiency to be 99.99% for 0.3 micron particles. The stack alarm setpoint, however, was discovered to be set somewhat higher than desirable, as described below.

The stack monitoring system is currently set to alarm at 4000 counts per minute (cpm). Upon alarm, the ventilation system automatically shuts down and the licensee is contacted by its security vendor, which continuously monitors facility alarms. The alarm setpoint was derived by the licensee based on a previous determination of the stack monitor's probe efficiency (4% for cobalt-60). This alarm setpoint translates to a 24-hour effluent concentration equivalent to 10 CFR 20.106 limits. However, since the monitoring system's G.M. probe efficiency is currently about 2.7% and not 4%, the licensee's stack alarm setpoint should be reduced to about 3000 cpm to better coincide with regulatory limits. This was discussed with the RSO during the inspection and the licensee agreed to lower the alarm threshold.

Based on evaluations performed by the inspectors and recent consultant tests of the ventilation system, the previously unresolved items (Inspection Reports No. 030-16055-90001(DRSS) and No. 030-16055-91002(DRSS)) associated with the licensee's stack monitoring and sampling system are closed.

As discussed above, the facility's HEPA filtered ventilation system effectively filters (traps) airborne particulates with a diameter in excess of 0.3 micron. The isokinetic sampling system installed in the hot cell exhaust stack continuously monitors the effectiveness of the filtration system by collecting particulate samples on fibrous media (i.e. filter paper). The filter paper is changed and analyzed by the licensee at least monthly. The analysis is conducted pursuant to Procedure ISP-8, "Air Monitor System Check" and ISP-4, "Well Counting Procedure". Calibration of the stack air monitor's G.M. probe is conducted quarterly pursuant to Procedure ISP-9, "Air Monitor Calibration". The latest in-situ calibration of the stack air monitor probe revealed the monitoring system's efficiency to be 2.7% for cobalt-60.

The inspectors reviewed the stack sampling system procedures and analysis methods and independently calculated several effluent release concentrations using the licensee's raw data. No significant problems were noted. However, the inspectors discovered that the licensee's computer program used to calculate effluent concentrations contained a conservatism factor of 4.8. This was unknown to the licensee. This overestimates the effluent release concentrations reported by the licensee by the value of this factor.

Licensee stack monitoring analysis records indicate that the average annual concentration of effluent released to the environment in calendar years 1980 - 1992 was less than applicable 10 CFR 20.106 limits. As reported in Inspection Report No. 030 - 16055/90001(DRSS), short term effluent concentrations would occasionally exceed 20.106 limits; however, when averaged over the calendar year (as permitted in the regulations), discharges were at or less than 18% of applicable limits. Average annual effluent release data obtained from licensee records is graphically depicted in Figure II (attached).

No violations of regulatory requirements were identified; however, a concern associated with a floor drain plug and two unresolved items were noted.

7. Area Surveys (Licensee)

The licensee routinely conducts direct reading and contamination (smear) surveys on monthly and semi-monthly frequency in restricted and unrestricted areas inside its London Road facility. Outside surveys are conducted by the licensee around the perimeter of its building on a quarterly basis. However, the NRC is concerned that building perimeter surveys are not necessarily conducted in a timely manner to identify changes in radiological conditions resulting from internal movement of sources and equipment. This concern is discussed further in Section 8(b).

The inspectors selectively reviewed records of the licensee's monthly and semi-monthly surveys conducted in 1993, and discussed the survey and documentation methods with the RSO. No significant problems were noted; however, the licensee's survey records do not routinely include localized areas of elevated radiation (hot spots), identified during the surveys. The licensee's survey records typically list only general area radiation levels. To address this concern, the licensee agreed to improve its survey documentation and record all hot spots identified during a survey, keyed to a schematic or map of the area. The licensee also committed to expand its surveys to include direct radiation measurements of floor drains, overhead pipe runs and wall penetrations.

No violations of regulatory requirements were identified. However, weaknesses in the licensee's area survey program were noted.

8. NRC Independent Surveys and Samples

The NRC inspection team conducted independent surveys throughout various restricted and unrestricted areas both inside and outside the licensee's facility, but within the site area boundary. Several types of samples were also collected and analyzed by the team. The survey and analysis equipment used by the NRC team is listed in section 9. Survey and sample analysis findings are described in the subsections below.

a. Inside Facility

NRC surveys included direct reading and contamination smear surveys throughout the facility, focusing in the basement and in other areas where liquid radwastes are generated, conveyed or stored. Surveys did not include the WHUT room which is sealed and inaccessible at this time. Water and/or sediment samples were also collected from floor drains and sink traps. Surveys consisted of measurements of discharge pipes used to transport radioactive liquids within the facility, floor drains, the holdup/batch tank in the front basement, and discharge pipes leading to the sanitary sewer system. No unusual or unexpected results were identified by the surveys or samples collected in restricted areas of the facility. However, small concentrations of cobalt-60 were identified in a sink drain trap located in an unrestricted area of the facility. This finding is further described in the paragraph below.

The inspection team randomly surveyed sinks, drains and associated piping located in various unrestricted areas of the facility and not designated for radioactive discharges. No radioactivity above area background was identified, with one exception. A sediment sample collected from the trap of a mop sink located in an unrestricted area exhibited a cobalt-60 concentration of 1 E-5 uCi/ml. This concentration is about 35% of the 10 CFR 20.106 unrestricted area effluent release limit and 1% of the 20.303 sanitary sewer discharge limit. According to the RSO, this sink is used to discharge waste water from hallway and bathroom floor mopping and is not designated for discharge of radioactive liquids. The origin of the sink trap contamination is unknown but likely accumulated and concentrated in the trap sediment generated over several years of mop water discharges. Although the mop sink sample did not exhibit a cobalt-60 concentration in excess of unrestricted area effluent release or sanitary sewer discharge limits, the NRC is concerned that the licensee was unaware of its existence and origin.

b. Outside Facility

External radiation level measurements were taken in the parking lot on AMS property and at the perimeter fence-line, using instrumentation capable of measuring radiation levels at or below natural background. Levels measured in these areas varied between 5-15 micro Roentgen/hour and were indistinguishable from background levels measured in the surrounding neighborhood. Levels measured along the brush line near the southern edge of the AMS building ranged from 20-28 micro Roentgen/hour. The 10 CFR 20.105 regulatory limits for radiation levels in unrestricted areas are 2 milli Roentgen in any one hour and 100 milli Roentgen in any 7 consecutive days. The chain link fence surrounding the AMS property was examined and found to be intact. The fence is about eight feet high and topped with multiple strands of barbed-wire.

Surveys at waist level on the exterior surfaces of the AMS building revealed levels ranging from 5 micro Roentgen/hour up to 1200 micro Roentgen/hour. Levels were indistinguishable from background on the north, east and west walls, except for two isolated areas along the west wall which measured 40-80 micro Roentgen/hour. Surveys along the south wall revealed elevated levels ranging from 160-1200 micro Roentgen/hour along nearly the entire area, but within 10 CFR 20.105 regulatory limits. These elevated levels were attributed to cobalt-60 sources housed in teletherapy heads and source exchange containers located within the back warehouse portion of the building. According to the licensee, several of the heads and containers were moved from other areas of the facility a few days earlier. The licensee was unaware of the elevated levels created along the south wall from these movements. During the inspection, several of the teletherapy heads and containers were relocated to other areas within the warehouse, reducing radiation levels along the south wall to less than 200 micro Roentgen/hour. To alleviate similar problems, the licensee committed to conduct surveys along the perimeter of its building, whenever source or equipment movement inside the facility could adversely affect radiological conditions outside.

In addition to the surveys described above, the inspection team collected a gravel sample from the roof of the AMS building near the stack, and five soil samples from within the site boundary. The soil samples were analyzed in the NRC mobile laboratory (Section 9) and exhibited cobalt-60 concentrations less than 0.5 picocuries/gram (pCi/g). The roof gravel sample showed a cobalt-60 concentration of 3.3 pCi/g. These results are equivalent to those measured by Oak Ridge Associated University during their surveys of the AMS facility in 1985 and 1988. These soil concentrations are within the NRC's unrestricted use release criteria.

External radiation level measurements, sediment samples and water samples were taken in the onsite combination sanitary and storm sewer manhole and two onsite catch basins. The manhole is located between the main entrance to AMS and London Road.

Radiation levels were measured at 70 micro Roentgen/hour at the top of the manhole increasing to 800 micro Roentgen/hour at about 3 feet from the bottom of the manhole. The highest contact radiation levels were from the outlet line going to the street, 11 mR/hour (11,000 micro Roentgen/hour), and the entry line from AMS into the manhole, 6 mR/hour (6000 micro Roentgen/hour).

Sediment samples from the manhole, as listed in the Table below, ranged from 790 to 73,500 pCi/g cobalt-60. Liquid samples from the manhole ranged from 5.9 to 16.4 pCi/g cobalt-60.

The radiation and contamination levels in the manhole are consistent with levels reported in the late 1980's when corrected for decay (cobalt-60 half-life = 5.27 yrs). Access into the manhole is controlled by the licensee with a padlocked grate and restricted area posting.

Sediment samples from two catch basins that collect storm water runoff on the AMS property showed no detectable activity in one and 2.5 pCi/g cobalt-60 in the other. The absence of any significant levels of cobalt-60 in the catch basins indicate that airborne releases by way of the ventilation system did not contaminate rain water runoff.

Sample Analysis Results from Onsite Manhole and Catch Basins

The uncertainties reported are two standard deviations.

Sample Location	Sample Type	Results (pCi/g) Co-60
Floor drain line from AMS as it enters manhole - Sample #1	Sediment #1	73,500 ± 920
	Water decanted from Sediment #1	16.4 ± 0.56
Floor drain line from AMS as it enters manhole - Sample #2	Sediment #2	53,500 ± 640
	Water decanted from Sediment #2	10.2 ± 0.6
Floor drain line from AMS about 1 meter up the manhole discharge pipe	Sediment	787 ± 6.1
Floor drain line from AMS as it enters manhole	Water	5.9 ± 0.36
Outlet line from manhole to street	Sediment	1380 ± 22
Catch basin near loading dock	Sediment	2.5 ± 0.23
Catch basin at north edge of lot near Mandalay Ave	Sediment	none detected

No violations of regulatory requirements were identified. However, a concern regarding the presence of contamination in a sink drain was noted.

9. NRC Survey and Analysis Equipment

The NRC Region III Mobile Laboratory was deployed to a secure site near the AMS facility, and its equipment was used for analysis of samples and smears collected by the inspection team. The survey instrumentation and analysis equipment utilized by the inspection team is listed below:

Ludlum Micro R Meters
Model 19, NRC No. 11021 and No. 14808
Last calibrated May 8, 1993 and May 13, 1993

Bicron Micro Analyst
NRC No. 028330
Last calibrated May 8, 1993

Eberline Ion Chamber
Model PIC-6B, NRC No. 034628
Last calibrated May 8, 1993

Eberline G.M.
Model E-520, NRC No. 009571
Last calibrated January 13, 1993

Canberra Model 802-3 Sodium Iodide 2x2-inch probe w/portable multi-channel analyzer Gamma Spectroscopy System

Ortec Gamma Spectroscopy System
w/ Intrinsic Germanium Detector

10. Exit Meetings

a. Licensee

Members of the inspection team met with the licensee representatives denoted in Section 1 at the conclusion of the site inspection on May 27, 1993, and summarized the scope and preliminary findings of the inspection. Inspection findings were further discussed with the licensee in a telecon with Messrs Caniano, Madera and Slawinski of the Region III staff on July 29, 1993. The following violations, unresolved items and concerns identified during the inspections were discussed with the licensee:

Violation

- Failure to complete a physical inventory as required by license condition (Section 5(a)).

Concerns

- Failure to conduct building perimeter surveys to identify changing radiological conditions (Sections 7 and 8(b)).
- Reliability of removable drain plug in back basement (Section 6(a)).

- Potential for unmonitored release resulting from a flood or other uncontrolled entry of water into the facility and ability to obtain a representative sample of these liquid radwastes. (Section 6(a))

- Failure to document localized areas of elevated radiation in area survey records and routinely survey overhead piping, floor drains and wall penetrations (Section 7).

- Failure to identify and control the buildup of contaminated water/sediment in a sink drain resulting from floor moppings (Section 8(a)).

Unresolved Items

- Adequacy of Procedure ISP-12 with respect to batch tank mixing and sampling. (Section 6(a))

- Application of facility water usage (dilution) data to sanitary sewer discharges. (Section 6(a)).

In addition to the above, the licensee agreed to maintain the water supply line valves for the hot cell sink closed and tag the valves to ensure their continued isolation.

b. Public

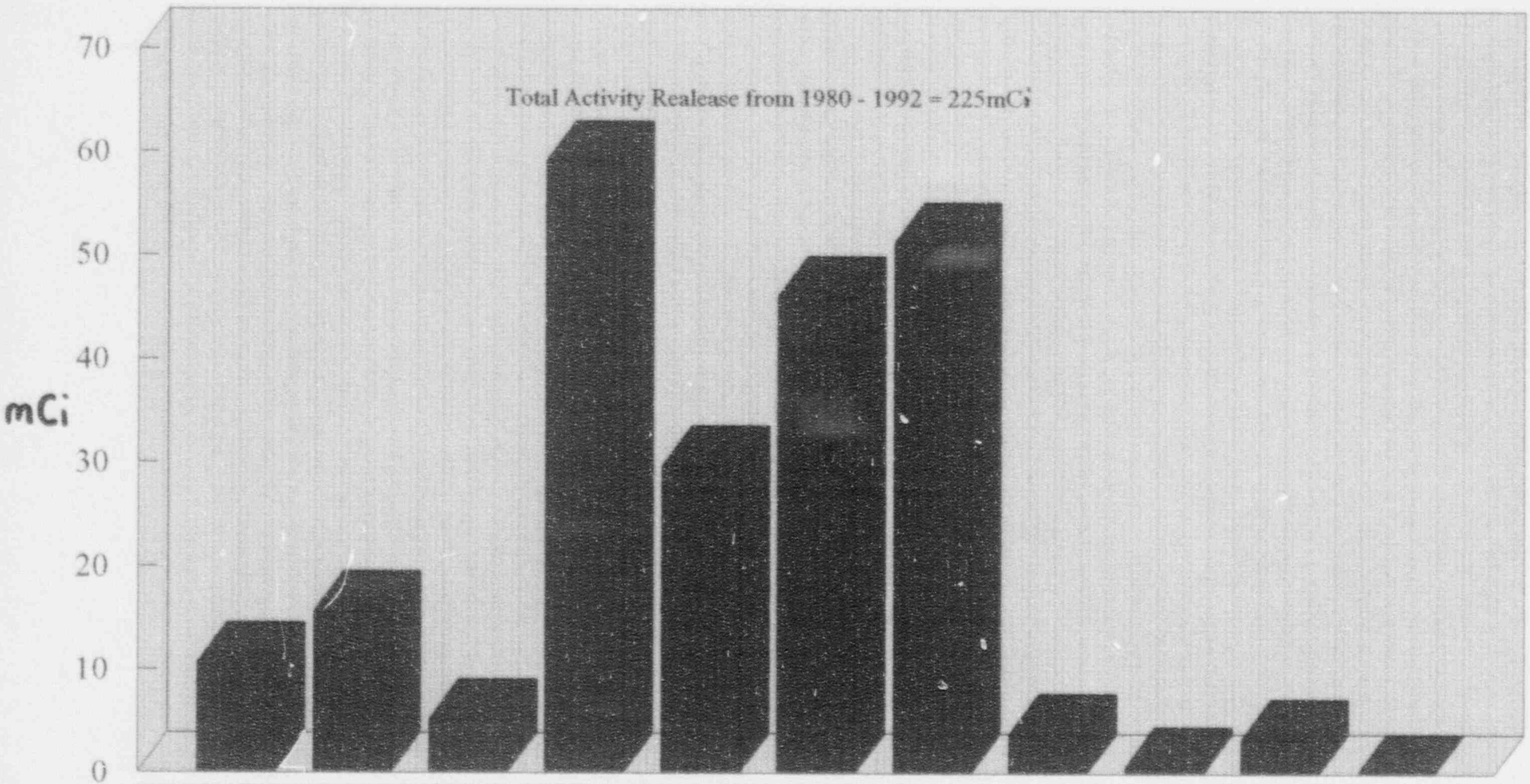
An NRC Region III management representative, members of the inspection team and NRC's regional public and government affairs staff conducted a public exit meeting at the Holy Redeemer Roman Catholic Church on May 28, 1993. The purpose of the meeting was to: (1) discuss the preliminary findings of the onsite inspection, as described in Inspection Report No. 030-16055/93002(DRSS); (2) describe the results of surveys conducted by the inspection team in neighborhood areas surrounding the AMS facility, as described in Inspection Report No. 99990003/93010(DRSS); and (3) respond to questions from elected officials and the public.

The public meeting was attended by state and local government officials, licensee representatives, several media representatives and approximately 25 members of the public that reside in the vicinity of the AMS facility.

Attachments:
Figure I-Sanitary Sewer Effluent Discharge Data
Figure II-Airborne Effluent Discharge Data

Figure I

ADVANCED MEDICAL SYSTEMS
Cumulative Sanitary Sewer Release Activity vs. Year

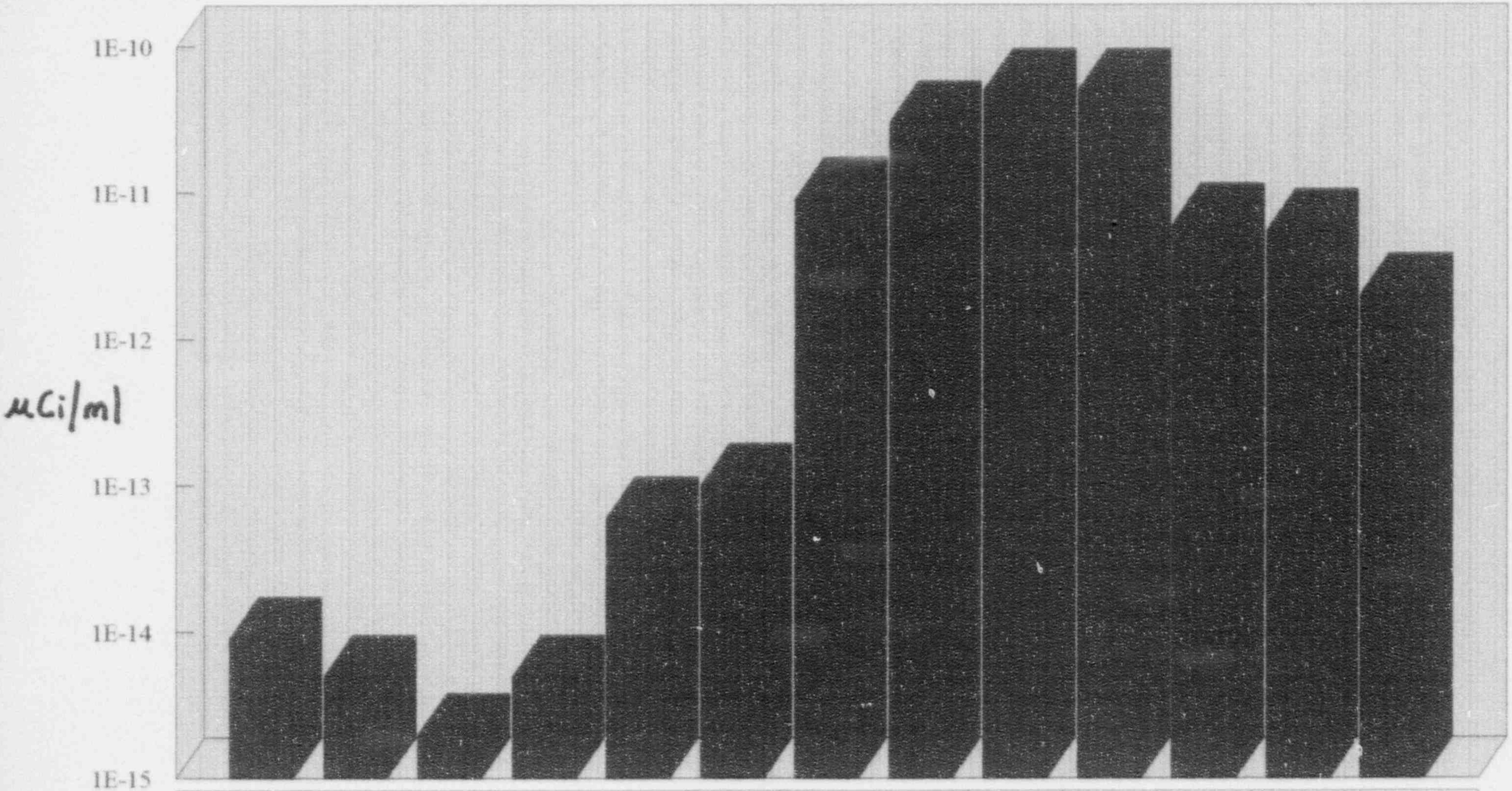


1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990-1992
10.6	15.6	5.1	59.1	29.6	46	51.2	3.8	0.6	3.3	0

Calendar Year

Figure II

ADVANCED MEDICAL SYSTEMS
Average Annual Stack Discharges vs. Year

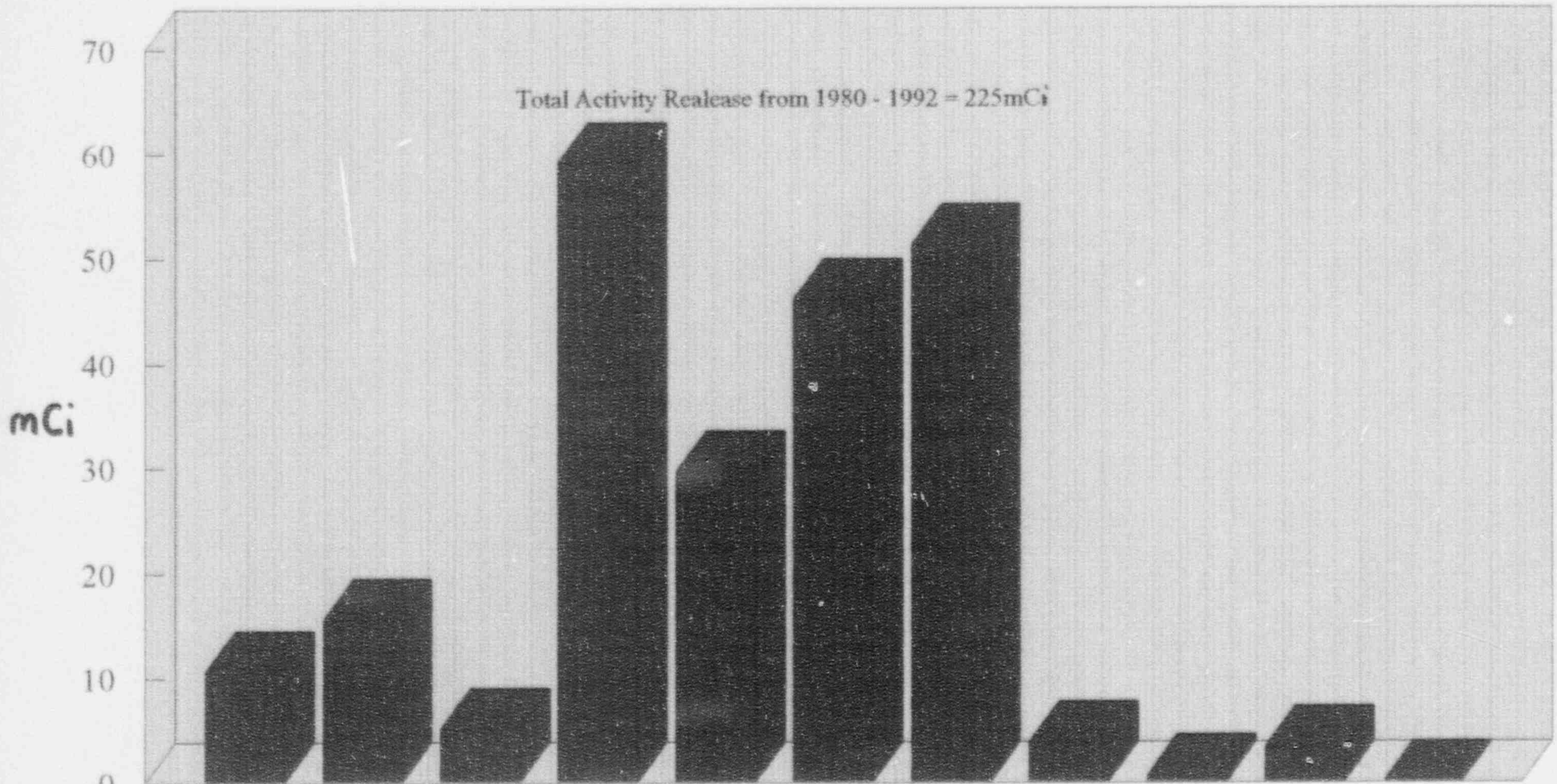


1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992
9.00E-15	5.00E-15	2.00E-15	5.00E-15	6.00E-14	1.00E-13	9.00E-12	3.00E-11	5.00E-11	5.00E-11	6.00E-12	5.50E-12	2.00E-12

Calendar Year

Figure I

ADVANCED MEDICAL SYSTEMS
Cumulative Sanitary Sewer Release Activity vs. Year

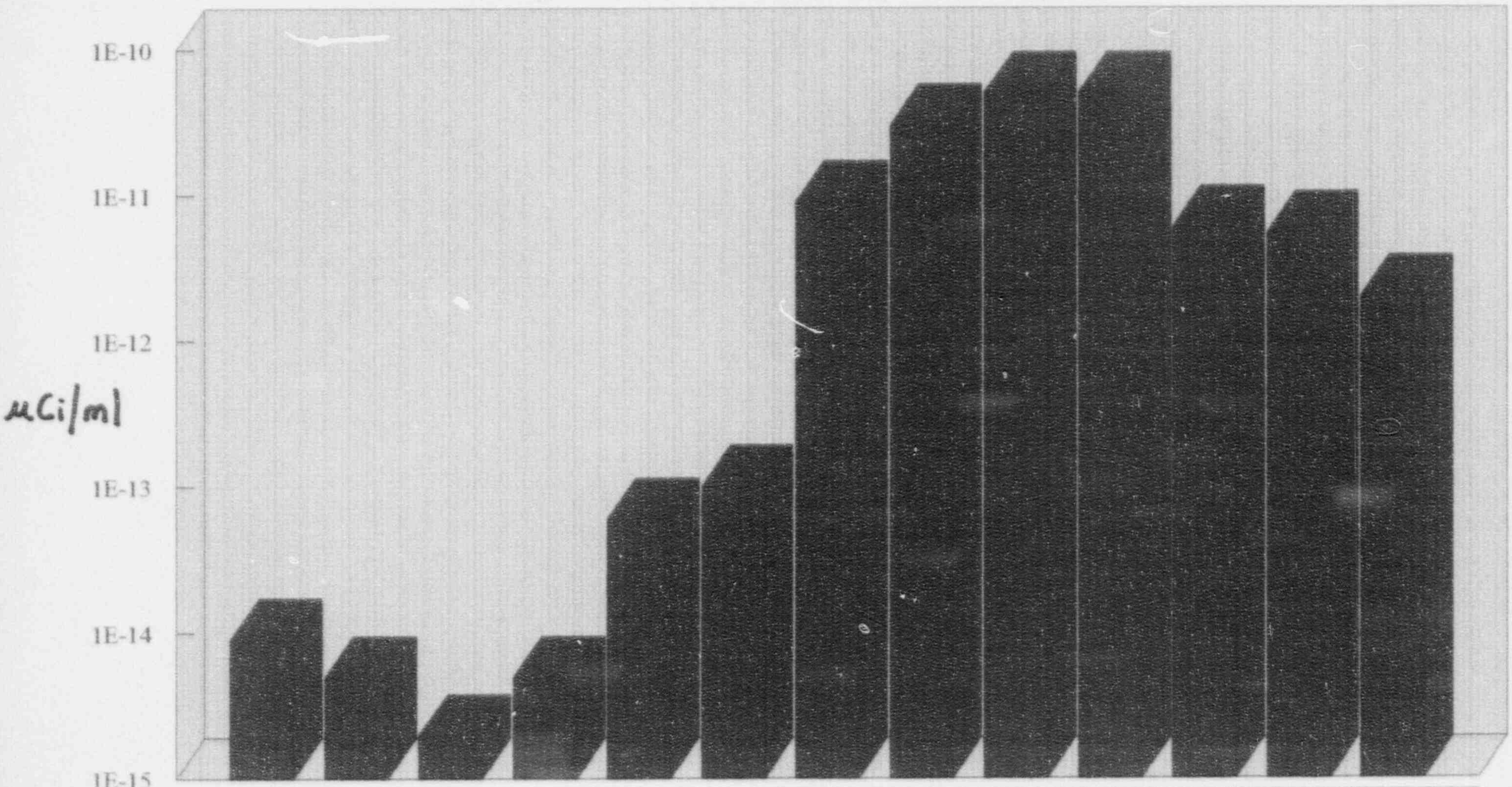


1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990-1992
10.6	15.6	5.1	59.1	29.6	46	51.2	3.8	0.6	3.3	0

Calendar Year

Figure II

ADVANCED MEDICAL SYSTEMS
Average Annual Stack Discharges vs. Year



1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992
9.00E-15	5.00E-15	2.00E-15	5.00E-15	6.00E-14	1.00E-13	9.00E-12	3.00E-11	5.00E-11	5.00E-11	6.00E-12	5.50E-12	2.00E-12

Calendar Year