Advanced Medical Systems, Inc.

1020 London Road
Cleveland, Ohio 44110
(216) 692-3270
Fax (216) 692-3269

October 24, 1996

Ms. Cindy Pederson
Director of Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Strategic Plan, Revision 4 (USNRC License No. 34-19089-01)

Dear Ms. Cindy Pederson,

On October 15, 1996 Revision 4 of the Advanced Medical Systems Strategic Plan was due for submission.

For a variety of reasons, AMS was not able to meet this commitment. We request a 30 day extension for submission. You may expect Revision 4 on or before November 15, 1996. Please call me at 216-692-3270 if you have any questions.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock
R.S.O.

cc: E. Svigel
C. Reed
C. Berger
D. Miller

C/118

11) Southerly Primary Sludge Gravity Thickeners
Once every 24 hrs

12) Southerly Ash in Incinerator
3 may be running at anyone time (depends on volume handled/treated at that time)
Once every 24 hrs (if on-line that day)

13) Southerly Secondary Grit
2 of 4 run each day
Once every 24 hrs

14) Southerly Ash in Ash Pond
Once every 24 hrs

15) Any other intakes into Southerly
4 different lines flow into Plant
Once every 24 hrs

D11

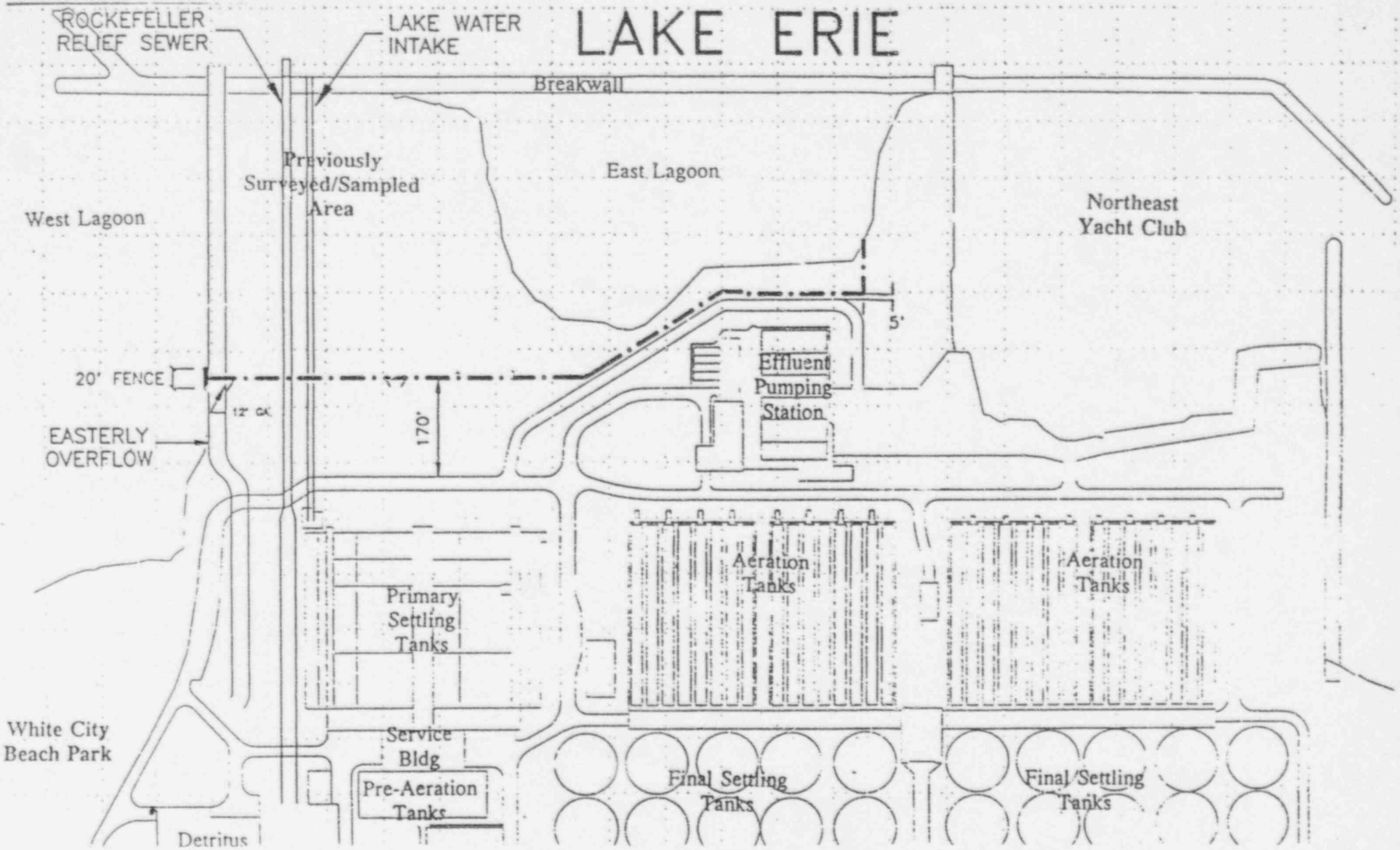
ROCKEFELLER
RELIEF SEWER
LAKE WATER
INTAKE
LAKE ERIE
Breakwall
Previously
Surveyed/Sampled
Area
East Lagoon
West Lagoon
Northeast
Yacht Club
5'
20' FENCE
Effluent
Pumping
Station
170'
EASTERLY
OVERFLOW
Primary
Settling
Tanks
Aeration
Tanks
Aeration
Tanks
White City
Beach Park
Service
Bldg
Pre-Aeration
Tanks
Final Settling
Tanks
Final Settling
Tanks
Detritus

Figure 4. Areas surveyed that were not Suspected of being Contaminated.

Surface Soil Sample Locations – X

Areas Surveyed with Ludlum Model 19 – ▨

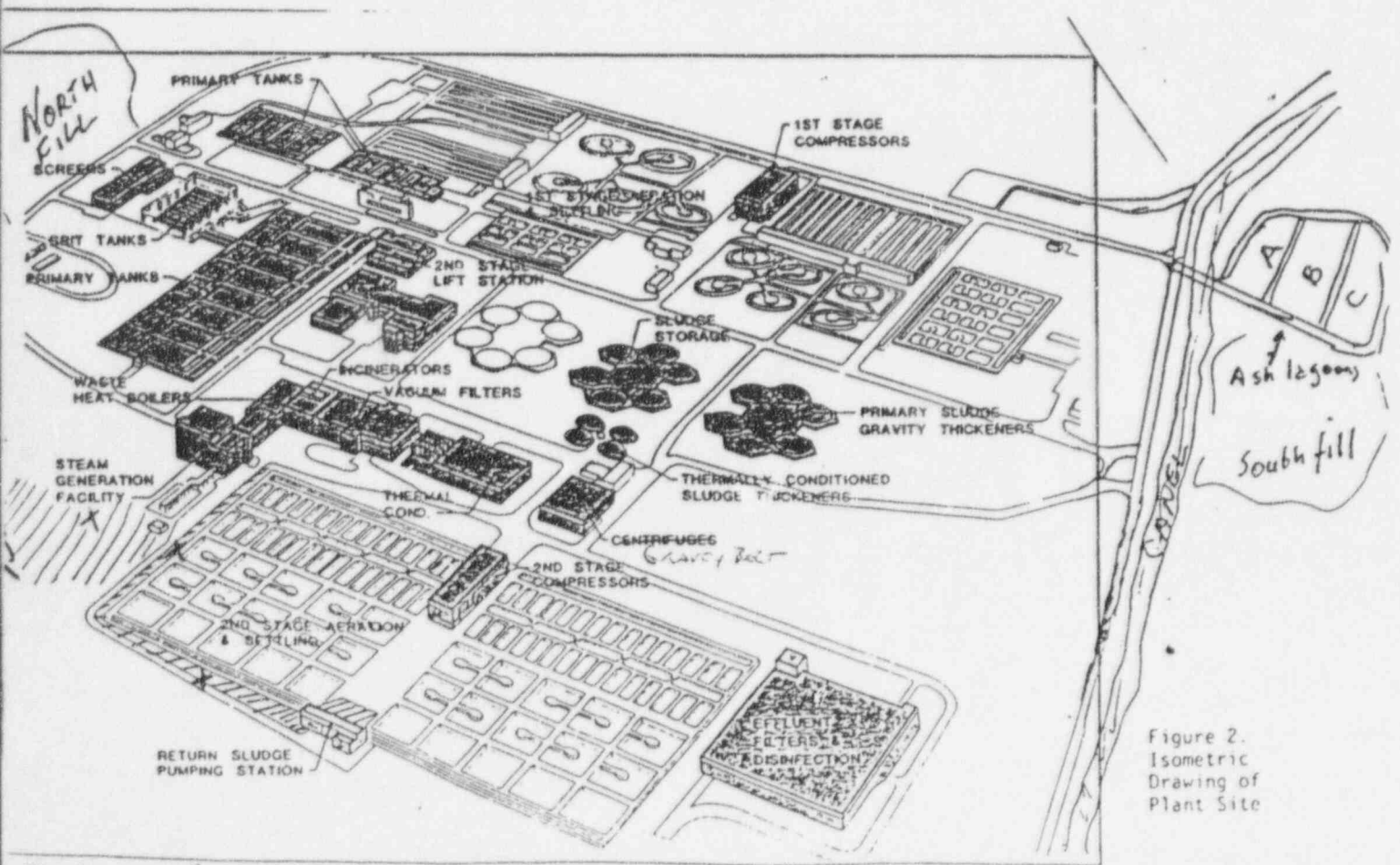

Figure 2. Isometric Drawing of Plant Site

FIGURE 4 PROCESS DIAGRAM AND SITE MAP

1) Status of HQ review of our letter to sewer district (NEOSD). re: response to Larry English letter - DelCicco
- will get back to us

to AMS
2) Status of HQ review of our cover letter that will go w/ Cosmic Industries inspection report. - DelCicco
will get back to me by end of day

3) Jerr: HQ need a position on written sampling procedures - Homogeneous mixture of sample from bottom of tank.

- test way tank for sol... ...

* RIII recommend ... ...
* Sampling technique

will ... ... procedure to HQ for review
* do not have - policy statement on this issue -
NMSS

1) Update on Sewer district ltr. concerning cc of comments on our letter to S.D.

10: Sampling on our findings

... our response to S. district.

... policy issue on ... sampling proposal

4) letter to ... status of ...

...

NMSS ... ... the last ...

HQ ... legal ...

D/2

ACTION PLAN FOR ADVANCED MEDICAL SYSTEMS, INC.

WATER ISSUES

GOALS

I. Develop and promptly implement a long term solution for the foundation drainage system deficiencies that have resulted in hydrostatic pressure build up on the exterior surfaces of the basement floor slab and walls.

II. Control the spread of sub-surface contamination.

III. Process/dispose of the contaminated waste water in the facility basement, above ground tanks, and manhole and pit.

IV. Remediate the contaminated sanitary and storm water piping, manhole, lateral and interceptor.

ACTIONS

I. Foundation Drainage

A. Steps should be initiated to prevent the flow of surface water into the manhole to minimize the injection of water into the soil structure around the facility through the connected underground piping. These steps should include plugging the 15 inch storm water line where it enters the manhole and replacing the surface grates with sealed solid manhole covers. Consideration should be given to other connected piping to the 15 inch line to ensure that no secondary problems are created by plugging this line.

B. Monitoring pipes and measuring systems should be installed into the ground on the east, south and west sides of the facility to allow accurate monitoring of ground water level near the facility basement walls and foundation.

C. Establish accurate measuring systems and procedures for water level measurement in the basement, the pit, and the manhole. For the basement and pit, measuring devices mounted on the walls should be adequate. For the manhole, a measuring procedure from the top of the manhole should be adequate.

D. Ground water level around the facility as measured in the monitoring pipes should be reduced by pumping at the manhole (lowest point possible). Ground Water level should be maintained approximately six inches above the basement interior water level to reduce the hydrostatic pressure on the basement walls and floor slab, while preventing the flow of contaminated water out of the basement. Should ground water level fall below the level of water in the basement, immediate action will be taken to reduce water level in the basement to prevent leakage of water from the

basement to the ground. This balanced approach should also be used during the processing of waste water.

II. Sub-Surface Contamination

A. Separate the perforated foundation drainage piping from the cast iron sanitary piping that leads to the manhole. Install seals in the wye connections to the cast iron pipe to minimize the risk of (further) cross contamination of the foundation drainage piping and soils around the facility.

B. Visually examine the interior of the perforated piping at the wye to establish whether the piping is functioning.

C. Cap the ends of the perforated piping or connect the ends together to allow effective elimination of water from the foundation area.

D. Install a plug in the sanitary piping where it enters the manhole to prevent future injection of surface water, that could become contaminated in the manhole and sanitary piping, into the soil structure beneath and around the facility basement.

III. Disposition Contaminated Water

A. Expedite the decision on the optimal method to disposition the waste water that is or may have become contaminated in the basement, in above ground storage tanks, in the manhole and connected piping, and in the gravel lense and soil around the facility.

B. Receive NRC approval for the method of disposition of waste water.

C. Expedite dispositioning of the waste water.

IV. Remediate Sewage Piping

A. Expedite the decision on the optimal method to remediate the contamination that has been deposited in the sanitary and storm water piping, manhole, lateral and interceptor.

B. Submit to NRC for review an options analysis addressing cost and technical issues to support their preferred option.

C. Receive NRC approval for the method of remediation of contamination.

D. Expedite implementation of the remediation plan.

External Distribution of Documents Received From AMS and Issued to AMS

Mayor Michael R. White
City of Cleveland
601 Lakeside Avenue
Cleveland, OH 44114

Lisa Mehringer
City of Cleveland Law Department
601 Lakeside Avenue Room 106
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Cleveland, OH 44115

Erwin J. Odeal, Executive Director
Northeast Ohio Regional Sewer District
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Cleveland, OH 44115

D/4

STANDARD DISTRIBUTION FOR ADVANCED MEDICAL SYSTEMS, INC.

Internal NRC Distribution

Hardcopy of documents issued to AMS and received from AMS

Jack Grobe, RIII
Gary Shear, RIII
Mike Stein, OGC
Cyndi Jones, NMSS
Steve Crockett, OGC
Gene Holler, OGC

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Bill Axelson, RIII
Jim Caldwell, RIII
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Gary Shear, RIII
Wayne Slawinski, RIII
John Madera, RIII
Kevin Null, RIII

Jack Goldberg, OGC
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John Cordes, OGC
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Gene Holler, OGC
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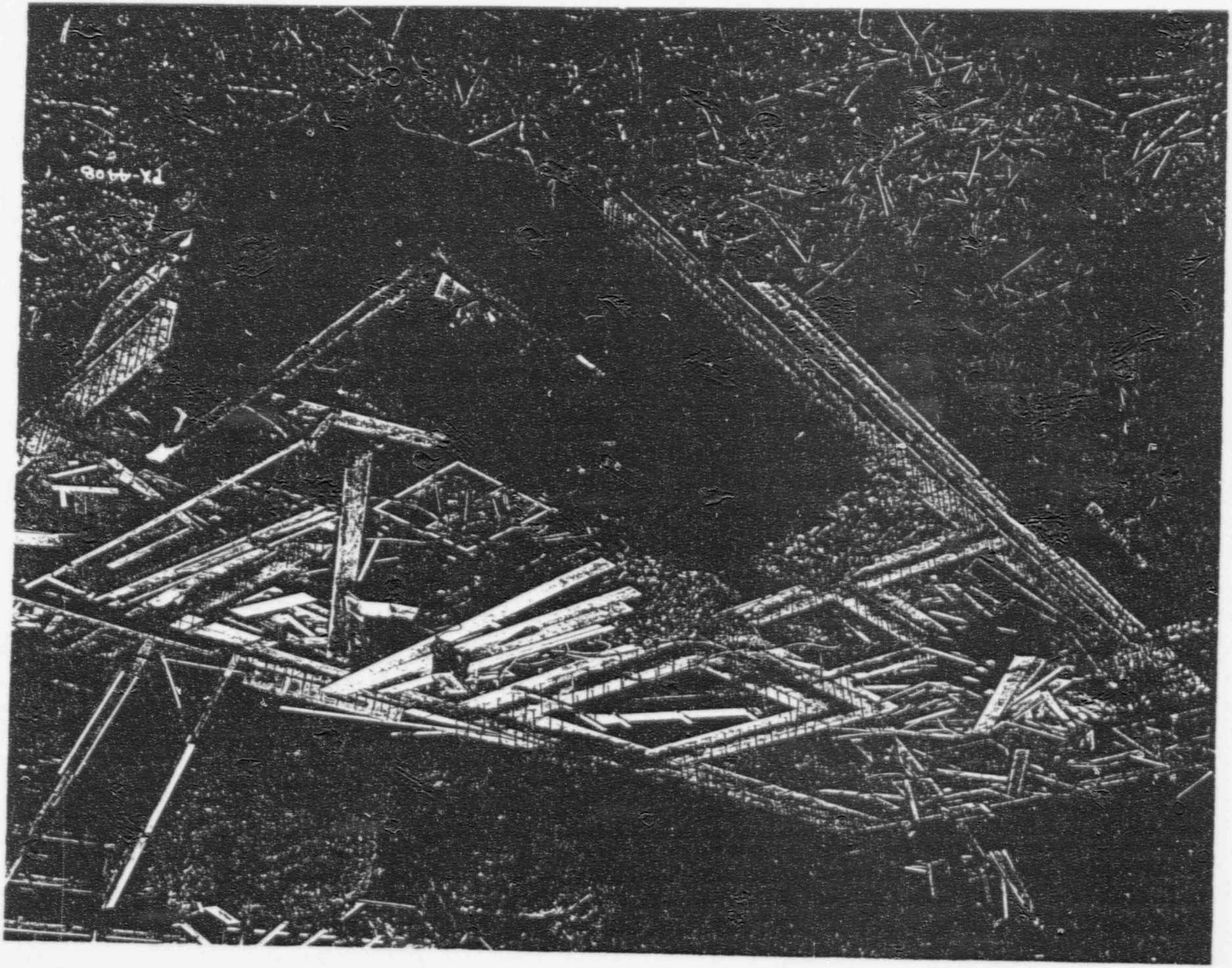
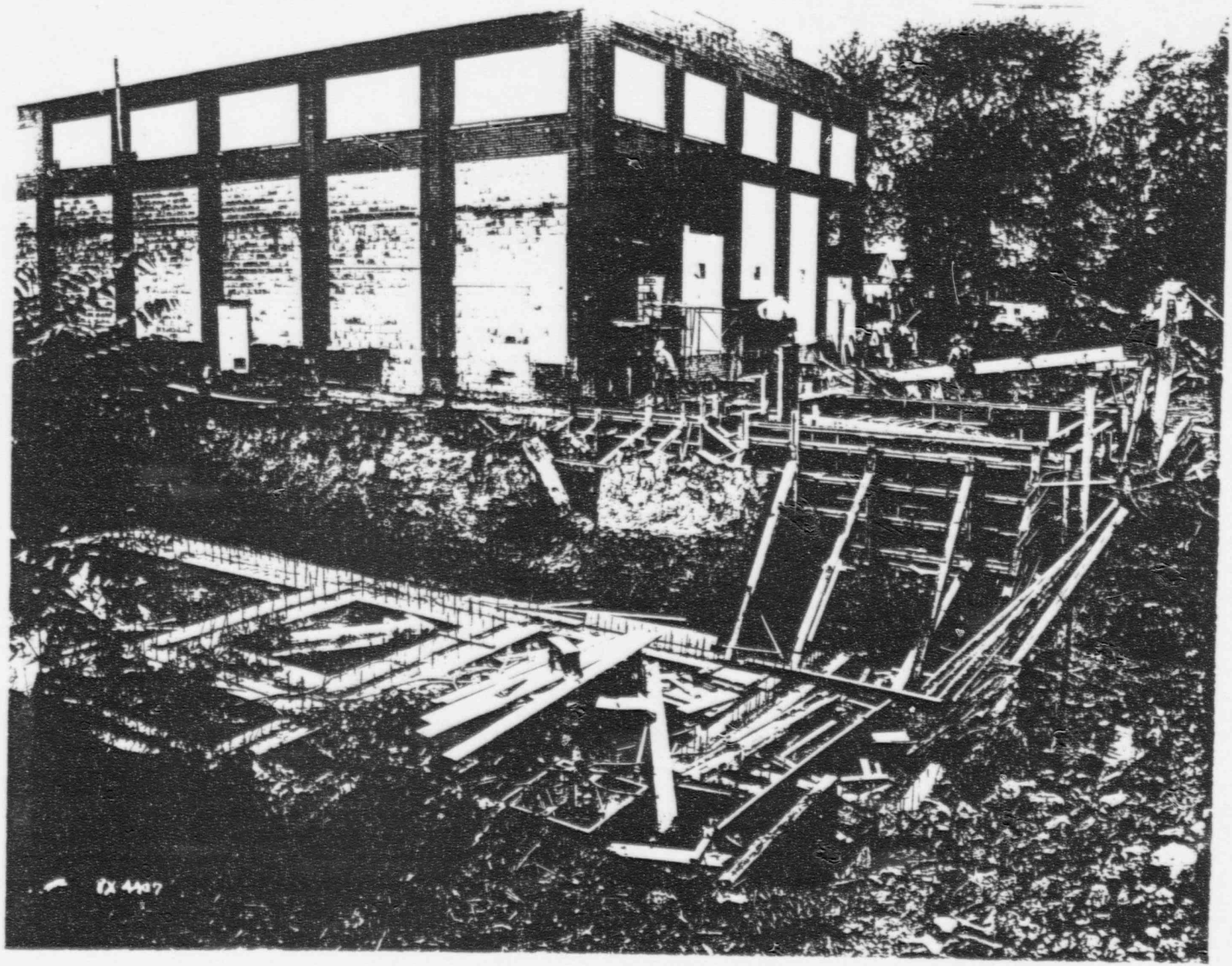
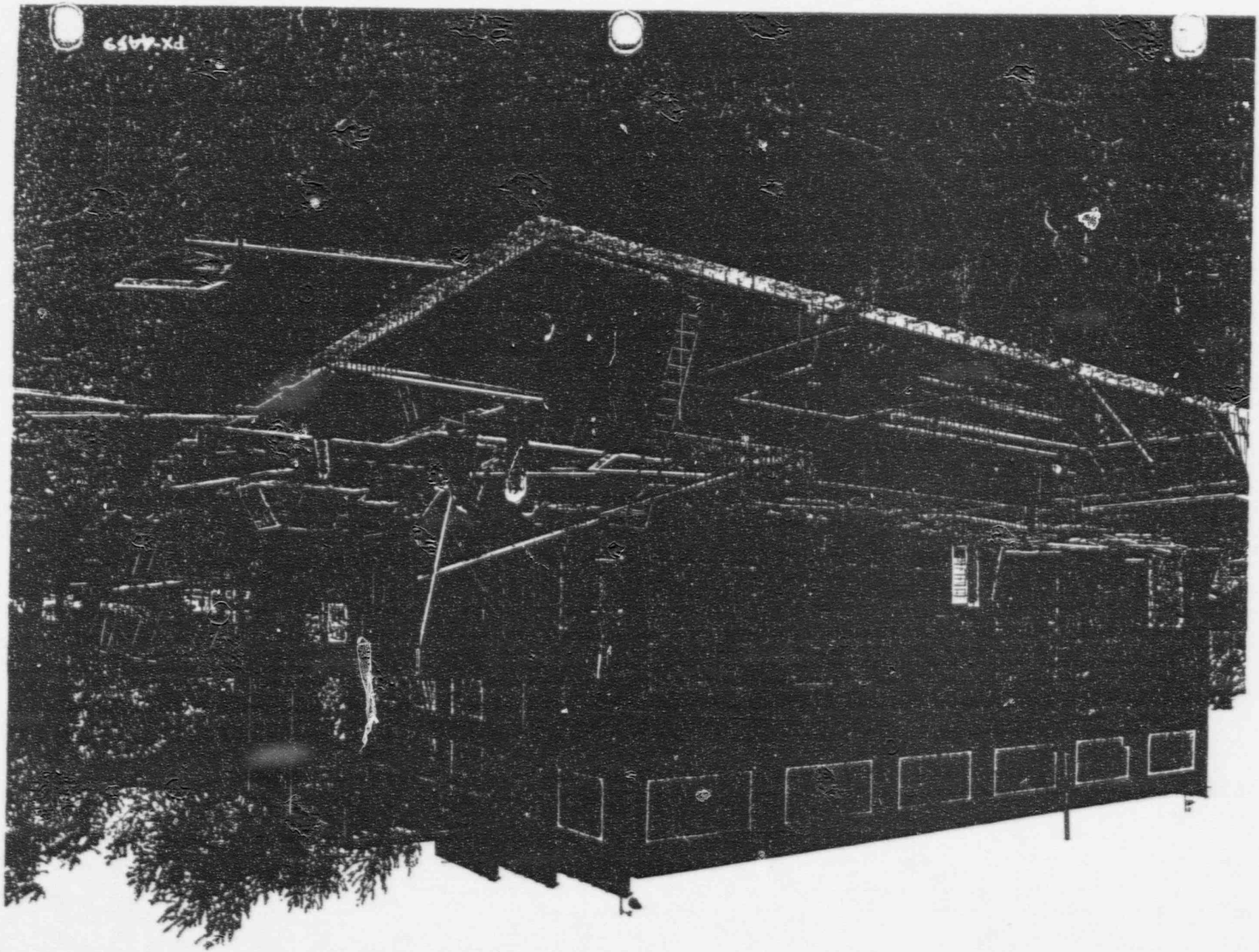
Carl Paperiello, NMSS
Bill Brach, NMSS
Fred Combs, NMSS
Cyndi Jones, NMSS
Joe DeCicco, NMSS
Tim Johnson, NMSS
Josie Piccone, NMSS

D/S



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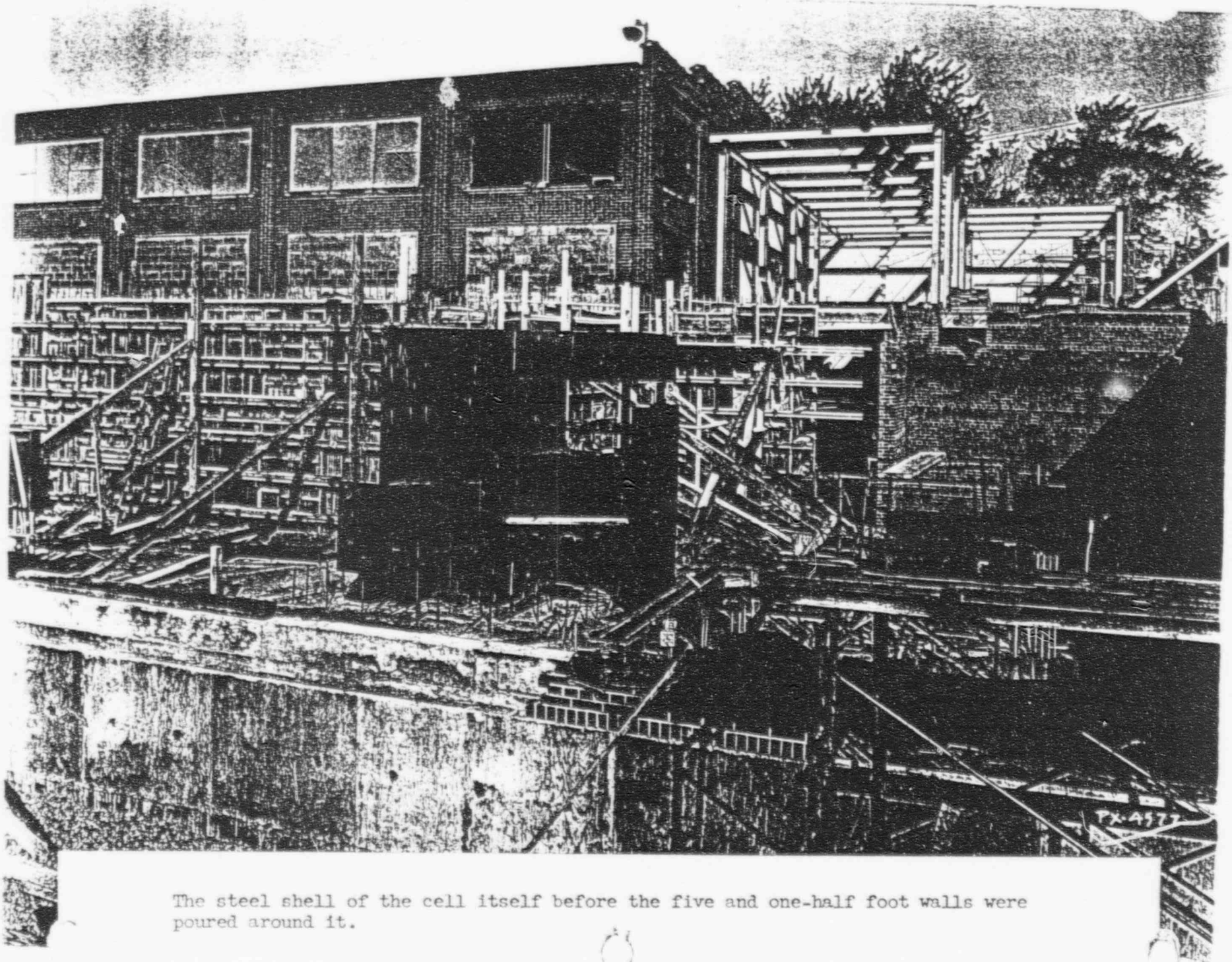
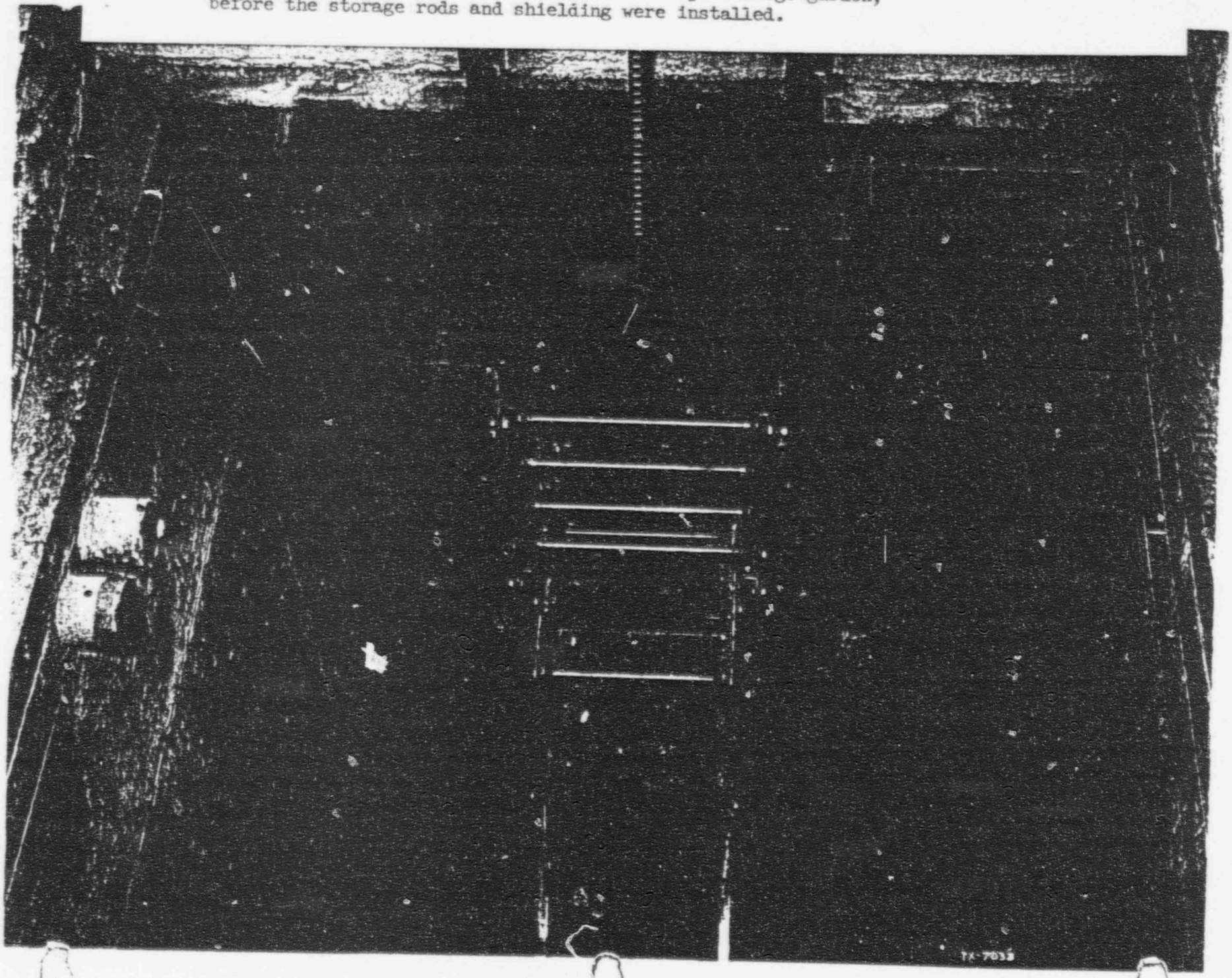
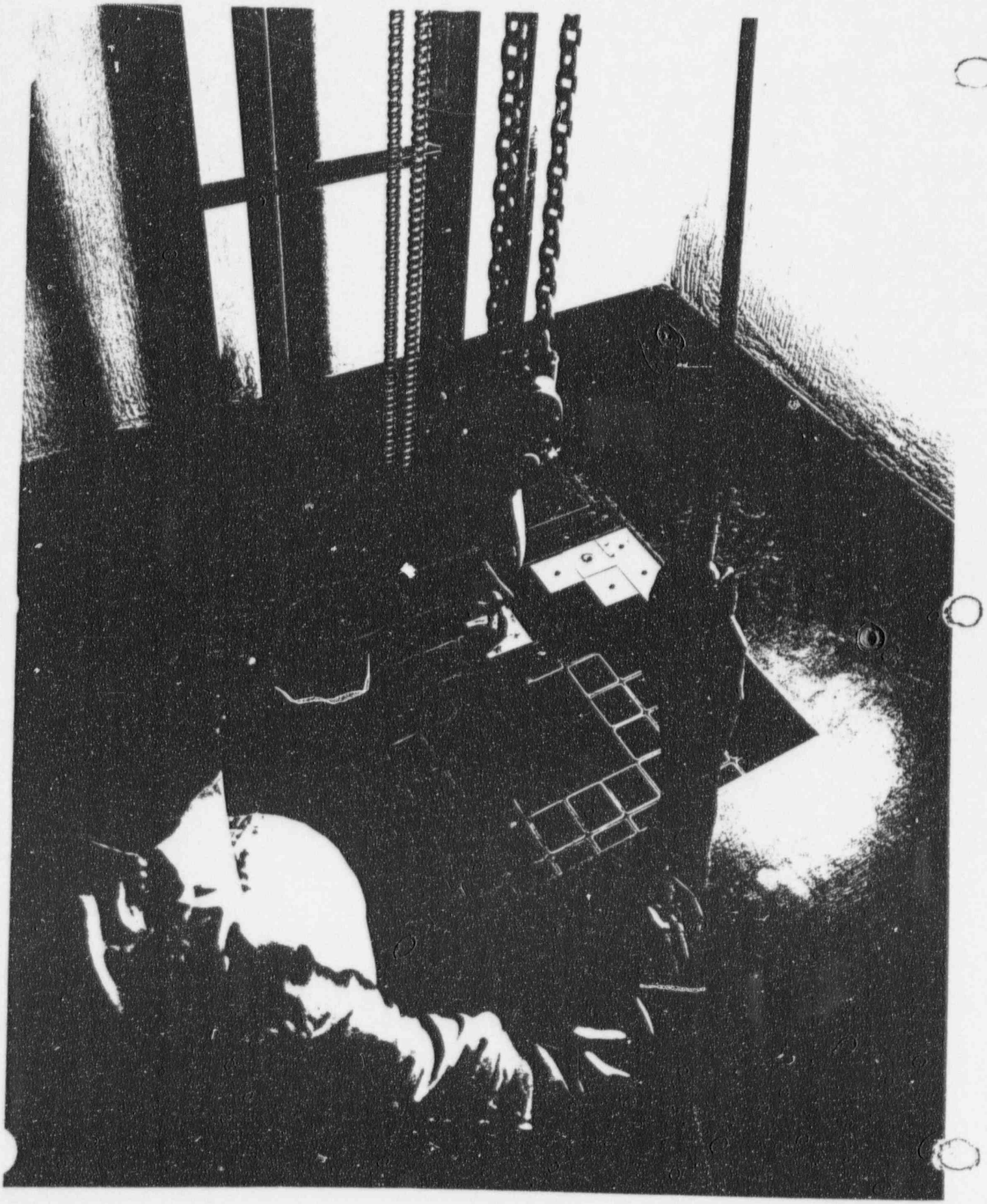


The steel shell of the cell itself before the five and one-half foot walls were poured around it.

PX-434

The elevator, which lowers beneath c sotope storage garden, before the storage rods and shielding were installed.





The isotope storage garden, located in the S/W corner of the isotope lab.

Advanced Medical Systems, Inc.
ATTN: Mr. David Cesar, Treasurer
121 North Eagle Street
Geneva, Ohio 44041

Dear Mr. Cesar:

We have reviewed your application dated November 29, 1994 requesting renewal of NRC License Number 34-19089-01 and find that we will need additional information as outlined below.

I. Organization and Committees

A. It does not appear from your organizational chart that the RSO has a direct reporting path to senior management. In addition to having ready access to all levels of an organization, the PSO should have the ability to report directly to senior management. In the past we have observed that a direct reporting path from the RSO to upper management RSO resulted in timely solutions to problems identified in a radiation safety program. Modify your organizational structure such that the RSO can report directly to upper management, or illustrate how your current system provides the RSO a direct communication path to the president.

B. Describe the method by which the Safety and Isotope Committees report their findings, concerns, issues, etc. to upper management. Also, please address/justify the apparent lack of involvement of the President of the company with either of the Committees.

C. Describe the duties and responsibilities of the Safety Committee. Distinguish how they differ from the duties of the Isotope Committee.

D. Confirm that you will maintain records of Safety and Isotope Committee meetings, and that these records will include, as a minimum, the date of the meeting, list of attendees and topics discussed, problems identified in the program, and corrective actions recommended/taken.

E. It is our understanding that the Engineering Manager will be responsible for determining if an AMS staff person will respond to a request for teletherapy unit service, or if the service will be subcontracted. Please describe the criteria the manager will use in making such decision. For example, will it be purely a business decision, or rather a technical decision, i.e. based upon the service requested, e.g. working on a particular piece of equipment, handling radioactive material, etc. If these decisions will be based upon the technical nature of the work to be performed, identify the Engineering Manager by name and submit a detailed description of his training and experience to show that he/she is qualified to make judgements on who should provide

D16

service.

II. Field Service Audits

Your application provides information relative to the performance of field service audits to be conducted on services engineers while they perform a simulated service call or source exchange. Our understanding is that such service performed by AMS staff is limited to Class 1 or 2 Service Engineers. After a review of the qualifications of your technical staff, it appears that AMS does not have a qualified Class 1 or 2 service engineer. Please acknowledge that AMS must receive an amendment to its license authorizing a Class 1 or 2 Engineer prior to initiating the service.

Regarding your field service audit program, please address the following:

A. Describe the content of a field service audit. From the NRC's point of view, we are more interested in the radiological aspects of the audit. Submit checklists, etc. that are used to conduct the audit. Describe the RSO's qualifications to conduct the audit. Has he received sufficient training in the equipment that is serviced such that he can audit another's performance relative to radiation safety?

B. You stated in your application that field service audits of service engineers will be conducted as they perform duties "during a simulated service call or source exchange". Given the limited amount of service that AMS will perform itself, we see no reason why the audits could not be conducted during an actual service call. We feel that it would not be overly burdensome to conduct an audit of each field service engineer once per year while he performs his duties during a service call. Modify your procedures to require audits be conducted during a filed service call, or provide justification why you feel audits of simulated service calls would be adequate.

C. Confirm that records of service performed will be maintained for NRC inspection. As a minimum these records should identify the service engineer, the date and type of service performed, problems identified, and corrective actions taken (if applicable). Also, make a commitment that records of audits will be maintained for inspection.

Audits should be a part of every radiation safety program. They can be a valuable tool in identifying weaknesses and taking appropriate action to prevent programmatic breakdown. In addition to conducting field service audits, we recommend that you establish a program for auditing the activities of RSO and his staff. This could be done on an annual basis, and include sel·ct

members of upper management and the Safety and Isotope Committees. Develop a program for conducting such audits and submit it for our review. An audit program of this nature would assist you in fulfilling the requirement of 20.1101(a).

III. Radioactive Material and Inventory

A. Item 5.G. of your application requests authorization for 40 curies of cobalt-60 for storage of waste incident to disposal, discharge and /or decommissioning. For purposes of licensing, please distinguish between material stored as waste (solid and liquid) and decommissioning. Cobalt-60 in the form of waste, and that which is intended for purposes of decommissioning, will be identified a separate items on your license. The activity level for each of these must be specified. Furthermore, specifically identify the facilities and equipment that will be subject to decommissioning.

B. Section 1.2 of your application states that bulk cobalt and cobalt-60 sealed sources will be transferred within the next 12 months. Assuming you mean within the next 12 months of the date of your application, this means that transfer will occur on or about November 29, 1995. Please confirm, or clarify, our understanding of this.

C. Please confirm that you will amend your license for possession limits and Decommissioning Funding Plan cost estimate (if applicable) following removal of the front plug and completion of an inventory of material stored this location.

D. Section 1.1 discusses your proposed inventory schedule. Based upon our findings during previous inspections, we do not feel that the conduct of a physical inventory every 60 months is adequate enough for you to maintain accountability of material in your possession. Specifically, Inspection Report no. expressed concern over your apparent lack of ability to account for all material on possession. Note that we do not consider an examination of records (as you mention in subitem B. of Section 1.1) every 6 months to be an acceptable method of performing inventory. Therefore, in accordance with NRC policy, please modify your inventory procedures to require a physical inventory be conducted once every 6 months, and describe in detail your method for complying with this duty.

E. Item 6.c. of Section 1.2 describes cesium-137 sources for use in devices for the purpose of calibrating instruments. Item 5 of your application requests authorization for 665 curies of cesium-137 for "use in devices, storage incident to waste disposal, discharge, and /or decommissioning". Please define the word "devices" and for purposes of licensing, please distinguish between cesium-137 activity requested in devices, waste disposal, and decommissioning. We will need activity levels for each of these, and they will be listed separately on your license. Also,

if you currently have cesium-137 sources in storage awaiting transfer to a third party, they must be included in the total activity until such time that the material is transferred. If necessary, modify your possession limit to account for this material.

IV. Individuals Responsible for Radiation Safety Program

Provide an update regarding the status of training for Christopher Reed and Vince Rocco. From your application it appears that each has completed Isotope Technician training, and is currently being trained to be an Isotope Handler. Provide an estimate as to when this training will be completed.

Also, it is apparent that at this time you do not have qualified field service engineers. Please indicate your plans for training someone to perform these duties, and submit a timetable for completing such training. Verify your understanding that upon of completion of training for isotope technicians and handlers you need to amend your license before trained individuals assume their duties.

V. Training

A. Ancillary Personnel

Item 2.2 of ISP-28 states that the RSO or designee shall be responsible for providing training to ancillary personnel. We will not approve the use of an unidentified instructor without the opportunity to review his/her qualifications. If you will have instructors other than the RSO, please specify them by name and describe how they are qualified by training and experience to provide basic radiation safety training to ancillary personnel.

Item 2.5 of ISP-28 states that ancillary personnel may be tested on their comprehension of training received. Please modify your procedures to require the administration of a test. Describe your method for evaluating comprehension of training and/or submit a copy of the test administered for our review. Include the correct answers and indicate the passing grade.

B. Isotope Technician Training

Item 1.0 of ISP-31 needs to be modified to change the word "routing" to "routine".

Please identify the instructors of the training as well as their qualifications to train individuals to perform the task of an Isotope Technician. Item 4.12 is not clear in this regard.

Submit a copy of the test given for Isotope Technicians, as well as the answers.

Section 5.0 describes the program of instruction. The topic in item 5.1 is entitled "Radiation Therapy and Safety Practices Course" (24 hours). Describe the relevance in giving 24 hours instruction in radiation therapy to an Isotope Technician. Provide a breakdown of the topics covered over the 24 hour period.

Your training program for technicians does not appear to incorporate instruction in personal dosimetry. Please modify the training to include instruction in the use of personal dosimetry as part of the training program.

C. Isotope Handler Training

Submit a copy of the test given to potential Isotope Handlers. Include a copy of the correct answers.

The training program does not appear to include instruction in your emergency plan (EP). Modify your program to incorporate training in the EP.

Please include a section in the training that discusses use of personal dosimetry.

Identify the instructor, and provide a summary of his/her qualifications.

D. Basic Radiation Safety Training Manual

The Basic Radiation Safety Training Manual, including the glossary, and to a lesser degree the Supplemental Radiation Safety Manual, are outdated. Some of the terminology and information is obsolete, and there are no references made to the revised 10 CFR Part 20. These comments also apply to the quizzes for each of these manuals. Given the change in the scope of your program, we do not feel that these issues need to be addressed immediately. However, it is strongly recommended that you do a comprehensive review of your training manuals to determine the extent to which they need to be updated and modified. provide a timetable for accomplishing this task.

VI. Facilities and Equipment

A. It is our understanding that you will not be in the business of manufacturing sealed sources. Therefore, please describe in detail the purpose for which the hot cell will be used.

B. On pages four and five of Section 1.5 you describe hot cell supporting facilities, including the exhaust system which forces air through a filter system. Submit a schematic diagram of the ventilation/exhaust system which services the hot cell. In the diagram, please identify the location of the filters. Also, describe your criteria for checking the filters for saturation, as well as replacing the saturated filters with new filters.

C. Concerning the air sampling system above the Hot Cell, please submit/describe the following:

1. Diagram of exhaust system that identifies locations of the stack, filters and pumps, monitors, stack, and sampling location(s).

2. Describe the filter collection media used to collect exhaust for the purpose of analyzing air effluent. Define it's collection efficiency for cobalt-60.

3. Describe how you measure the total volume of air that is sampled. If you use an air mover, e.g. rotameter, submit your calibration procedure for the instrument.

4. Your application describes an air monitor located in the clean equipment room. Describe the monitor used, e.g., side or end window G.M., pancake G.M., NaI probe, etc. Also, you state that the monitor has a preset level whereby the exhaust shuts down. Define what this level and how it relates to Part 20 limits for air effluent for cobalt-60.

   Describe who is notified if the alarm is tripped, as well as what action would be taken. Confirm that records will be maintained concerning events that trigger the alarm, and that the records will indicate what the problem was and action taken to correct the situation and prevent future occurrences.

5. Confirm that the only potential point of release of cobalt-60 to the atmosphere is through the air handling system for the hot cell. If there are other locations, then the above items a. through c. must be addressed for these locations as well.

D. Describe how the source garden is used relative to retrieving and/or replacing sources. Describe safety procedures established for these activities.

E. On pages 13, 14 and 15 of Section 1.5, your application describes Gamma Alarms that are <u>mounted</u> in specific areas within your facility. ISP-23 provided procedures for calibrating <u>portable</u> instruments. Confirm that the mounted gamma alarms are calibrated in accordance with ISP-23, or submit procedures for calibrating the <u>mounted</u> gamma alarms.

F. Submit a current evaluation of radiation levels and contamination in restricted areas of your facility. Also, submit results of any decontamination activities that you have implemented since your last license renewal.

VII. <u>Radiation Safety Program (Section 1.6)</u>

This section follows the format used in Section 1.6 of your application. The first set of deficiency items relate to Chapters 1 - 8, pages 1 - 46. The remainder deals with deficiencies pertaining to Advanced Medical System's Operating Procedures (ISP's).

The Forward to Section 1.6 states that "revisions and modifications will be made as required". Be aware that prior to implementing "revisions and modifications", you must request and receive an amendment to your NRC license.

A. Chapters 1-8 (Notebook I of Application)

1. Chapter 1

Inspection Report no. described many concerns pertaining to the Victoreen Model 550 high energy probe located in the hot cell. For example, it was noted that the electrical wiring was brittle, and the last date of calibration of the probe was, at the time, unknown. As with all other instruments used for the purpose of measuring dose, this probe must also be calibrated at the same frequency.

2. Chapter 2 - Safety and Health

a. Submit your procedure for calibrating self reading pocket dosimeters.

b. Add a statement to Item C., top of page 27, stating that dosimetry will be required per 10 CFR 20.1502(a)(3).

c. Under Item I.B. on the bottom of page 27, it is stated that personnel are responsible for tracking their exposure and maintaining their exposure within administrative limits. It is also the responsibility of the licensee to monitor and track dose received by an employee. In order for an individual to track his/her dose, he/she must be supplied with dosimetry data. Please modify this section to clarify that the licensee is also responsible for tracking dose, and dosimetry data will be provided to employees so that they can track their own dose.

d. Confirm that the dosimetry service used by AMS fulfills the requirements of 10 CFR 20.1501(c).

e. Item III.A. on page 28 you provided a sample calculation for determining intake of radioactive material based upon airborne concentrations. Please modify the formula to include the units. Also, describe the criteria used to determine if an individual should receive a whole body count. Reference Item III.D. on page 28.

Note: We have enclosed Regulatory Guide 8.9 for your assistance in developing a comprehensive bioassay program. Please commit to following this guidance, or submit an equivalent program for our review.

f. Item II. C. on page 31 states: "It is preferred that the RSO be on-site for all Cell entries". Given the extreme hazards associated with entry into the Hot Cell, we find this statement to be unacceptable. Please modify this section to require that the RSO be physically present for all Cell entries.

g. Item II.D. on page 32 describes a schedule for performing Routine Safety Assurance checks. Subitem 1.f. states that source inventory will be checked on a daily basis. Describe what "source inventory" means, and how it is performed.

h. As noted in Item C.4 of this letter, please modify your physical inventory procedure on page 33 of this section to require a physical inventory be done once every 6 months.

2. Chapter 3 - Procedures for Handling Radionuclides

a. Please modify your General Operating Procedures, as found in Item I on page 34, to include the following: 1) personnel will monitor themselves for contamination immediately upon exiting a restricted area, 2) protective clothing will be worn by all personnel who enter a restricted area, 3) personnel monitoring devices (film badges, SRPD's, and extremity TLD's if applicable) will be worn by all personnel who enter a restricted area.

b. Include in Item III on page 37 a statement that the RSO will be notified "As Soon As Possible" in the event of an accidental leakage or spillage.

3. Chapter 4 - Storage of Isotopes

Describe in detail provisions made for security (e.g. secured doors, proper postings, etc.) for all isotopes placed in storage. This should include waste held in storage.

4. Chapter 5 - Transportation of Isotopes

Sentence two of the opening paragraph for this section makes reference to "transportation of isotopes to other areas, or from one area to another in your building, for the purpose of research and development work, is permissible....". You have not requested authorization for research and development, nor are

you currently licensed for this activity. Delete the reference to research and development from this chapter.

5. Chapter 6 - Monitoring

Item F under Personnel Monitoring on page 42 allows personnel contamination up to 100 cpm above background. We do not find it acceptable for trigger levels above background for personnel contamination. Please modify your procedure to state that any reading above background is not acceptable, and that decontamination will be performed until levels reach background.

B. Operating Procedures - ISP's

General Comments: We have noted throughout your ISP's numerous procedures that state certain aspects "should" be done, rather than "shall" be done. Furthermore, in comparing these procedures to your old ISP's, it is clear in many instances that the word "shall" was replaced with "should". Please modify your procedures to change the word "should" to "shall", or specifically identify those procedures that you feel flexibility is appropriate, and provide justification.

Also noted are several references made to recording dose rates in mR/hr. Part 20 requires that dose rates be recorded in mrem/hr. Please make the necessary modifications to your procedures.

We would like you to modify all your survey forms to specify what the trigger levels are, and include a statement that the RSO be notified in the event trigger levels are exceeded.

1. ISP-2 Area Survey Procedure

In accordance with 20.1301(a)(2), modify Item 3.3.2 to include the requirement that the dose in any unrestricted area from external sources does not exceed 0.002 rem in any one hour.

In addition to the survey frequencies described in Item 3.3.4, we also recommend that daily surveys be performed after use of material. Therefore, include in item 3.3.4 a requirement that surveys be conducted at the end of each day of use of material. Item 3.3.4.a describes survey frequencies conducted in controlled areas. As noted in Inspection Report no. controlled areas should include

areas outside the south side of the building outside the isotope shop and warehouse for the purpose of monitoring changing conditions. Please include these locations as controlled areas, and therefore, the survey plan for controlled areas as well.

Regarding the attached forms to ISP-2, delete item no. 1 from form 2A. It is our understanding that a lean equipment room does not exist. Add a new item to incorporate the area outside the south side of the building located exterior to the isotope shop and warehouse as noted above. Due to the source term and associated hazards with the WHUT room, add an item to form 2C to include the exterior walls of the WHUT room as a restricted area survey location. This should replace item 21. of this form. Add an item no. 38 for the roof area above the hot cell. Our concern here is that if the filters become saturated this area could become a High Radiation Area.

2. ISP-3 Counting Instrument Checks and Usage

Please expand upon the formula used to calculate minimum detectable counts. We are not certain as to where the values 2.71 and 3.29 came from. Our reference material indicates that the calculation for minimum detectable activity = 2.71 + 4.65(sqre. root of background).

3. ISP-4A Daily Checklist

Modify your checklist to include what is considered to be the trigger levels for the air monitor chart. This will enable the individual who conducts the daily checks to quickly identify an abnormal reading.

4. ISP-6 Monthly Checklist

In comparing this checklist against the old one, we noted that you deleted a check of the Isotope Shop Air Samples. Please justify why this has been removed, or modify the new checklist to include it.

5. ISP-7 Air Monitor System

Modify this ISP to include procedures and frequency for calibrating the air pump used in your air sampling system.

Item 2.1 states that routine safety checks will be done monthly <u>or</u> any time there is an abnormal increase. At a minimum, these checks must be done monthly, therefore please change the word "or" to "and".

In accordance with ALARA, trigger levels should be no greater than 10 percent of Part 20 limits. Modify the limit specified in item 3.9 to be 10 percent of the Part 20 limit

for air effluent concentration to be consistent with ALARA. Also, add the trigger level to the air system monitor check sheet, ISP-7A.

6. ISP-8 Air Monitor Calibration

Item 3.9 describes how you will calculate the alarm set point for air monitors. The calculation uses the DAC for cobalt-60 (1E-8 μCi/ml). In accordance with the ALARA philosophy and 20.1502, modify the calculation to use 10 % of the DAC for cobalt-60 as an alarm set point.

7. ISP-9 Portable Air Samples

In accordance with 10 CFR Part 20 and current available guidance on air sampling, i.e. NUREG-1400, your policy for performing breathing zone sampling should require that samples be collected when operations are likely to create a situation where airborne contamination will exceed 10 percent of the applicable derived air concentration (DAC). The value of 1E-8 μCi/ml airborne activity is the DAC for cobalt-60. Section 20.1502(b)(1) requires air monitoring if a worker is likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI. Applying this to the DAC (one ALI = 2000 DAC-hours), an action level of 10 percent of the DAC (i.e. 10 % of 1E-8 μCi/ml (DAC for Co-60)) should be used. Alteratively, you can demonstrate that an individual is not likely to receive, in one year, an intake in excess of 10 percent of an ALI.

Also, include in this ISP a procedure for calibrating air pumps associated with the portable sampling stations.

8. ISP-11 Entering the Hot Cell

Item 2.5 contradicts statements made in Item C.1 on page 31 in Chapter 2. We need a clear commitment that the RSO <u>will be present</u> during all entries into the hot cell

Item 2.6 states that individual must be adequately trained prior to being allowed entry into the hot cell. Please define what you mean by adequate training. Specify what the minimum dosimetry requirements will be for individuals who will enter the hot cell.

Item 3.1.1 states that "all isotopes must be placed in the shielded floor containers" prior to entry. Define what you mean by "all isotopes".

Expand upon item 3.1.2. Provide a maximum acceptable level of decontamination. The statement "decontaminated as completely as practicable" lacks specificity.

Item 3.1.5 states that a survey of the hot cell will be

performed prior to entry using a "remote instrument". Please describe the remote instrument. Provide make and model number, radiation detected, and range covered.

Item 3.1.6.b. discusses alarming rate dosimeter trigger levels, and indicates that the RSO can determine appropriate levels for the devices to be set at. Describe the criteria that the RSO will use to determine trigger levels. Also, specify an upper limit trigger level.

Describe what you mean by the term "at the door opening". What was the basis for choosing the 20 R/hr as a limit for proceeding with work in the cell?

Describe how personnel will "monitor exposure periodically" as stated in item 3.3.3. What dosimetry device(s) will be used?

As a final comment on this section, we recommend you incorporate procedures for performing continuous air sampling while working in the hot cell. The likelihood of creating an airborne situation increases when work is being done. Commit to continuous air sampling while performing work in the hot cell, or justify why you feel it would not be necessary.

9. ISP-12 Exhaust Filter Change in the Cell Machinery Room

We have an overall concern with this procedure. It is our understanding that you currently do not have any staff that has performed this function. After review of the procedure, we question whether it provides enough detail such that the filter change could be accomplished by someone who has never done it before. Also, it may be helpful if the procedure included diagrams of the key steps of the procedure. Please address our concern.

Explain how you determine when filters need to be changed. for example, we suspect that filter change may be warranted when they become saturated and survey readings reach a certain point, there is a measured change in pressure across the filters, or the stack monitor reaches a trigger level. Describe in detail the criteria used to determine filter change.

As noted in ISP-11, define what is meant by "all isotopes", as noted in Item 3.1. As far as we are aware, the only isotopes used at your facility are cesium-137 and cobalt-60.

This procedures does not indicate that your portable HEPA filter system will be used while changing out filters. In order to reduce the likelihood of an intake of radioactive material as well as a means of preventing escape of material outside the room, we recommend that you modify the procedure

to require that the portable unit be used. If the unit is inoperable, submit a timetable for getting it repaired.

Item 3.10.7 states that the removed filter is "places in a special radioactive filter box". Describe what the "special radioactive filter box" is. A photograph may be helpful.

In order to evaluate the likelihood of an intake of radioactive material while wearing a respirator, item 3.16 should include a step that requires a smear be taken of the inside of a respirator after work is done and before it is placed in a bag for disposal. Please incorporate this step into the procedure.

10. ISP-13 Receipt of Radioactive Material

Items a. and b. of Section 3.2.1 should be reversed. That is, upon receipt of a package containing radioactive material, the package should first be surveyed at 1 meter, followed by a survey at contact.

11. ISP-14 ALARA program

Please include a review of air sampling results in the periodic reviews conducted by the RSO as described in Section 3.2.2.

Item 3.2.3 a. indicates that the RSO will schedule briefings and educational sessions to inform workers of ALARA Program efforts. What does this mean? What will be the criteria for scheduling a briefing? What will be the minimum frequency of the educational sessions?

12. ISP-15 Control of Transient Combustibles

In comparing these procedures with the old ISP on this topic, we noted that you have removed the section containing definitions. For ease in understanding this topic and to assist in our review, we recommend that you insert the definitions into the new ISP.

Please clarify Item 2.3. We're not sure what you mean when you say the "the handling, use and temporary staging of ordinary combustible materials shall be governed by the RSO". This implies that the RSO can change procedures, make modifications, etc. at will. If this is the case, demonstrate how the RSO is qualified to evaluate and make such changes.

Explain what sentenced no. 2 of Item 3.4.3 means. We are not sure what is meant by "source related activities".

Once again, as appears in numerous ISP's, Item 3.4.4 grants the RSO the ability to designate someone else to fulfill a

specific duty. Describe the criteria the RSO will use to determine if another individual is qualified to fulfill this responsibility.

13. ISP-21 Packaging and Labeling Depleted Uranium Parts and Subassemblies

The shipping paper must also include an emergency response telephone number. Also, the shipping paper must be accompanied by an emergency response sheet (reference 49 CFR 172, Subpart G). Please make these necessary modifications.

14. ISP-23 Calibration of Portable Radiation Detection Instruments

Include in this ISP a procedure for calibrating your alarming dosimeters, and specify at what frequency survey meters, pocket and alarming dosimeters will be calibrated.

15. ISP-24 Dosimetry Procedure and policy

Item 3.10.1 states that anyone desiring to know their film badge report should contact the RSO. 10 CFR 19.13 requires that radiation exposure be reported to the individual. Please modify the ISP to reflect the requirement of Section 19.13.

16. ISP-25 Packaging of Solid Radioactive Waste

Item 2.8 discusses breathing zone air samples during compactor operation. It is our understanding that you do not perform waste compaction, therefore please remove the reference to compaction from this procedure.

17. ISP-26 Shipment of Solid Radioactive Waste

Item 3.5.2 provides a description of items that must be included on a Bill of Lading. In accordance with DOT regulations, please incorporate a description of emergency procedures must be added as well. Please modify item 3.5.2 to include emergency procedures..

Item 3.6.3, under the Section for transport vehicle requirements, only applies to exclusive use vehicles. This is not made clear in the procedure. Please modify the procedure to clarify this point.

18. ISP-29 Radiation Work Permits

References are made throughout this ISP that imply the RSO or designee will be responsible for preparation, use, etc. of radiation work permits. We do not feel that these tasks should be delegated to anyone. Therefore, please modify your procedure to remove all references to a designee.

Item 3.3.1 c states that prior to entering an area that requires a radiation work permit, workers shall obtain radiation safety job coverage, if required. It is our feeling that prior to performing any work that requires a radiation work permit, radiation safety job coverage would always be required. Please describe criteria used to determine the need for radiation safety job coverage.

19. ISP-30 Respiratory Protection Program

As noted in Item 2.6, it is our understanding that you do not plan on taking credit for using respiratory equipment by applying protection factors. If this in fact is your intent, then we recommend that you remove this procedure from your application. If it remains a part of the application it will be tied down in your license and is therefore subject to inspection. If you want to leave it in your application, then we recommend you review the procedure against the requirements of 10 CFR Part 20, Section 20.1703. We have reviewed ISP-30 and determined that it does not satisfy Sections 20.1703(a)(3)(i) and (ii).

Describe the methodology/equipment used to determine the percent available oxygen as noted in Item 3.3.1.

Item 3.5.1.g. states that filters used in respirators will be replaced if, after or before each use, the radiation level is greater than 2 mR/hr. This is not acceptable, and is clearly not in keeping with the concept of ALARA. Any filters that read greater than background should be replace. Please modify your procedure accordingly.

20. ISP-31 Isotope Technician Training Program

Item 3.0 D. states that upon completion of training , the candidate will be able to calibrate survey instruments and meters. Is it your intention to calibrate instruments in-house? Based upon ISP-23, it is our understanding that survey meters will be shipped to the vendor for calibration. If you plan to calibrate instruments in-house you must submit your procedures for our review.

21. ISP-32 Isotope Handler Training Program

Item c. of Section 3.0 states that upon completion of training, an Isotope Handler will be able to leak test and calibrate sources. Describe what "calibrate sources" means.

22. ISP-33 Inspection and Procedure for Containers with Overpacks Authorized for the Shipment of Radioactive Material

Survey procedures described in Item 3.0 should be modified to first require a survey of the container at a distance of

1 foot, then at the surface, followed by a wipe test.

VIII ~~IX~~. Waste Management

A. References were made in your operating procedures which indicate AMS will be compacting waste. However, in Section 1.7 of Notebook 2 to your application, compaction of waste is not discussed. Compaction of radioactive waste presents a number of potential hazards including the potential for intake of material, spread of contamination, etc. If you will compact waste at your facility you must address the attached document pertaining to compaction. If you will not compact waste at your facility please so state. Also, verify your understanding that you must request and receive an amendment to your license prior to compacting radioactive waste at AMS.

B. We have reviewed your proposal to store radioactive for on-site waste at your facility and ask that you submit the following additional information:

1. Identify any additional permits or approvals necessary for storage (i.e., EPA hazardous waste permit, State or Local approvals, etc) and the status of each required approval.

2. Demonstrate that the waste will be protected from weather at all times. Describe vulnerability to hazards such as tornadoes, flood, industrial accidents, etc.

3. Describe expected exposure rates, needs for shielding (if any) and any changes in personnel monitoring which will be required as a result of waste storage. It is recommend that TLDs be place in specified areas in and around the area to monitor exposure.

IX ~~X~~. Service Operations

A. The section entitled General on page 3 of Notebook III implies that certain service operations may be performed by service personnel who are certified by the Isotope Committee. This implies that such individuals need not be approved via an amendment to your NRC License prior to performing service. Please modify this section to make it clear that in addition to being approved by he Committee, AMS must receive an amendment to its NRC license authorizing service engineers.

B. Please indicate what trigger level will be set for personnel who wear the alarming rate dosimeters as described in Item C. on page 8 under the section entitled Personnel Monitoring.

C. Under Items B.2. and 3. on page 15 under the Section entitled Head Leakage Radiation Survey, it is implied that source leakage is evident if the sample smear results in greater than 2000 cpm.

Without knowing the efficiency of the instrument used, results in cpm are meaningless. Smears initially evaluated with a GM that result in levels above background should be analyzed for dpm to determine the activity removed. This value can then enable you to truly determine whether or not the source is leaking. Please modify your procedure.

~~XI.~~ Cost Estimate for Decommissioning Funding Plan

- APS

  # pages in Section I ? without ...

  19 pages + what revision # for each page

1- I-19 - all Rev. 1

How many pages in each Section & appendix + what revision at each page.

Also, there are pages & page #'s, maps

I. B. → Does NRC have an engineer to look at the licensee's submitted re: engineering analysis.

Fire Wall

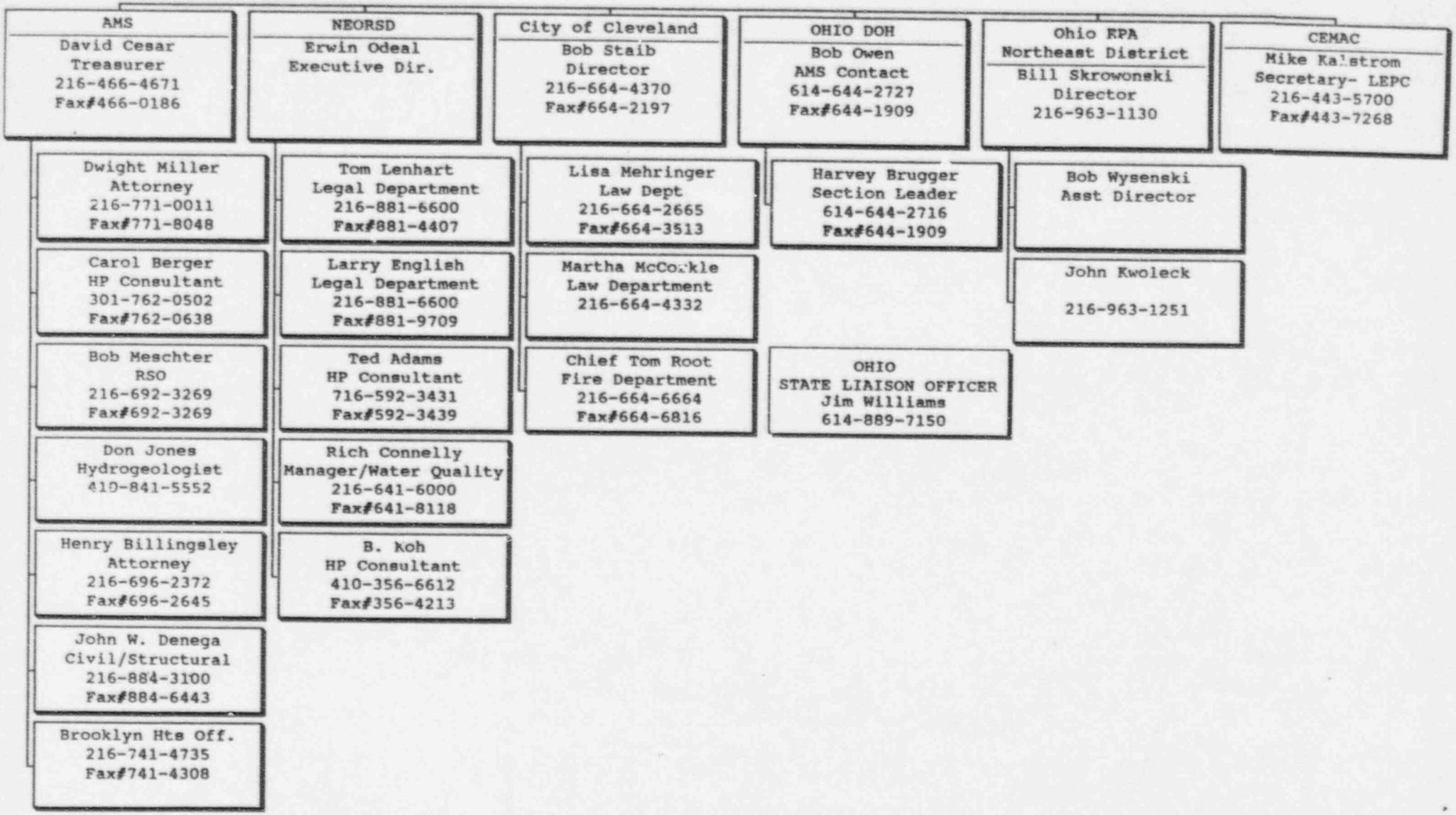
Ask Shemanski to look at our letter (I.B).

... example → ... earthquake ... & ... source ... garden.

+

D17

ORGANIZATIONS INTERESTED IN AMS ISSUES



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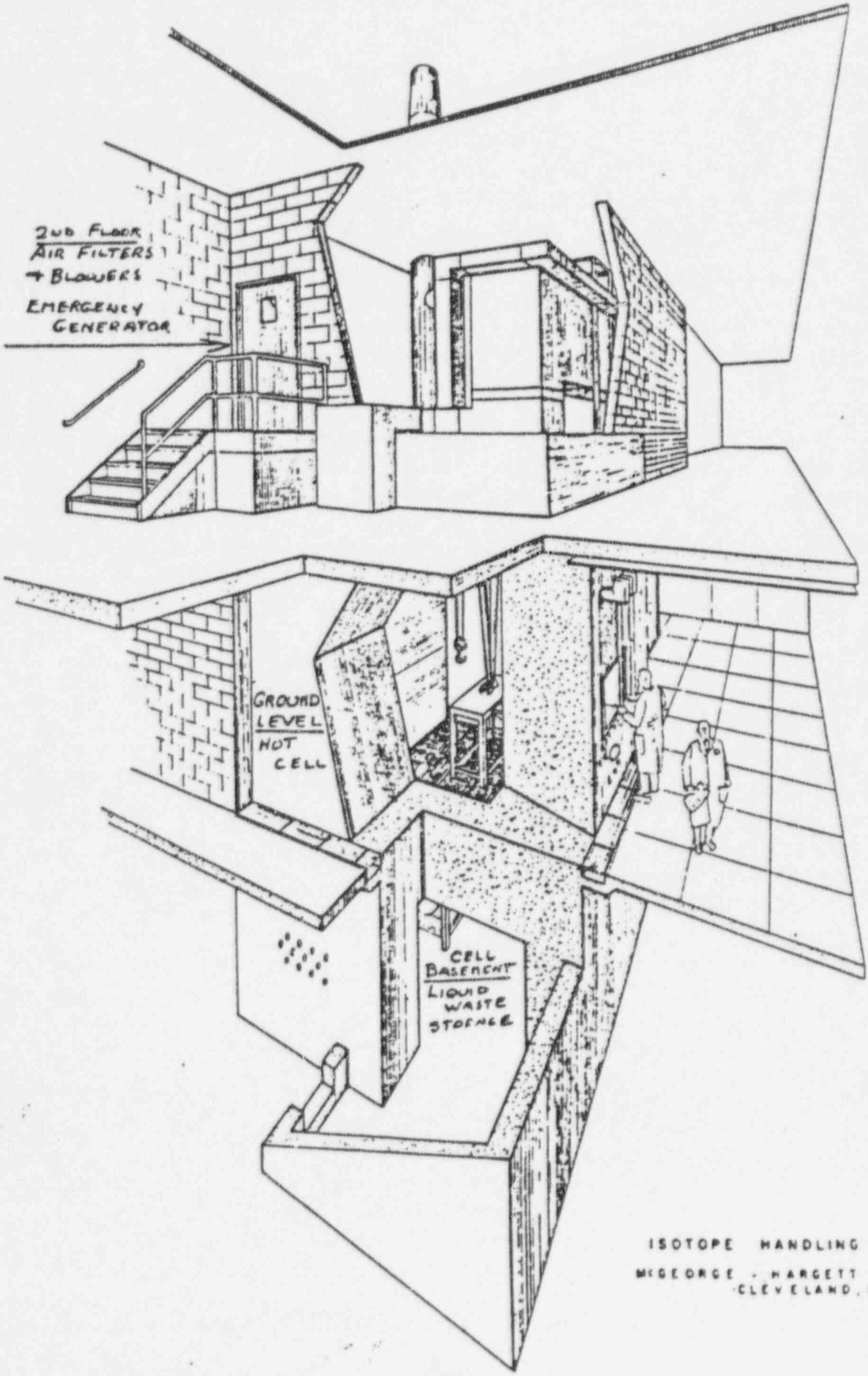


ISOTOPE HANDLING FACILITY.

McGEORGE - HARGETT & ASSOCIATES
CLEVELAND, OHIO

D/9

DESCRIPTION OF THE ISOTOPE FACILITY

The design of the facilities follows the pholosophy of containment of activity within small working areas. Health and safety considerations have been based on minimum hazard in controlled areas and zero hazard in uncontrolled areas, with confinement of emergency situations to the Isotope Shop Area.

The Isotope Facility is situated on 6.3 acres of land which lies on the boundary between industrial and residential areas. Because of proximity to these areas, special care has been exercised in planning the safety program. The Isotope Shop Area is located in the south end of the building on the first floor. There are no windows in the Isotope Shop Area because windows were felt to be of questionable value for a number of reasons. Safety considerations and protection against un - authorized entry into the Isotope Shop Area are simplified when there are no windows. The maintenance of proper air flow balance and of uniform lighting is also simplified. Other considerations were the noise trans - mission of windows from the adjacent railroad tracks and the special procedures required for cleaning windows inside controlled areas and the possible radiation hazards of cleaning windows on the outside.

The one story projection of the southwest corner of the building con - tains the stairwell to the basement and the source storage garden. The door located in this stairwell is for emergency exit use only.

Page 22 is a floor plan of that portion of the first floor of the facility which contains the Isotope and Shielded Work Areas. The controlled access areas are enclosed by the heavy dashed line. The location of the heavy shielding for the shielded work room and the cell provides an unbroken radiation barrier between the isotope areas and the high occupancy areas of the rest of the building.

The activity centers of the facility are the high level hot cell, the Shielded Work Room, the offices and the Isotope shop area and an isotope storage and irradiation facility.

The areas in which radioisotopes are handled are reached through a change area located in the southeast corner of the building.

THE SHIELDED WORK ROOM

The Shielded Work Room has a minimum of three (3) feet of concrete shielding and a labyrinth entrance. The broad corridor through the labyrinth entrance permits large objects to be moved into the room

This room is used for development, manufacture and testing of equipment.

HOT CELL

The Hot Cell has been designed and equipped to encapsulate the largest sources used for medical therapy and industrial radiography. With the exception of the shielding walls themselves, virtually every item in the cell structure and equipment is removable to permit changes which the future may require.

The hot cell is six feet square inside, and has 5 - 1/2 foot concrete walls and 4 foot floor and ceiling. The floor pan is stainless steel and the inside walls are 1/4 inch steel plate to a height of 11 feet. The cell is closed at the rear by a 42 ton hinged door which provides a full 6 foot wide entrance to the cell when open. Numerous small access ports are located on the front and side faces of the cell, and a 20 inch square port opens from each side. Observation of cell operations is possible through a 60 inch glass and zinc bromide window. Remote handling is accomplished with a pair of Model 8 Manipulators and a 2 ton overhead crane.

All cell operating controls are located on the cell face, so that normal operation does not require entry into the contaminated isotope areas. The isotope areas may be observed from the cell control area by a window through the southeast corner of the cell in line with mirrors placed against the south wall. The Isotope areas are connected to the control area by an intercom system.

The viewing window for the cell is removable from the outside of the cell. (D) The viewing components consist of an eight inch inside coverplate of nonbrowning glass, a 2" plate glass, 48 inches of zinc bromide solution and a two inch outside coverplate of safety glass. This construction provides shielding equivalent to 66 inches of 150 lb/ft^3 concrete with only two glass/zinc bromide interfaces. The entire metal structure in contact with the zinc bromide solution is coated to prevent introduction of impurities which might cloud the zince bromide solution. The window was designed and constructed in 1984 by Hot Cell Services Corporation, Kent, Washington.

The Model 8 Master Slave Manipulators are mounted above the window using the roller - tube mounts. The roller tubes are positioned on 28 inch centers in concrete within a 24 by 58 inch steel - lined opening in the cell wall. This method of mounting in an oversized opening will permit installation of new types of manipulators as they become available, or relocation of the present manipulators to a different centerline if required by future operating conditions.

The cell door is located at the rear of the hot cell and opens into the decontamination room. The door is an internally braced steel tank filled with concrete. The upper and lower stub shafts of the door are mounted on bearings which permit the door to rotate about a vertical line through on end without touching the floor or ceiling at any point. This construction permits a

smooth unbroken level floor into the cell over which heavy shipping containers can be easily moved. The 40 ton door is removable in case of bearing failure, but due to the low rotational speed and infrequent operation of the door, a long service life is anticipated. The turntable upon which the door rides contains a heavy duty bearing mounted on a hemispherical ball - joint to permit alignment of the lower bearing with the upper bearing. The upper hinge has the bearing mounted in a block which can be moved by means of wedges and power screws to obtain the necessary alignment for a true axis of rotation. The stub shaft connecting the upper hinge to the door is removable through a 9 foot vertical tube to the second floor level. The upper bearing is a sealed unit and should require no lubrication. The lower bearing, at floor level, may become dirty or contaminated even though a neoprene wiper rides the edge of the turntable. The lower bearing may be lubricated, or flushed and lubricated if dirty or contaminated, by means of a tube which runs beneath the floor level to the service trench on the south side of the cell. The door is opened and closed electrically by means of a motor mechanism mounted on the outside of the door. An electrical interlock prevents the electrical door drive from being actuated until the switch at the cell face and the drive motor switch are simultaneously operated. Release of either button stops the door opening. This safety feature makes it impossible for the cell door to be opened without the knowledge and consent of the cell operator, or for the cell to be opened by a person working alone. The two ton overhead crane inside the hot cell is electrically powered and controlled. In order to cover the six foot square floor area of the cell with a minimum of travel, an electrically powered trolley was mounted on an I - beam rail which can be rotated 180°. The crane assembly is mounted in a removable plug in the cell ceiling.

Storage facilities for isotopes within the cell are provided by two lead containers inserted in steel sleeves in the floor.

Two prefilters for the hot cell are mounted just above the viewing window.

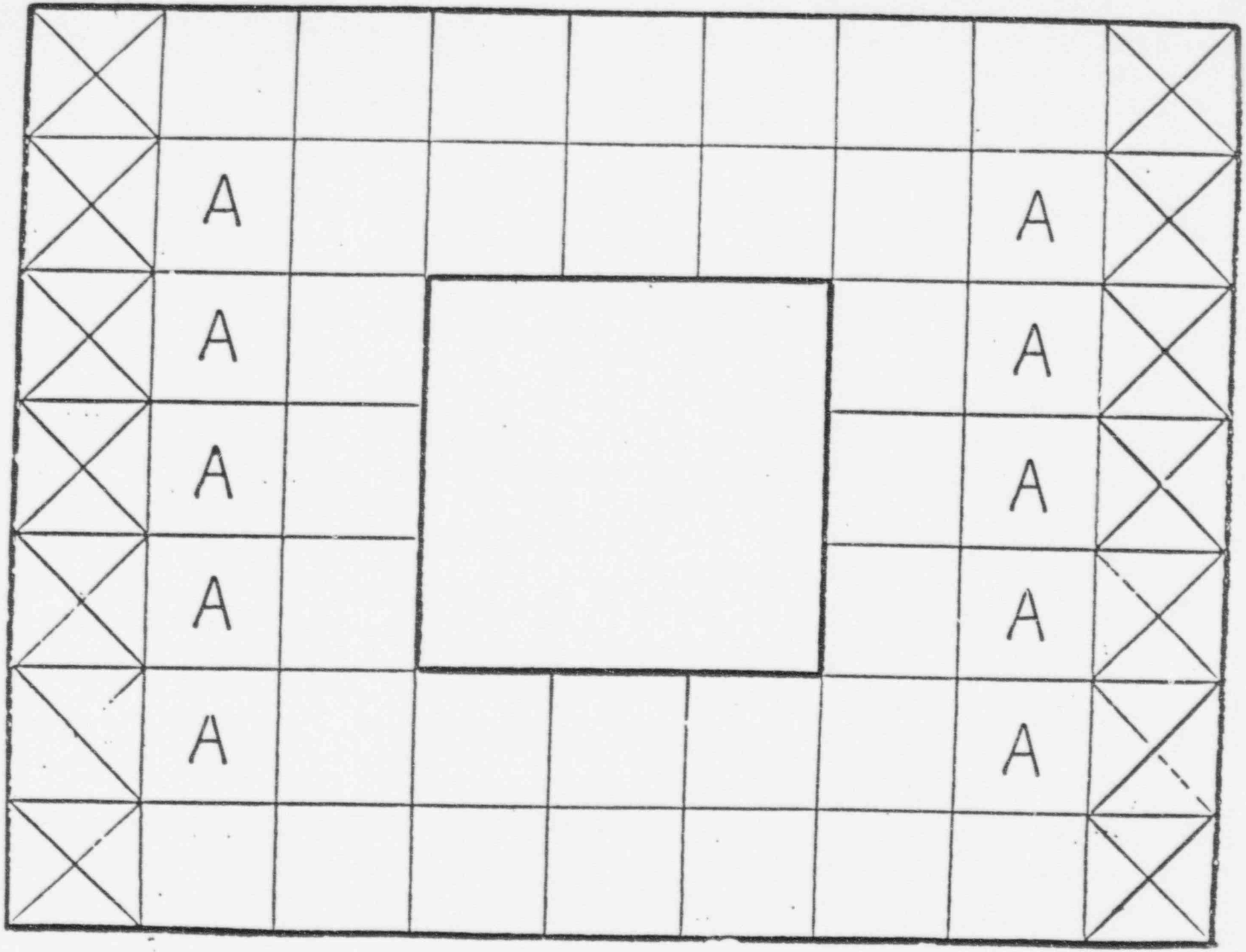
As mentioned previously, the hot cell is shielded by 5 - 1/2 feet of concrete, with 1/4 inch steel plate on the inside faces. The shielding thickness was chosen as sufficient to handle the largest sources currently available with complete safety, and to provide adequate shielding for the larger sources the future may require. Calculations indicate that the shielding is adequate for 1.5 million Curies of Cobalt - 60.

STORAGE GARDEN AND IRRADIATION FACILITY

The facility is located in the southwest corner of the building and contains vertical storage tubes in a six foot square well extending from the first floor level to the basement floor level. An L - shaped shield around the well is provided by two sand filled shield rooms which are accessible through man - holes in the first floor. Coarse concrete sand with a bulk density of 127 lb/ft^3 was used as the shielding material for a number of reasons. Imme - diate shielding requirements are easily handled by the use of sand, which can, of course, be replaced easily by a higher density material in the future, if desired. The rooms have been waterproofed and a well drilling point extends to the basement floor level beneath each manhole cover so that temporary additional shielding may be obtained by flooding the voids of the sand with water. Flooding increases the shield density by 7 lb/ft^3. If storage needs ever require it, the rooms can be emptied and filled with concrete, steel shot or other higher density material.

The storage 'garden' is constructed with 54 vertical storage tubes in a rectangular array. The tubes are arranged in a 7 x 9 array with the center nine spaces left open, (see next page). The center space is fitted with an irradiation plug which can be used to irradiate objects up to 8 - 1/2 inches square by 12 inches high. Each of the tubes marked 'A' can also be used for irradiation by placing sources in the four tubes around each which have a common side. The two outer rows of seven tubes, marked by crosses, extend about two feet below the bottom of the tubes in the central 7 x 7 array. This permitted installation of an irradiation facility beneath the garden with two parallel rows of sources between which objects up to a 17 inch cube can be irradiated.

The source storage tubes terminate in a metal container through which cooling air is drawn from the room through the 'garden' to the absolute filter exhaust system.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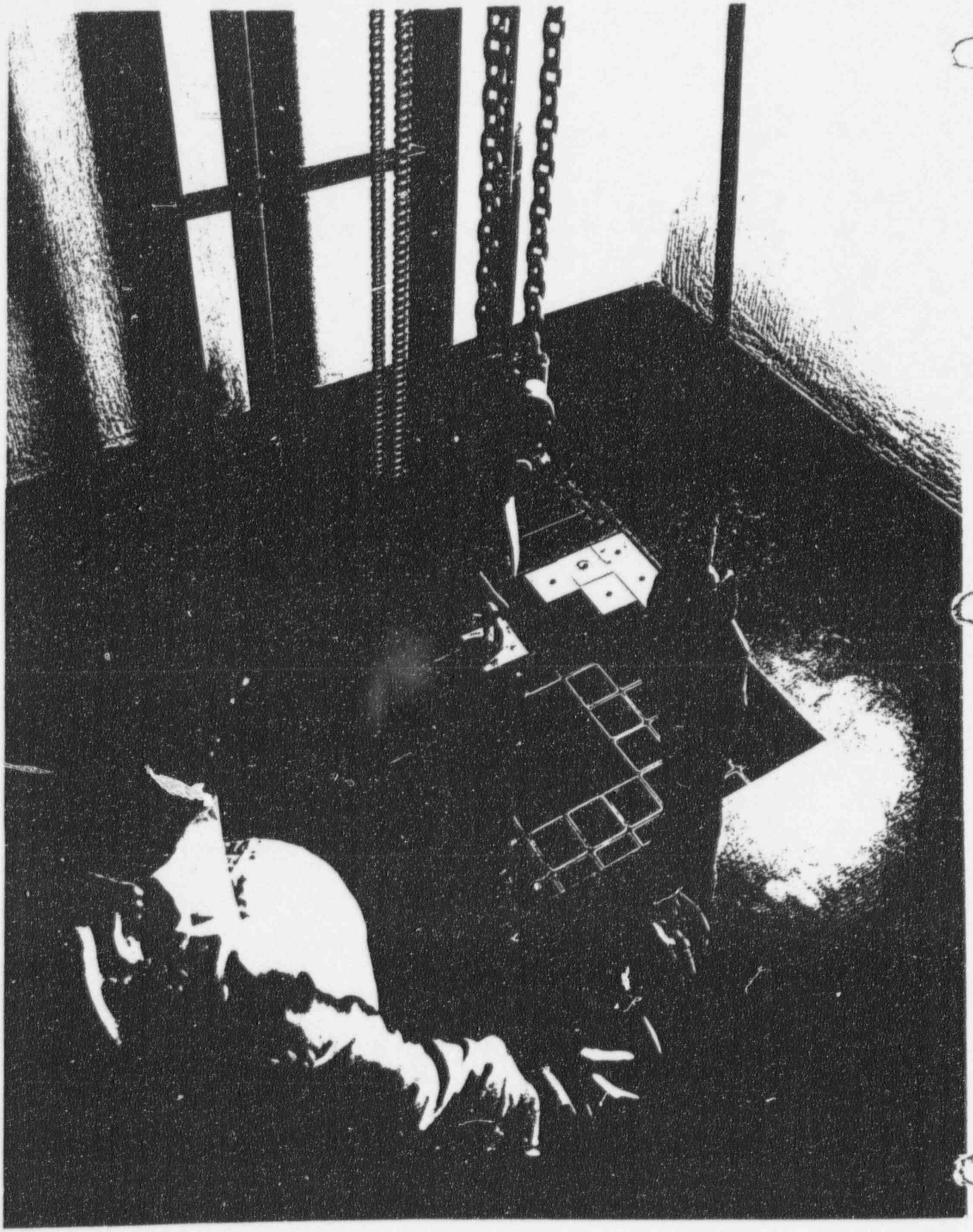


The isotope storage garden, located in the S/W corner of the isotope lab.

I. MASTER ALARM SYSTEM

Six safety and monitor devices are connected to the Master Alarm Panel in the Cell Control Area and to the Remote Alarm Panel in the Isotope Shop Area. The separate red lights for each controlled item are always dimly lit on the panel, so that faulty operation of the panel itself is indicated by no light. When a controlled item malfunctions, the alarm light is increased in intensity and flashes on and off. In addition, a loud buzzer sounds on and off in synchronism with the flashing lights. This will continue until the acknowledgment button is depressed, causing the buzzer to stop and the flashing light corresponding to the malfunctioning item to change to a steady bright red. The alarm can be erased only by correcting the difficulty after depressing the acknowledgement button. In addition, two other warning lights show on the Master Alarm panel; one for the Equipment room door and for the Cell Machinery room door on the second floor, and one for the basement door in the Isotope Shop Area. These will indicate steady bright red lights when the doors have been opened and indicate to the Hot Cell operator that personnel are in this area. Evaluation tests indicated that no unusual hazards exist in these areas under normal cell procedure, but the precautions should be taken nevertheless. On five of the six major systems, any alarm is transmitted to the local burglar alarm company so that malfunctions during non - working hours are reported to a responsible person. The emergency generator will not trip the other five alarms if it restores power before the fans stop.

The following are the six safety and monitoring systems and the conditions which will cause an alarm:

A. Cell Exhaust Fan
   1. Shut down from lack of power or switch turned off.
   2. Sudden pressure drop across air filter indicating ruptured filter.
   3. Improper pressure across filter indicating broken belts, fan inoperative, or plugged filter.
   4. Excessive radiation on the air monitor.

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

C. Air Monitor

1. Excessive radiation on filter paper in air monitor or electronic malfunction of monitoring equipment.

D. Cell Temperature

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

E. Supply Fan

1. A thermostat in the intake system after the heaters will give an alarm signal for temperatures below 50° F.

F. Emergency Generator

1. Signal given on power failure when generator starts.

II. HOT CELL SYSTEMS

A. Door Interlock: An electrical interlock secures the door in the closed position until two switches, one on the outside of the door and one on the cell face in the Cell Control area, are de - pressed simultaneously. This safety feature makes it impossible for the cell door to be opened without the knowledge and consent of the Cell operator, or for the door to be opened by a person working alone.

B. Cell Probe: A high energy probe, Victoreen Model 550 Series or equivalent, is used within the Cell to locate loose Cobalt 60 pellets and other high radiation levels. It is connected to Victoreen Model 510 Rate - meter or equivalent located on the Cell face in the Cell Control area. The Ratemeter is autoranging up to 2000 R/min.

C. Gamma Alarm: A Technical Operations Gamma Alarm Model 492c (or equiv.) is mounted opposite the Cell face in the Cell Control Area. Since it is connected to a loud buzzer, it gives both an audible and a visible alarm (flashing red light) continuously when radiation levels are in excess of the preset level of approximately 2 mR/hr. The Gamma alarm features fail safe circuitry to provide a signal at all times. Failure of any element either turns on the red lamp or turns off the green (safe) lamp, signalling improper operation.

III. DECONTAMINATION ROOM

A. The Hot Cell Exhaust fan is driven by a two speed motor which is controlled by the position of the double doors connecting the De - contamination Room with the Isotope Shop Area. With the doors closed, the fan operates at normal speed which is indicated by a yellow light on the locked switch control at the Cell face. With the doors opened, the fan speed is increased for about 50% greater capacity. This prevents reverse flow of potentially contaminated air of the Decontamination Room into the Isotope Shop Area. High speed mode is indicated by a red light on the locked switch control at the Cell face.

IV. ISOTOPE SHOP AREA

A. Gamma Alarm: A Technical Operations Gamma Alarm, Model 492D, (or equiv.) is mounted on the west wall between the Storage Garden and the De - contamination room adjacent to the source transfer operation. This will give a visible flashing red light when radiation exœeds the preset level of 5 mR/hr.

B. Basement Door: When the basement door is opened, a steady red light turns on above the door. Also, a steady red light shows on the Master Alarm Panel.

C. Air Locks:

1. The doors at either end of the Change Area are electrically inter - locked to prevent simultaneous opening which might disturb the air flow pattern. The entrance to the Change Area from the Cell Control Area is an air lock by itself. The first door is interlocked with the door on the opposite side of the Change Area leading into the Isotope Shop Area.

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

V. EQUIPMENT ROOM

A. This room is directly above the Shielded Work Room. This room contains the heating and intake air fan as well as the air conditioners. The floor is shielded with two (2) feet of concrete. A Technical Operations Gamma Alarm, Model 492B,(or equiv.) set at approx. 2 mR/hr is mounted in the center of the room. It remotely indicates a signal above the entrance to the room. No one is permitted to enter this room without permission of the Radiation Safety Officer or Supervisor. Also, PERSONNEL ARE NOT PERMITTED IN THIS ROOM WHEN THERE IS NO SIGNAL WHITE LIGHT OR WHEN THERE IS A RED LIGHT. In Addition, when the door is opened, a steady red light shows on the Master Alarm Panel.

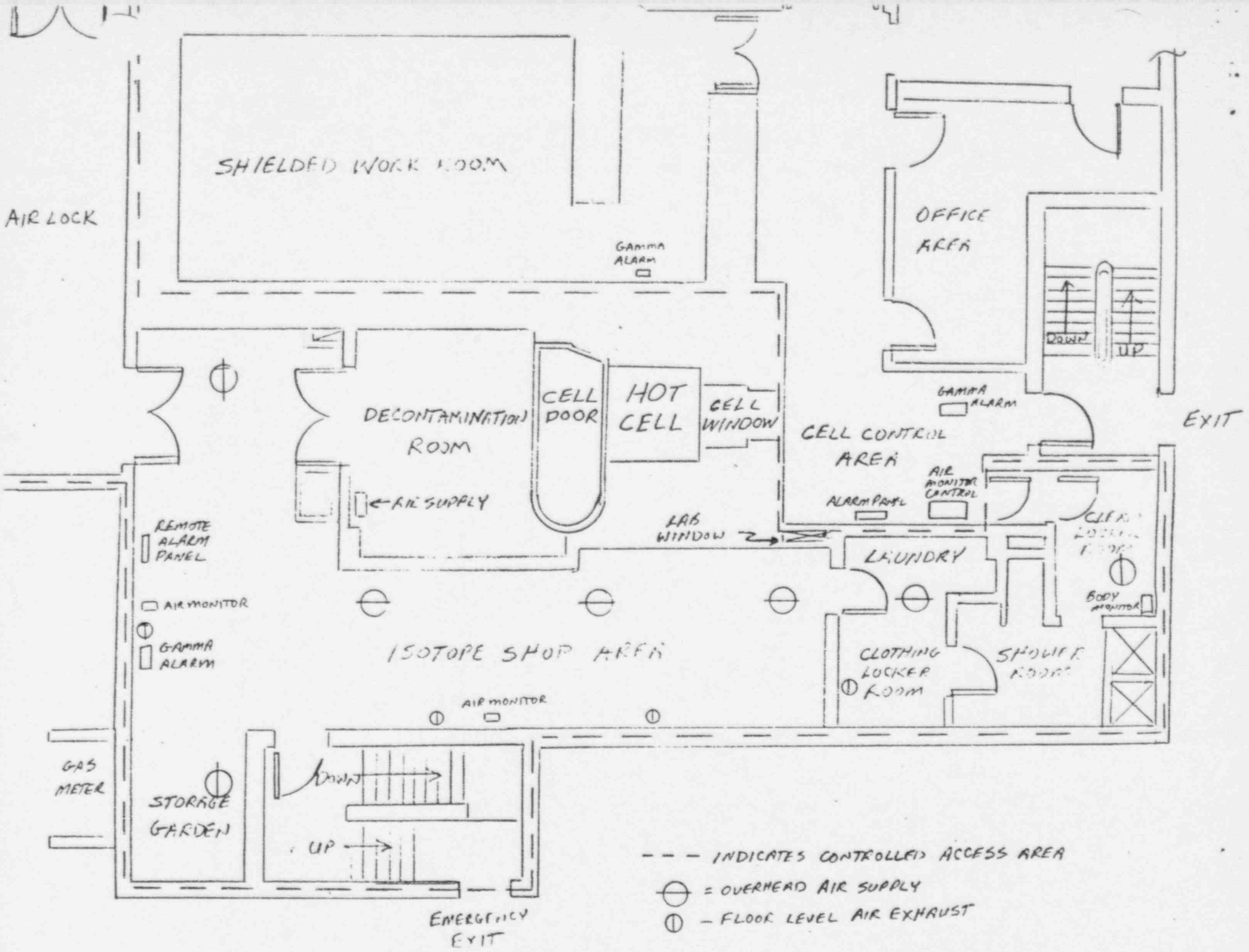
VI. SHIELDED WORK ROOM

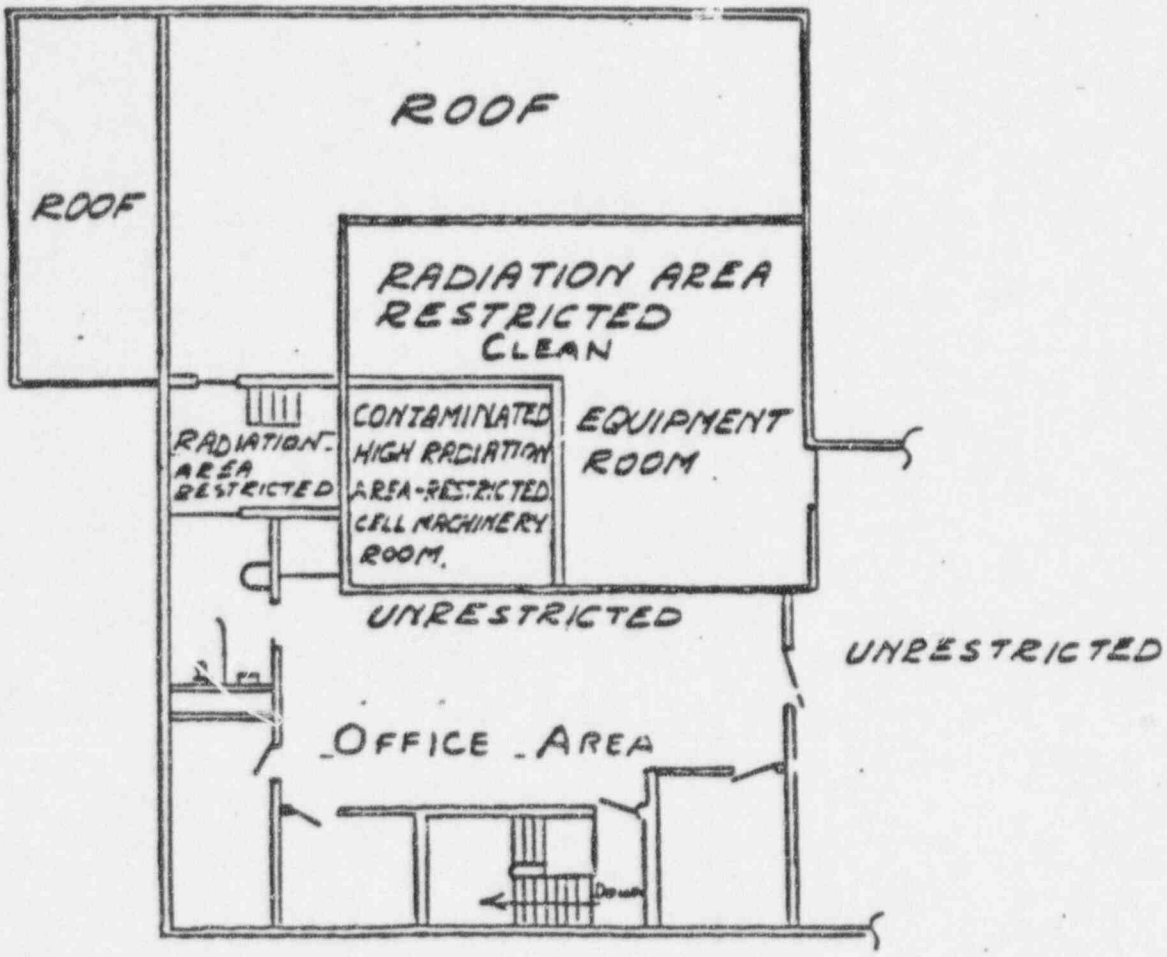
A. Gamma Alarm: A Technical Operations Gamma Alarm, Model 492C,or equiv.set at approximately 5 mR/hr is mounted at the end of the maze in the room. A remote indication over the entrance shows red when the radiation level is in excess of 5 mR/hr and white when the radiation level is below the preset level.

VII. DOORS

A. Only authorized personnel have keys to any Isotope Area. Doors to controlled areas are kept locked at all times. This includes the following:

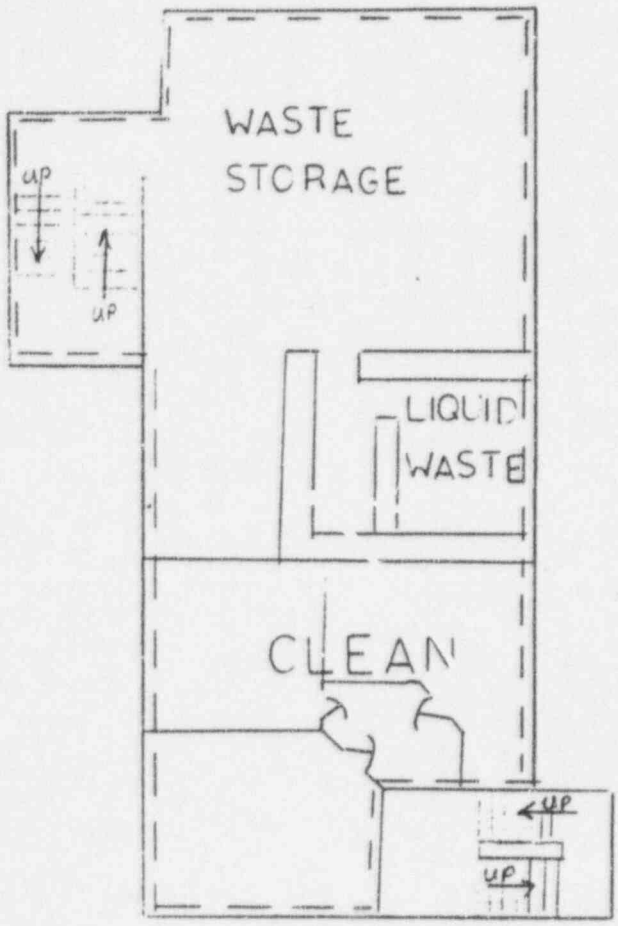
1. Air lock from Cell Control Area to Change Area.
2. Doors from the shop area to the air lock
3. Doors from the Warehouse to the above air lock.
4. Doors from the air lock to Isotope Shop Area.
5. Doors from the Warehouse to the shop area on the Northeast side of Warehouse.
6. Equipment Room on second floor.
7. Cell Machinery Room on second floor.
8. Room adjacent to Cell Machinery Room.
9. Basement door opening to clean side of basement.
10. In addition to above, the perimeter of the entire facility is tied in with a local burglar alarm company (ADT).


SHIELDED WORK ROOM
AIR LOCK
GAMMA ALARM
OFFICE AREA
DOWN
UP
EXIT
DECONTAMINATION ROOM
CELL DOOR
HOT CELL
CELL WINDOW
GAMMA ALARM
CELL CONTROL AREA
AIR MONITOR CONTROL
ALARM PANEL
AIR SUPPLY
REMOTE ALARM PANEL
LAB WINDOW
LAUNDRY
AIR MONITOR
GAMMA ALARM
ISOTOPE SHOP AREA
BODY MONITOR
CLOTHING LOCKER ROOM
SHOWER ROOM
AIR MONITOR
GAS METER
STORAGE GARDEN
DOWN
UP
EMERGENCY EXIT
- - - INDICATES CONTROLLED ACCESS AREA
= OVERHEAD AIR SUPPLY
- FLOOR LEVEL AIR EXHAUST



ISOTOPE FACILITY ~ 2ND FLOOR.

APPROXIMATE SCALE $\frac{1}{16}$" = 1 FT.



---INDICATES RESTRICTED AREA
CONTROLLED ACCESS

BASEMENT

SCALE 1/16"

Exerpt from "Rad Services"
1986 Decon Plan

PRELIMINARY SURVEY
WEST BASEMENT

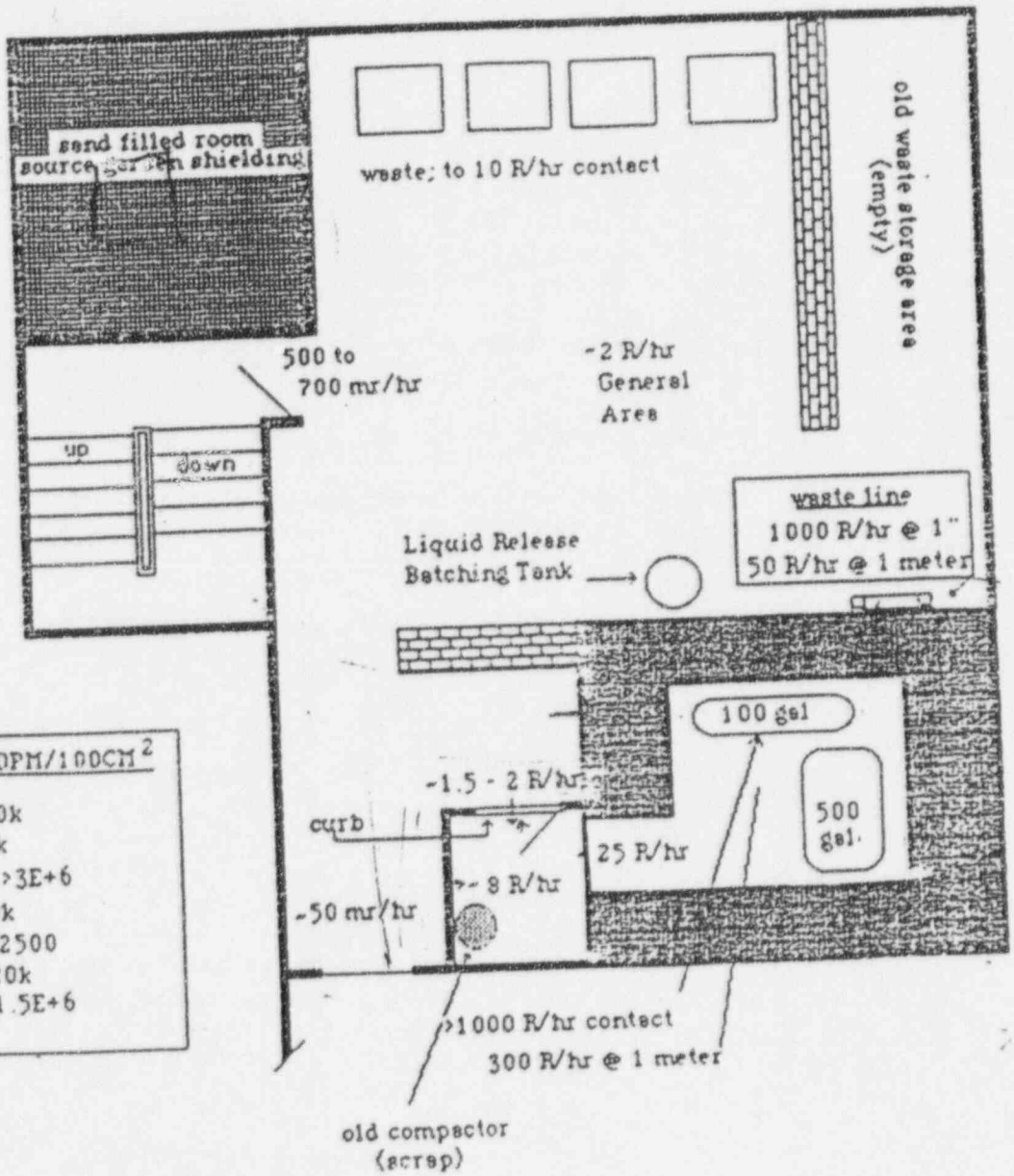
Surveyed by: P Gianutsos & T Spohn

Date and Time: Aug. 21/22, 1986

Survey Instruments: RO-2a #003 Lud 177
1345, Teletector #28821 PRM-6 #2525

Air Sample Concentration: 8.9E-10 µCi/cm³

MPC (assume ^{60}Co): 10%



CONTAMINATION LEVELS, DPM/100CM²

Floor at door:	40k to 150k
Lower steps:	40k to 90k
First Landing on Stairs:	>3E+6
Upper Steps:	20k to 60k
Walls:	<1000 to 2500
Hand Rails:	60k to 120k
Basement Floor:	90k to 1.5E+6

Approximately 1-2 inches of dry sludge out to curb in Waste Tank cubicle. Unable to measure dose rate from sludge due to shine from tanks. No samples taken at this time. Condition of floor in cubicle: Floor in general basement area is unpainted concrete. Shield blocks in area also unpainted. Floor drain plugged.
Contamination on stair well landing probably due to past storage of leaking rad waste

Advanced Medical Systems, Inc.
121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 810-4272-183

February 8, 1988

U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Attention: Bruce S. Mallett
George McCann

Re: License No. 34-19089-01

Gentlemen:

The AMS/NSS Decontamination Plan dated October 16, 1987 (last revision), approved by the NRC, presents one unresolved issue. This issue involves the proposed isolation of the Waste Water Hold Up Room. NSS had proposed the isolation of this room in lieu of decontamination. The isolation procedures would be conducted in order to prevent any danger to the environment or public health and safety. The NRC stated during a conference telephone call between T. J. Hebert, AMS; James Elkins, NSS; and Bruce Mallett, et al NRC, on October 22, 1987 that they would consider the isolation proposal pending further information and discussion.

NSS has proposed a brief, attached to the letter, which outlines the reasons why this area should be isolated, the methods used in isolation, and the procedures for monitoring the area after isolation.

Also attached to the AMS Decontamination Plan are letters from Dr. Allen Brodskey (AMS Consultant) which states his opinion in reference to the risk benefit ratio associated with the decontamination of the Waste Water Hold Up Room.

AMS does not intend to have any future use for the Waste Water Hold Up Room following the completion of the facility's decontamination. This discontinued use will not adversely affect the AMS operations of the Hot Cell and Isotope Handling facility. The use of water as a cleaning agent will be discontinued in favor of more current methodologies. The limited volume of water generated in the hot cell to test source leakage will be confined to the hot cell. As generated, this water will be evaporated or solidified and handled as solid waste. Waste water generated at the clean change (locker room) area for personal hygiene will be monitored and released to the city sewer system according to Regulation 10CFR, Part 20.303. The discharge from the clean change area was previously rerouted from the area to be isolated.

AMS has in place an NRC approved decommissioning plan which involves the active contribution to a trust fund designated solely for the purpose of financing the facility's decommissioning. The isolated Waste Water Hold Up Room would be decontaminated and/or decommissioned at the time of the facility's closure. A copy of the decommissioning plan and trust agreement are attached.

ATTACHMENT A

NUCLEAR SUPPORT SERVICES, INC.
POST OFFICE BOX 3120, HERSHEY, PA 17033 PHONE 717-838-8125

February 8, 1988

Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, OH 44041

ATTN: Ted Hebert
General Manager

SUBJ: Revision of the AMS Decontamination Plan to allow isolation of the Waste Hold Up Tank (W.H.U.T.) Room.

REF: a) Meeting at the AMS London Road Facility on Friday January 29, 1988 between Jim Elkins (NSS), Joe Harverson (NSS), Leland Schroder (NSS), Ted Hebert (AMS) and Howard Irwin (AMS) regarding the above subject.
b) Meeting scheduled with NRC, AMS and NSS on Wednesday February 10, 1988 regarding the above subject.

ENCL: NSS Recommendation dated February 8, 1988 to AMS regarding remedial action (isolation) for the Waste Hold Up Tank Room at the London Road Facility.

Dear Mr. Hebert:

As requested during the meeting referenced above, NSS completed an in depth reveiw of the Waste Hold Up Tank Room to determine whether decontamination or isolation would be a more logical approach based on total exposure, environmental impact, dollar cost and risk benefit ratios. The completed NSS evaluation of the Waste Hold Up Tank Room is enclosed for your review and submittal to the NRC.

Joe Harverson will be at your London Road Facility on Wednesday February 10, 1988 to answer any and all questions pertaining to our recommendation on isolation of the Waste Hold Up Tank Room. Joe will also be available to meet with the NRC in order to address any questions that the commission might have regarding the Technical approach and methodology NSS used to evaluate the Waste Hold Up Tank Room.

I feel that our isolation approach to the Waste Hold Up Tank Room is very reasonable and that the commission may have questions pertaining to the "how" but should not question the "why" portions of our evaluation.

At the present time we are still on schedule with the original decontamination plan and if approved, isolation of the Waste Hold Up Tank Room should not impact the original schedule at all. If you have any question pertaining to the information contained in this package please feel free to contact me at our Corporate Office in Hershey, PA at (717) 838-8125.

Respectfully,

James E. Elkins
Vice President
Manager,
Technical Support Group

cc: Larry Strassner
Joe Harverson
Robert Flournoy
Mike Williams
Leland Schroder

NUCLEAR SUPPORT SERVICES

RECOMMENDATION TO

ADVANCED MEDICAL SYSTEMS

FOR

REMEDIAL ACTIONS FOR THE WASTE HOLD UP TANK ROOM AT THE LONDON ROAD FACILITY

Prepared by:

Joe Harverson
NSS Project Manager
8 February 1988

Reviewed by:

James E. Elkins
Vice President
8 February 1988

ADVANCE MEDICAL SYSTEMS, INC.
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

TABLE OF CONTENTS

0267p

ALLIANCE MEDICAL SYSTEMS, INC.
SECTION A
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

INTRODUCTION

In October of 1987 Nuclear Support Services, Inc. (NSS) of Campbelltown, PA was retained by Advanced Medical Systems (AMS) to provide the necessary expertise to decontaminate it London Road Facility. At that time, NSS performed a detailed radiological survey of the facility and submitted a Decontamination Plan (NSS Proposal Number 87-217-HP, Dated October 30, 1987) to AMS for approval. In this initial proposal, NSS recommended that the Waste Hold Up Tank Room be isolated due to the danger to personnel in working with the extremely high dose rates found in the room. The proposal was accepted by AMS but was questioned by the Nuclear Regulatory Commission (NRC). In a letter modifying the AMS license to include the NSS Decontamination Proposal, the NRC altered the Decontamination Plan by deleting the paragraph concerning isolation of the Waste Hold Up Tank Room and changing the schedule heading to indicate that decontamination of the Waste Hold Up Tank Room was required. After further study of the room, its condition, the feasibility of safe decontamination, and the need for decontamination NSS still arrives at the same initial conclusion that it was best to isolate the room until such time as the radiation levels decay to a manageable point. AMS requested NSS conduct a detailed study and generate a more in depth report supporting the initial isolation proposal.

ALLIANCE MEDICAL SYSTEMS, INC.
SECTION B
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

FACILITY DESCRIPTION

The London Road Facility's primary function is the manufacture of CO^{60} teletherapy sources. It has been in operation since the mid 1950's when it was owned by Picker Corporation, and contains: 1 Hot Cell, 1 Laboratory, a controlled ventilation system and a controlled liquid waste system. This "isotope area" is only a small part of the building at 1020 London Road. The remainder of the building is vacant. Please refer to appendix "A" (facility blueprints) for detailed drawings, the building and site. As can be discerned from the drawings, the cell and its two (2) support rooms are "stacked" (e.g. the liquid waste room is below grade). The cell sits on top of Waste Hold Up Tank Room and the ventilation room sits on top of the cell. These three (3) rooms are not only structurally interconnected among themselves but also provide support for the remainder of the building. The prevailing isotope is CO^{60} with an extremely high specific activity. The waste generated from the facility is exclusively CO^{60} oxide dust from exposing and handling the pellets in the cell.

0267p

ADVANCE MEDICAL SYSTEMS, INC.
SECTION C
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

WASTE HOLD UP TANK ROOM DESCRIPTION

The Waste Hold Up Tank Room is located directly beneath the Hot Cell and is designed to hold the liquid radioactive wastes generated in the Hot Cell and the isotope area. The Waste Tank Hold Up Room is divided into two areas, an entrance way and the room proper. (See Figure 1 Section G for dimensions and layout of the room). The room contains two (2) tanks, one (1) 500 gallon tank that received waste water from the showers, sinks and drains in the laboratory and one (1) 100 gallon tank that receives waste water from the cell sink and floor drain. The tanks are interconnected in such a fashion that the 100 gallon tank will drain into the 500 gallon tank when overfilled. There are also two (2) small Ion Exchange Columns mounted to a table in the room. There is one (1) piece of non-permanent equipment located in the entrance way: an old mechanical drum compactor. All surfaces of the room are unpainted, poured concrete. There is no light or power operating in the room. There are no floor drains in the room and the entrance way is diked to prevent migration of spilled liquid. The room is ventilated by one (1) exhaust duct and the tank vents are connected to the controlled ventilation system. Numerous pipes, conduits, ducts and vents penetrate the room's walls in various locations. There is only one (1) personnel access into the Waste Hold Up Tank Room.

also clean room drain

0267p

ADVANCE MEDICAL SYSTEMS, INC.
SECTION D
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

RADIOLOGICAL SURVEY DATA

Due to the high ambient Gamma dose rates, only one (1) radiological survey and sample collection was performed in the Waste Hold Up Tank Room. Two (2) smears were taken on the floor; One (1) in the room, and one (1) in the entrance way. Both smears collected approximately one (1) gram of sediment each. Gamma dose rates were taken in the entrance way and room proper at different heights to ascertain sources of the dose rates. A brief visual inspection was made to determine surface and equipment conditions.

At some time in the facilities history, a major spill occured in the room. The water gradually evaporated, leaving approximately one (1) inch of sediment uniformly distributed on the floor. The tanks appear to have retained their integrity (both are made of stainless steel) and the ion exchange columns are disconnected. The old drum compactor appears to weigh in excess of 300lbs, is rusted all over, and encrusted with dried material.

Each sediment smear produced a dose rate of 1.5 R/hr at 1 cm. The maximum dose rate in the room could not be discerned exactly, (it exceeded the range of a Telector). A fair estimate would put it around 2000R/hr. Ambient dose rates in the entrance way start at 5 R/hr and escalate to 300 R/hr within 3 - 4 ft. Dose rates climbed in the vicinity of the tank indicating that substantial material is still present in them. The sediment in the room has the consistency of talcum powder and becomes airborne with the slightest disturbance in the room. It is interesting to note that the dose rates climbed sharply in proximity to the ceiling. This is due to sources stored in the cell floor plugs above.

By making some reasonable assumptions, a total activity contained in the room was arrived at. All material on the floor is considered to be CO^{60} in the same concentration as the samples taken. The material in one tank is assumed to be deposited on the bottom of the tank in a single location (under the fill line).

Activity contained in the tank:

Dose Rate at 30cm approximately 2000 R/hr

Using the specific Gamma constant formula: (Γ = 13.2R/mCi @ 1cm)

Exposure rate = $\Gamma A/d^2$ solving for A yields

Exposure rate $(d^2)/\Gamma$ = activity in mCi

$2000 (30^2)/13.2 = 136.4$ curies in the tank

Activity of the floor:

Volume of sludge on floor 388,687 ml

CO^{60} 8.9 Grams/ml = 1.01 mCi/ml X 388,687 ml

A = 393.1 Curies on the floor

Total room activity 529.4 Curies, CO^{60}

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ALVANCE MEDICAL SYSTEMS, INC.
SECTION E
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

RECOMMENDED REMEDIAL ACTIONS

Based on the existing radiological survey data, the physical conditions, the structural constraints, the need for, and the extreme hazards associated with, the Waste Hold Up Tank Room, NSS proposes that the Waste Hold Up Tank Room be completely isolated and sealed till such time as the activity decays to a manageable level. Since this facility contains CO^{60} (5.272 year half life), the time required for decay to a manageable level is not excessive. Six (6) effective 1/2 lives would reduce the activity to approximately 1.6% of its present level. By the year 2018, the dose rates in the Waste Hold Up Tank Room would be manageable.

0267p

ADVANCE MEDICAL SYSTEMS, INC.
SECTION F
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

REASONING TO SUPPORT THE ISOLATION RECOMMENDATION

The following is the reasoning NSS used to arrive at its recommendation for isolation of the Waste Hold Up Tank Room:

1) ROOM SERVES NO PURPOSE. At present, the room is not being used for any purpose. AMS has already developed methods to deal with the small quantities of waste water generated without using the hold up tank. Portions of the piping to the room have already been disconnected and rerouted to a new batch tank. There is no reason whatsoever for anyone (e.g. AMS, Contractors, NRC and others) to enter this room and no use remains for the equipment inside.

2) REMOVING THE ACTIVITY FROM THE ROOM WILL NOT ALLOW THE ROOM TO BE UTILIZED. Even if a successful decontamination was performed, dose rates in the room would still be too high for entry or use of the room. This is due to the proximity of the bulk cobalt storage plugs in the cell floor located above. Typical activity in the storage plugs ranges from 20,000 Ci to 60,000 Ci Co^{60}. There is only one (1) foot of concrete between the cell storage area floor and the Waste Hold Up Tank Room ceiling. With or without the decontamination, extreme dose rates would still not be eliminated from the room.

3) THE ROOM "AS IS" POSES NO THREAT TO AMS EMPLOYEES OR THE GENERAL PUBLIC. The activity contained in the room makes no significant contributions to the dose rates in the occupied areas of the isotope shop (see room survey of isotope shop contained in Section J). As can be discerned from the survey, the dose rates at floor level are not significantly higher than dose rates above the floor. In some places they are even lower and in no place would extremity dosimetry be required for monitoring (i.e. feet). The Waste Hold Up Tank Room is surrounded by three (3) foot thick concrete walls and a four (4) foot thick ceiling. As shown by the clean side basement survey, this thickness is ample for reducing dose rates to a tolerable level (5mr/hr - 20mr/hr). Since the whole room is below grade, no contribution is made to exposure rates outside the restricted area. The room, as it is, contributes no excessive exposure to occupied areas of the isotope shop or any unrestricted areas.

4) THE ACTIVITY WILL DECAY OFF GRADUALLY. Since all of the activity is cobalt, it will decay with a 5.272 year half life. By the year 2018 will only be 1.6% of what it is now. This relatively short half life of cobalt 60 will enable AMS to easily decontaminate the room at decommissioning.

5) EXCEPTIONALLY HIGH RISK INVOLVED IN DECONTAMINATION. The dose rates and specific activities of the material are high enough to cause biological damage in a short period of time. If decontamination were attempted, the material would have to be removed from the room. It is unreasonable to think that this could be performed without workers coming close to the material. The location of the room and the room itself do not facilitate sensible transfer methods. In the removal, transfer, and packaging of the waste, very high radiation fields would be mobile in the facility. These fields would not only pose a serious threat to AMS employees, but to the general public

also, since now the material will have been removed from its safely shielded location. The form of the material lends itself to becoming readily airborne or easily spilled. This would pose a significant inhalation, personnel contamination, and offsite release hazard.

6) INABILITY TO MODIFY THE EXISTING ROOM CONFIGURATION AND THE LIMITED PHYSICAL SIZE OF THE ROOM. The structure of the Waste Hold Up Tank Room would be difficult to modify in any manner to support decontamination because it provides support for the cell, ventilation room, and the surrounding building. The room is very small and access is constricted due to the labyrinth type entrance way. These constraints would most certainly necessitate a limited number of room entries. If a worker slipped, or was injured during an entry, he would sustain a biologically damaging dose prior to being helped out of the room (based on ambient dose rates of 33.3 R/minute). The configuration of the room does not lend itself to remote work.

7) SUMMARY. These six (6) reasons all reduce to one concept; the risk benefit ratio and the extraordinary risks incurred in decontamination are in no way justifiable based on the small benefit gained. Realistically, there is no benefit to be gained because the room, as it is, (especially if it is isolated) and is not a health threat to AMS employees or the general public. If decontamination is attempted, a real threat will be present. If it is successfully performed, the area will still have to be isolated because of the close proximity of the stored bulk cobalt 60 located in the Hot Cell above. NSS believes that the Waste Hold Up Tank Room should be decontaminated only at a future date when it is safe to do so and when the Hot Cell located above is no longer in use. Isolation of the Waste Hold Up Tank Room would reduce what little risk there is now and isolation would safely contain the activity until a future date when it has decayed to a manageable level.

ADVANCE MEDICAL SYSTEMS, INC.
SECTION G
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

METHODS OF ISOLATION

The reasoning behind the complete sealing of the room is to prevent additional activity from being introduced into the room, thus negating the benefit of decay time and to prevent activity from escaping from the room and causing a hazard to employees and the general public. Sealing the room will also prevent any inadvertent entry into the room. To this end, the room must be sealed as water and air tight as possible.

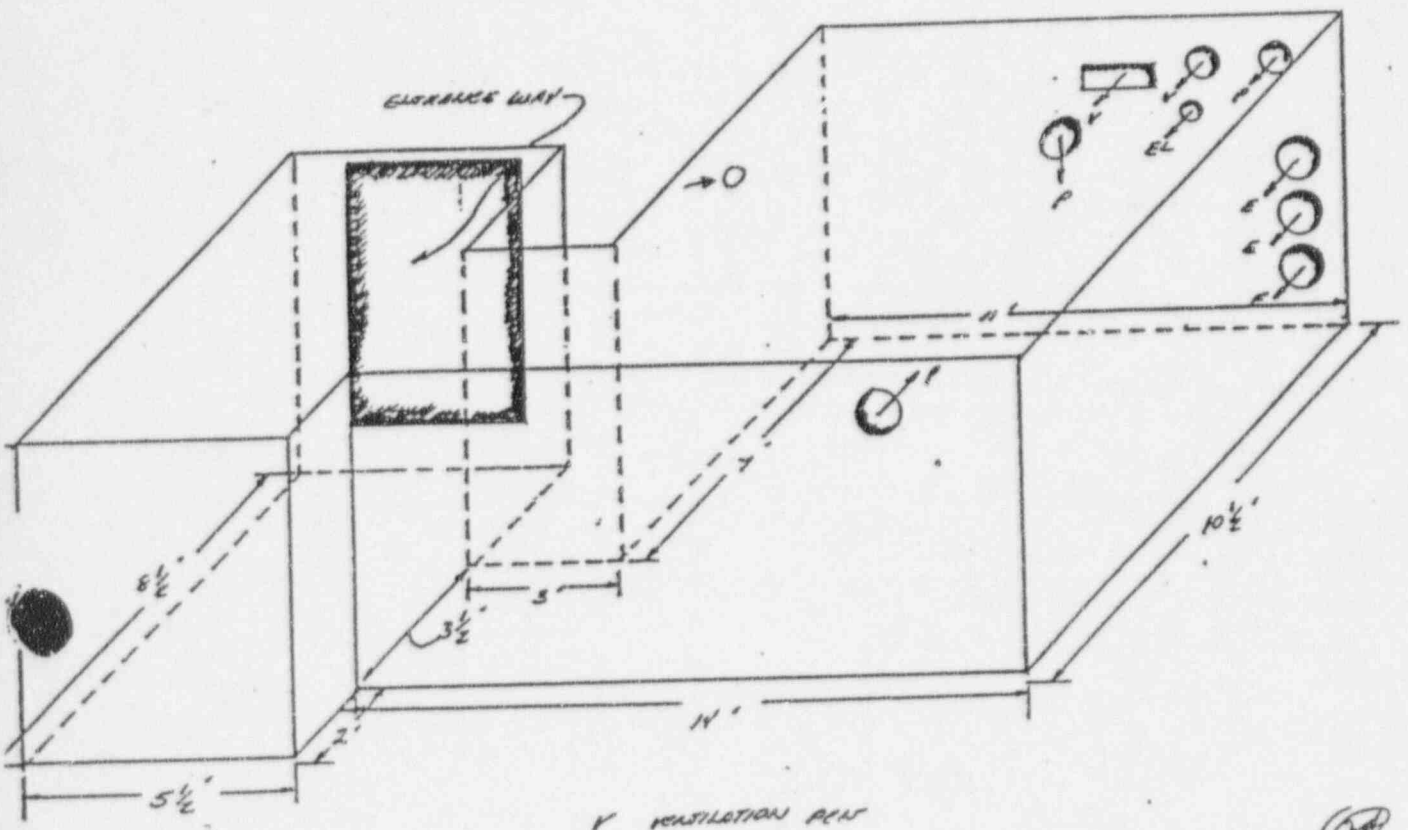
There are ten (10) physical penetrations in the walls and ceiling of the room; two (2) vent penetrations, one (1) electrical, three (3) pipe, three (3) empty and one (1) doorway (see figure 1). The penetrations vary in size from 3/4" dia. to 3' X 6'. Any existing pipes, conduits and ductwork will be severed on the outside of the room and the remaining pipe, conduit, or duct will be pushed into the room leaving an empty hole. These holes will be permanently blocked with material that has the same or greater shielding effect as the surrounding surface. The doorway will also be permanently sealed to the same shielding capacity of the surrounding walls. Watertight seals will be applied to all penetrations (see figure 2).

After the room has been sealed, metal signs warning personnel of the danger of on the other side of the wall shall be permenatly affixed to any external accessible surface.

0267p

SECTION G - FIGURE 1

PENETRATION/ROOM DIMENSIONS



V VENTILATION PEN

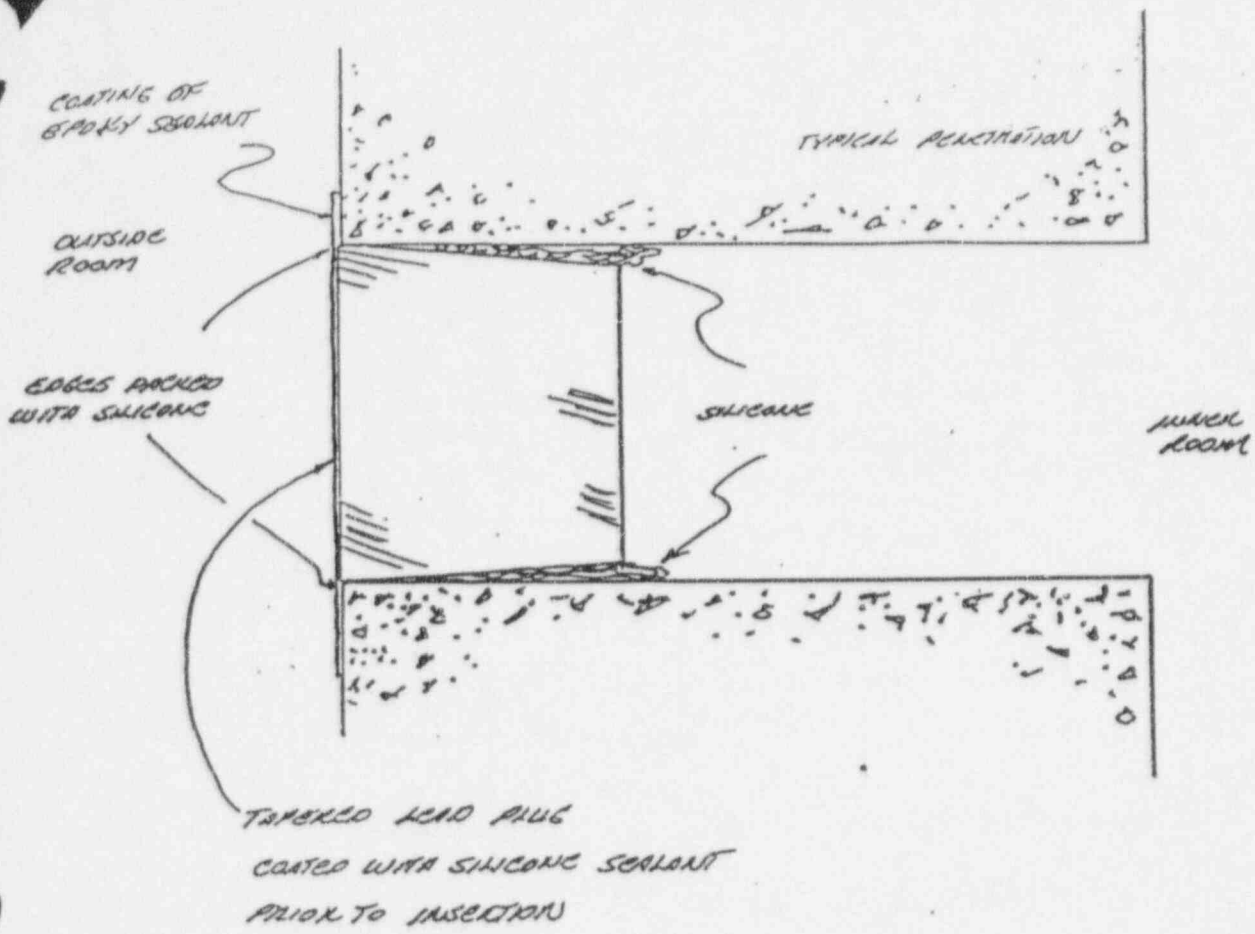
P PIPE PEN

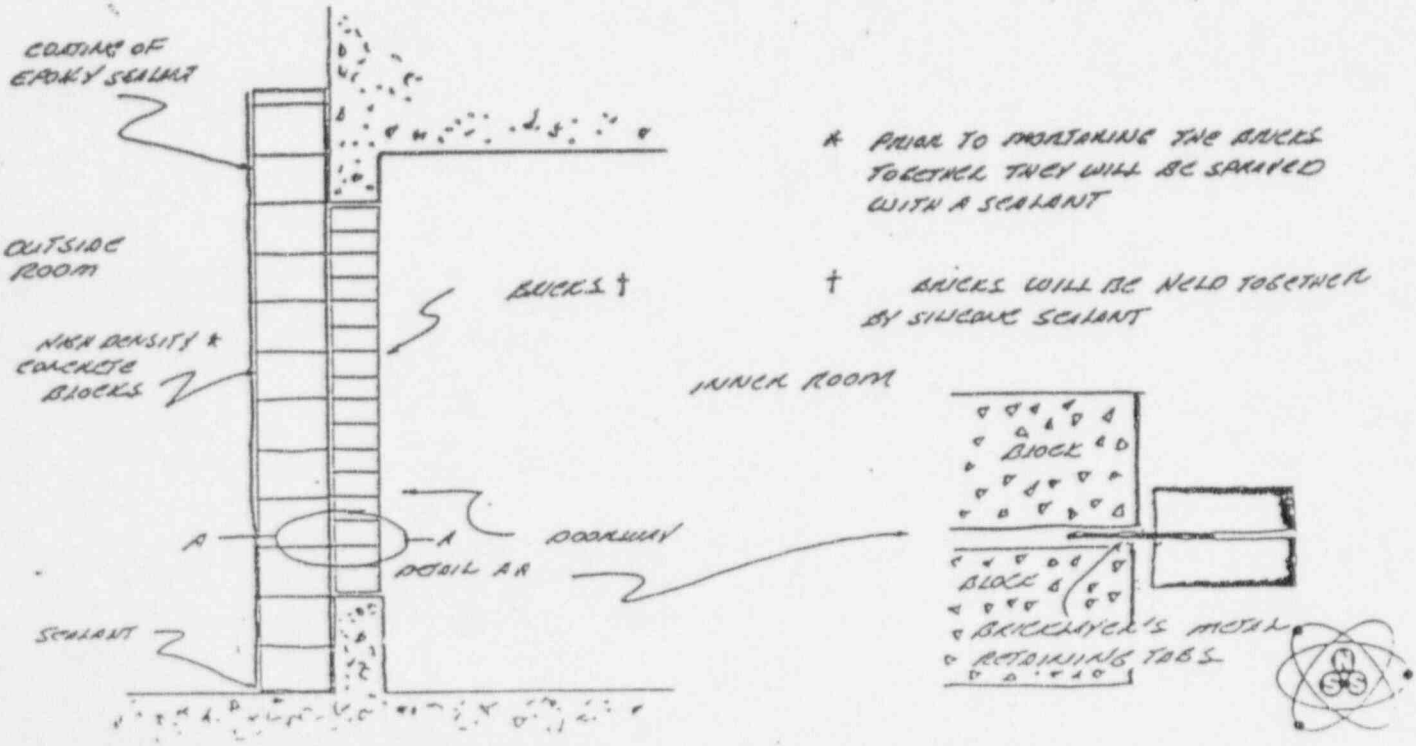
EL ELECTRICAL PEN

E EMPTY PEN

SECTION G - FIGURE 2

PENETRATION SEALING DETAILS





* PRIOR TO MORTARING THE BRICKS TOGETHER THEY WILL BE SEALED WITH A SEALANT

† BRICKS WILL BE HELD TOGETHER BY SILICONE SEALANT

ADVANCE MEDICAL SYSTEMS, INC.
SECTION H
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

MAINTENANCE OF THE ISOLATED STATE

In order to ensure that the Waste Hold Up Tank Room remains in the isolated state, a monitoring program will be implemented. This monitoring program will consist of weekly visual inspections and radiological surveys of the accessible exterior surfaces of the Waste Hold Up Tank Room. The visual inspection will include checking all the penetration blocks and surrounding walls for physical integrity. Any defects will be noted and corrected immediately. All lower wall sections will be inspected for seepage. Dose rates and smears will be taken in exactly reproducible locations on the exterior walls, preferably where the wall meets the floor. Any change in dose rates, or the presence of smearable activity will be investigated to determine if leakage is the cause. Smears will also be taken on the seams of all accessible penetration blocks.

Procedures addressing the room and its status will be included in AMS's facility ISP's. These procedures will address, at a minimum: excavation near the room, altering the building's structure, periodic surveys and inspections of the room, and actions to be taken if a leak from the room is suspected.

0267p

ADVANCE MEDICAL SYSTEMS, INC.
SECTION J
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

APPENDIX "B" - SURVEY DATA SHEETS

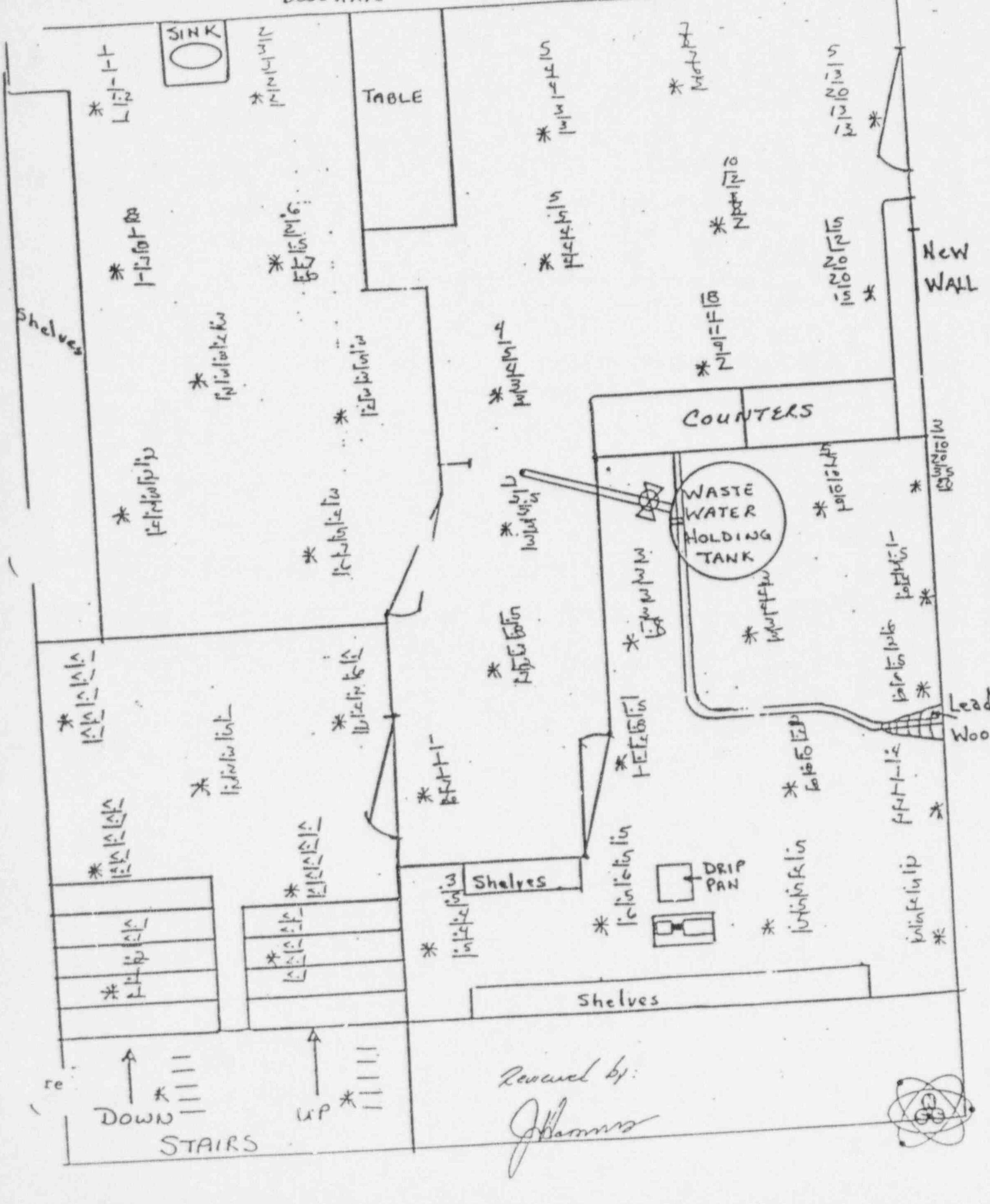
This section contains Radiological survey maps of the following London Road Facility areas:

- Airlock Area
- Basement (front part)
- Isotope Shop
- Isotope Shop (change area survey map)
- Isotope Shop Stairwell to Basement
- Outside Area (south and east)
- Sewer Outside Building South Entrance

,ONT PART OF BASEMENT.

DATE: 1-27-88
TIME: 0900
Technician: Schroeder

ISTRUMENTS: Tektector #28821 / DOSE RATE : Cal. Due Date: 2-28-89 / ~~CONTAMINATION~~



SEWER (OUTSIDE BUILDING SOUTH ENTRANCE (

DATE: 1-21-88
TIME: 0900
TECH: R. JUCIUS
TYPE of SURVEY: Verification
A/S RESULTS: N/A uci/cc

INSTRUMENTS USED:

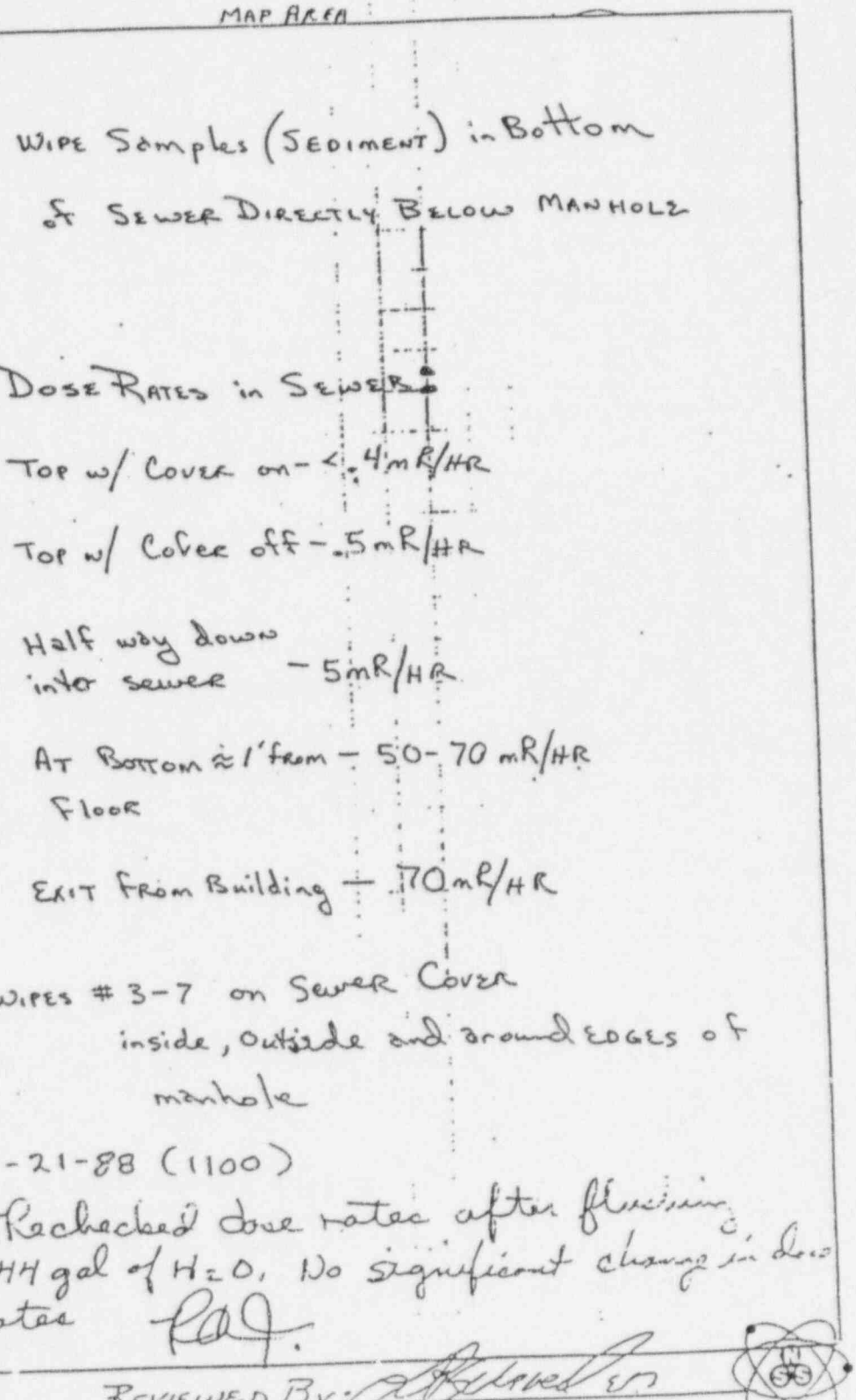
1. TYPE:	Spect-o-scaler	Teletector
2. Serial No.:	04696	28821
3. Cal. Due Date:	5-20-88	2-28-88

4. EFFICIENCY: .16 cpm/dpm
5. BACKGROUND: 33 cpm
6. COUNT TIME: 1 min.

SMEAR RESULTS

SMEAR NO.	C.P.M.	dpm/100cm²
1	12210	121,770
2	4317	42,840
3	31	—
4	36	30
5	41	80
6	34	10
7	36	30

MAP AREA



REVIEWED BY:

SEWER OUTSIDE BUILDING SOUTH ENTRANCE

STRUMENTS USED:

1. TYPE : Spect-escaler | Teletector
2. Serial No.: 04696 | 28821
3. Cal. Due Date: 5-20-88 | 2-28-88
4. Efficiency: .10 cpm/dpm
5. Background: 33 cpm
6. Count Time: 1 min.

DATE: 1-21-88
TIME: 0900
Tech: R. Jucius
Type of Survey: Verification
A/S Results: N/A uci/cc

SMEAR RESULTS

SMEAR NO.	C.P.M.	dpm/100cm²
①	1221.0	121,770
②	4317	42,840
③	31	—
④	36	30
⑤	41	80
⑥	34	10
⑦	36	30

MAP AREA

Wipe Samples (Sediment) in Bottom of Sewer Directly Below Manhole

Dose Rates in Sewer

Top w/ Cover on - <.4 mR/HR

Top w/ Cover off - .5 mR/HR

Half way down into sewer - 5 mR/HR

At Bottom ≈ 1' from Floor - 50-70 mR/HR

Exit From Building - 70 mR/HR

Wipes #3-7 on Sewer Cover inside, outside and around edges of manhole

1-21-88 (1100)
Rechecked dose rates after flushing 144 gal of H_2O. No significant change in dose rates

Reviewed By:

ATTACHMENT C

☆ SUSPECT SOURCE MATERIAL IN FRONT PLUG

WAFER SOURCES			
TS - 51	3 Ci	AS OF	10-1-93
TS - 68	35 Ci	" "	10-1-93
PICKER			
PX 292	23 Ci	" "	10-1-93
PX 347	298 Ci	" "	10-1-93
CESIUM 137			
CS - 10	664 Ci	" "	4-1-93
BULK CAPSULE			
XVII	389 Ci	" "	10-1-93
XI	543 Ci	" "	10-1-93
XV	436 Ci	" "	10-1-93
VI FRONT / IV REAR	1304 Ci	" "	10-1-93
COMPETITIVE			
NPI 577	551 Ci	" "	10-1-93
GET 15-15	99 Ci	" "	10-1-93

4345 Ci

BASEMENT

Survey prior to application of strippable coating.

Date 11-17-94 Inst. RO2/Frisker S/N 6087/41296

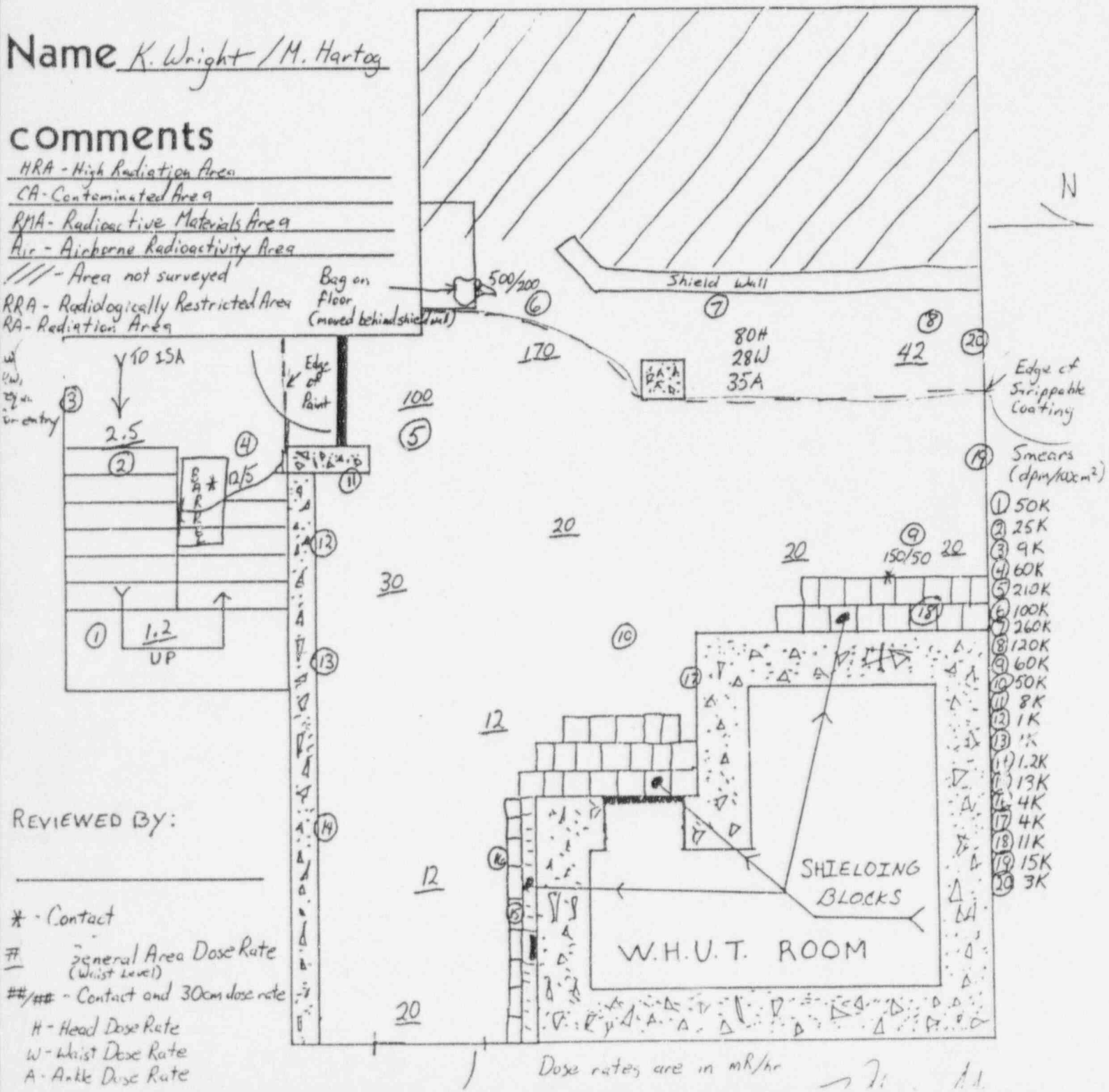
cal. date 1-18-95 / 4-18-95

Time 1700

Name K. Wright / M. Hartog

comments

HRA - High Radiation Area
CA - Contaminated Area
RMA - Radioactive Materials Area
Air - Airborne Radioactivity Area
/// - Area not surveyed
RRA - Radiologically Restricted Area
RA - Radiation Area



REVIEWED BY:

* - Contact
# - General Area Dose Rate (Waist Level)
##/## - Contact and 30cm dose rate
H - Head Dose Rate
W - Waist Dose Rate
A - Ankle Dose Rate

Dose rates are in mR/hr

Date 11-17-94

TIME 1700

TECH K. Wright / M. Hartog

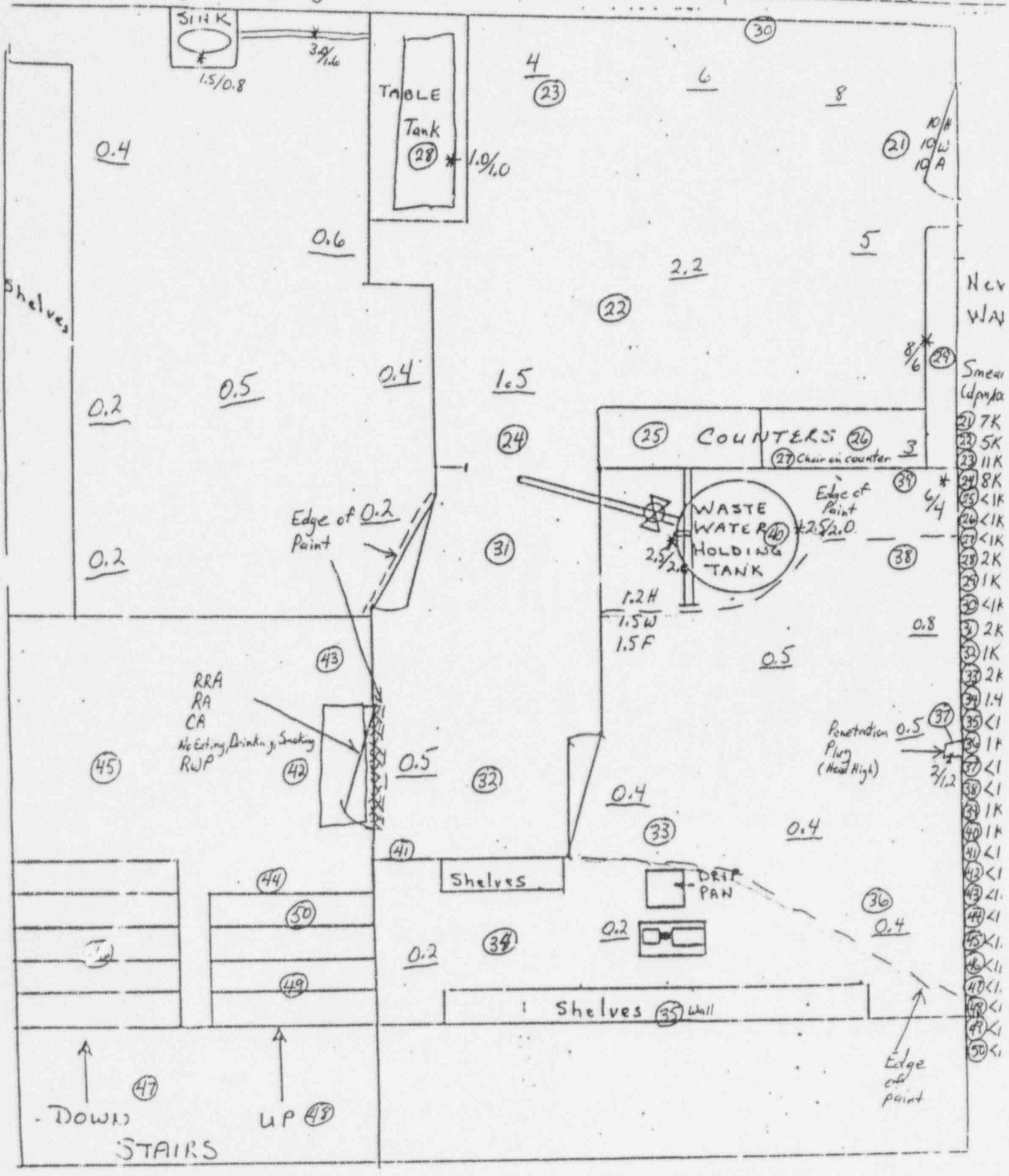
Type of survey Survey prior to application of strippable coating.

Inst RO-2 / LM177

S/N 6087 / 41296

Comments

Reviewed by R Quevedo



XXXXX - Radiological Boundary

BASEMENT

Post-painting, pre-cutting survey

Date 11-19-94

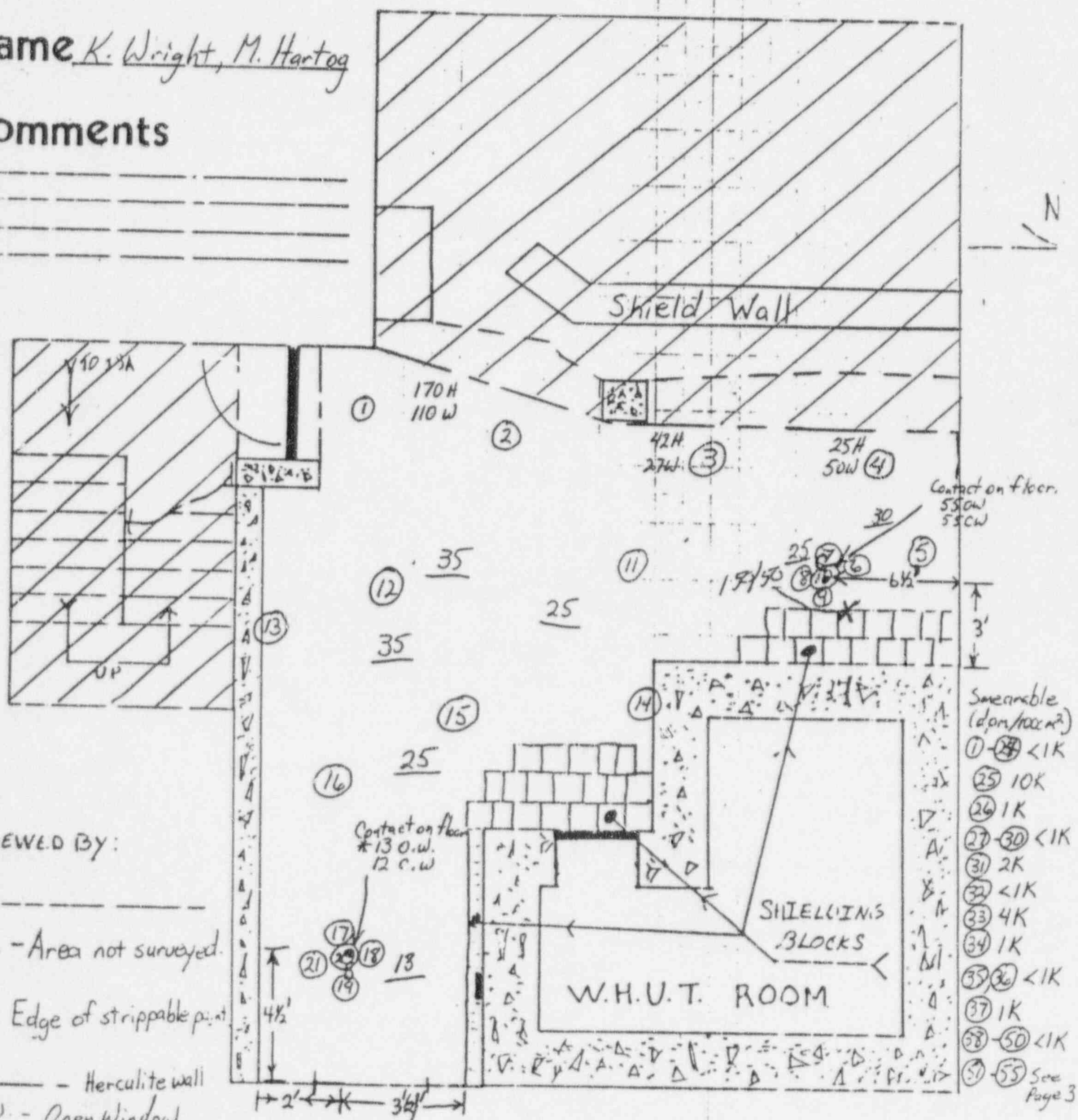
Inst. RO-2/LM.11 S/N 6087/47703

cal. date 1-18-95 / 4-18-95

Time 1400

Name K. Wright, M. Hartog

comments



REVIEWED BY:

- Area not surveyed.
- Edge of strippable paint
- Herculite wall

O.W. - Open Window
C.W. - Closed Window

Date 11-19-94

TIME 1400

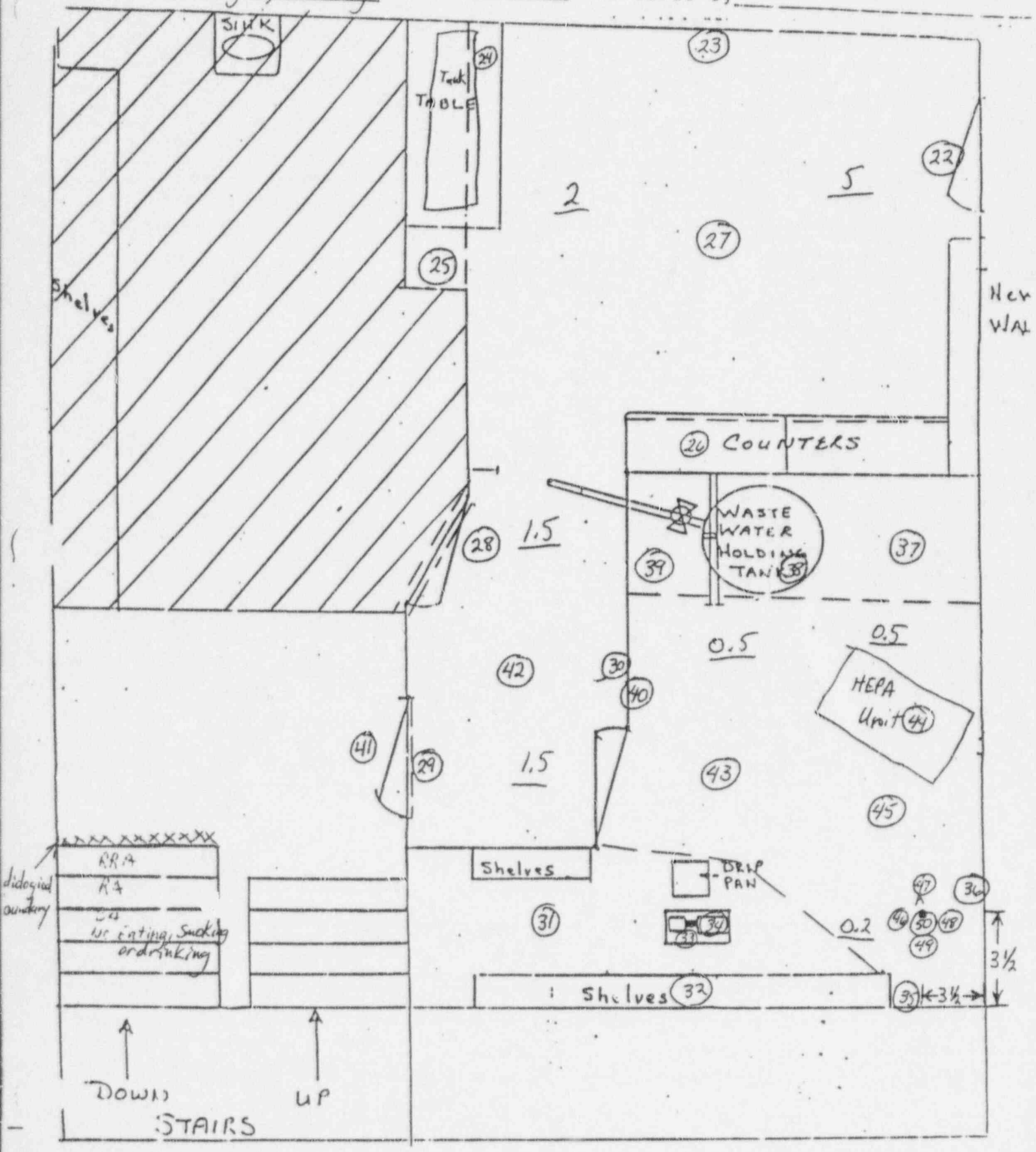
TECH K. Wright, M. Hartog

[illegible] OF BASEMENT ... 2 of 3

Type of survey Post-painting, pre-cutting

Inst RD-2 / LM-177 Comments

S/N 4087/47703 Reviewed by



Post-painting, pre-cutting survey

3 of 3

page 1 of 1 SW

11-19-94

LOOSE SURFACE CONTAMINATION SURVEY

A 11/19/94 INST.: Well Counter S/N: 04896 BKG. 22 CPM

IME: 1430 CAL. DATE: 1/8/95 C_{eff} .10 %

AME: V. Rocco AREA/ITEM SURVEYED Hole 'A' Front Basement - Tank Room

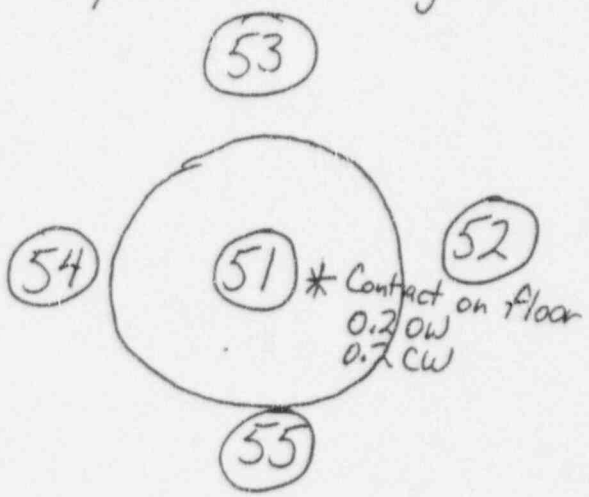
Avg. smear area 100 cm^2

No.	G_{cpm}	C_{cpm}	DPM
51	26	4	40
52	18	ND	ND
53	24	2	20
54	18	ND	ND
55	21	ND	ND

N/A

DRAWING

Hole 'A' location after strippable coating was cut away for cement coring.



Comments Pre-cut survey of floor prior to coring for soil samples.

Reviewed by

Dat. -29-94 WHUT ROOM SHIELDING/ISOLATION S / FORM

Time: 1600

Name; M. Hartog

Inst; RO2/LM-177

S/N; 6087/41296 Cal.Date; Due 7-18-95/4-18-95

Comments; All smears taken are 100cm² area

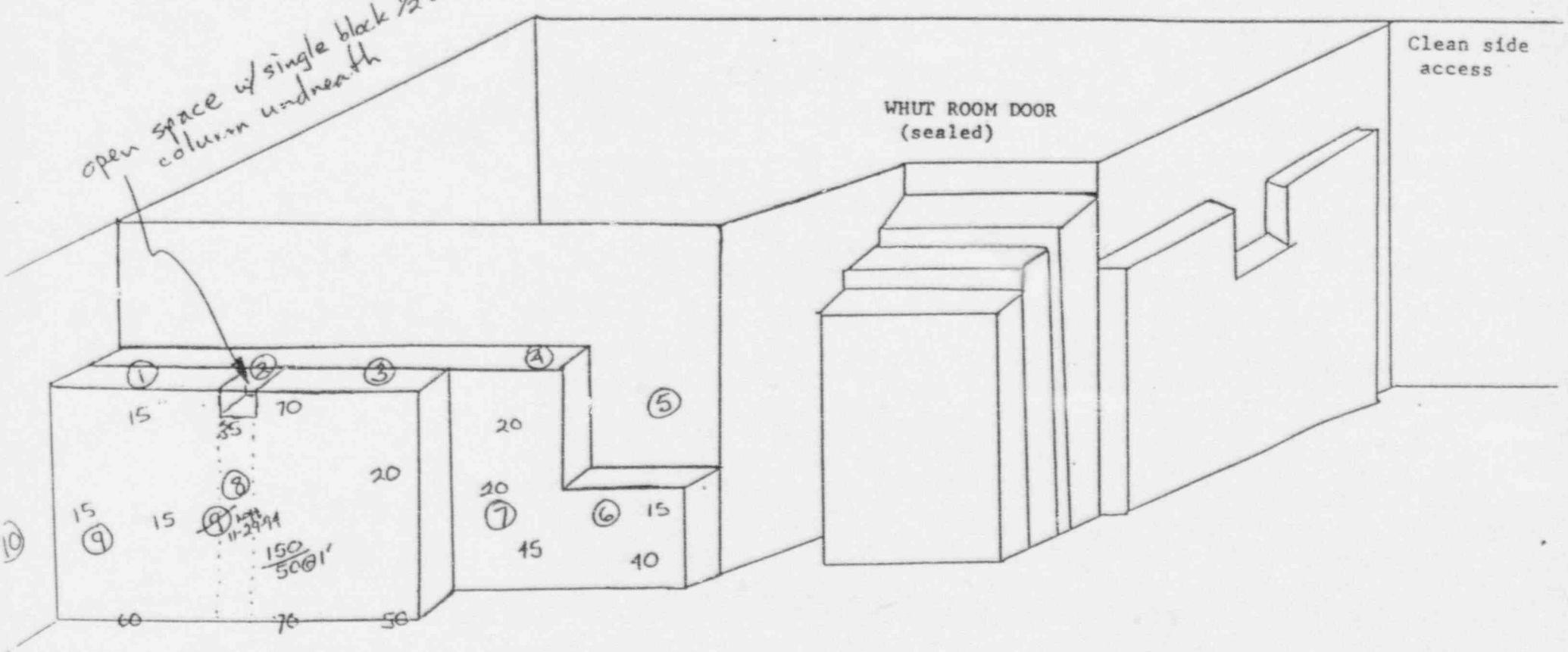
All dose rates taken are contact on wall or ~~5ft~~ floor @ wall unless otherwise noted. 11-29-94

Legend; *= contact dose
x= general area waist level
x = general area @ 6' high
@

Reviewed By; Robert Meredith

Smears:

1	7K	6	1K
2	20K	7	<1K
3	1K	8	2K
4	4K	9	1.5K
5	1K	10	1.5K



WHUT ROOM SHIELDING/ISOLATION SUF FORM

Date; 10-94

Time; 1500

Name; M. Hartog / nosh

Inst; RO-2

S/N; 6087 Cal.Date; Due 1-18-95

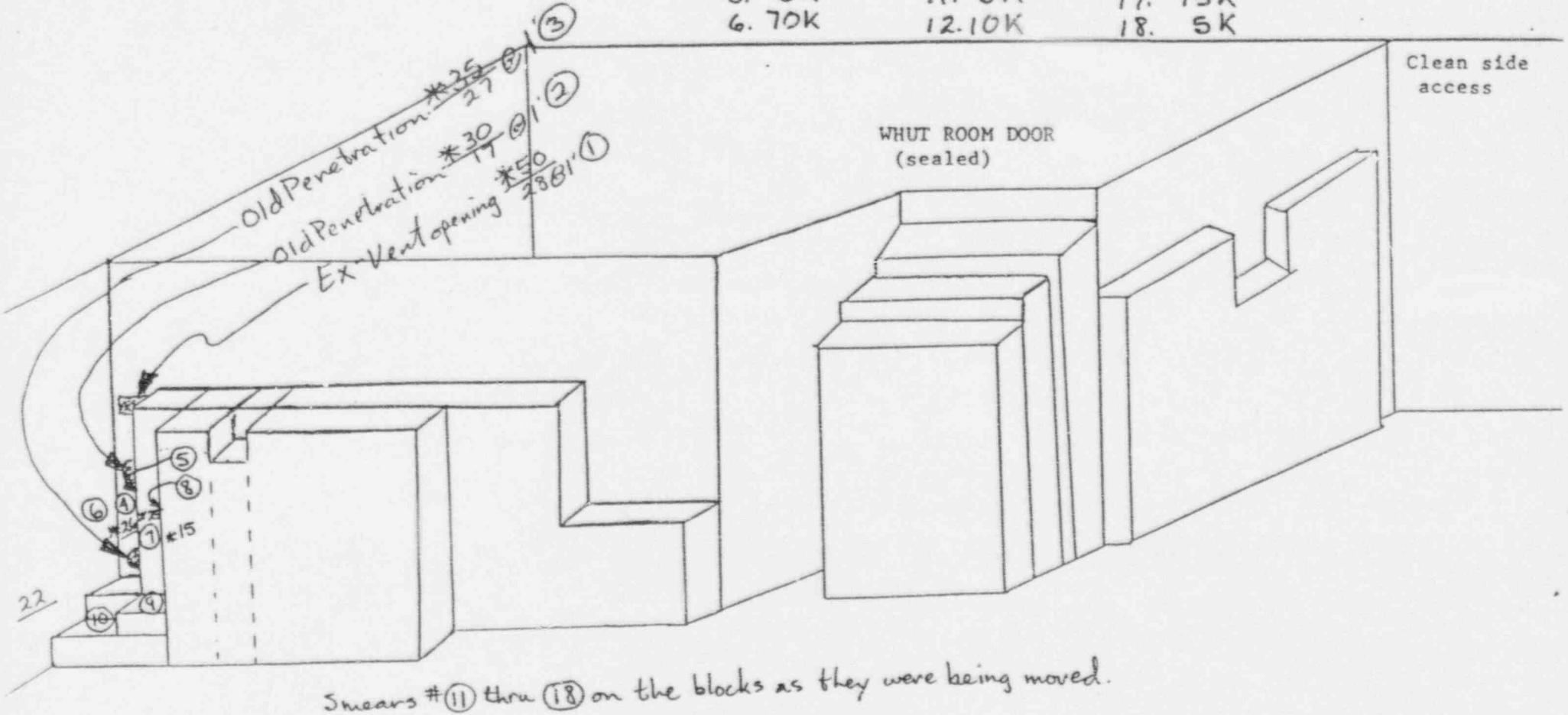
Comments; Penetrations & Vent opening plugged w/ Pb & grouted closed. Area over old penetrations, on wall & blocks covered w/ herculite ... holes cut to expose old penetrations

Legend; *= contact dose
x= general area waist level
x = general area @ 6' high
⊕

Reviewed By; R Meredith

Contamination Levels (K = X1000) Lvls in dpm/100cm²

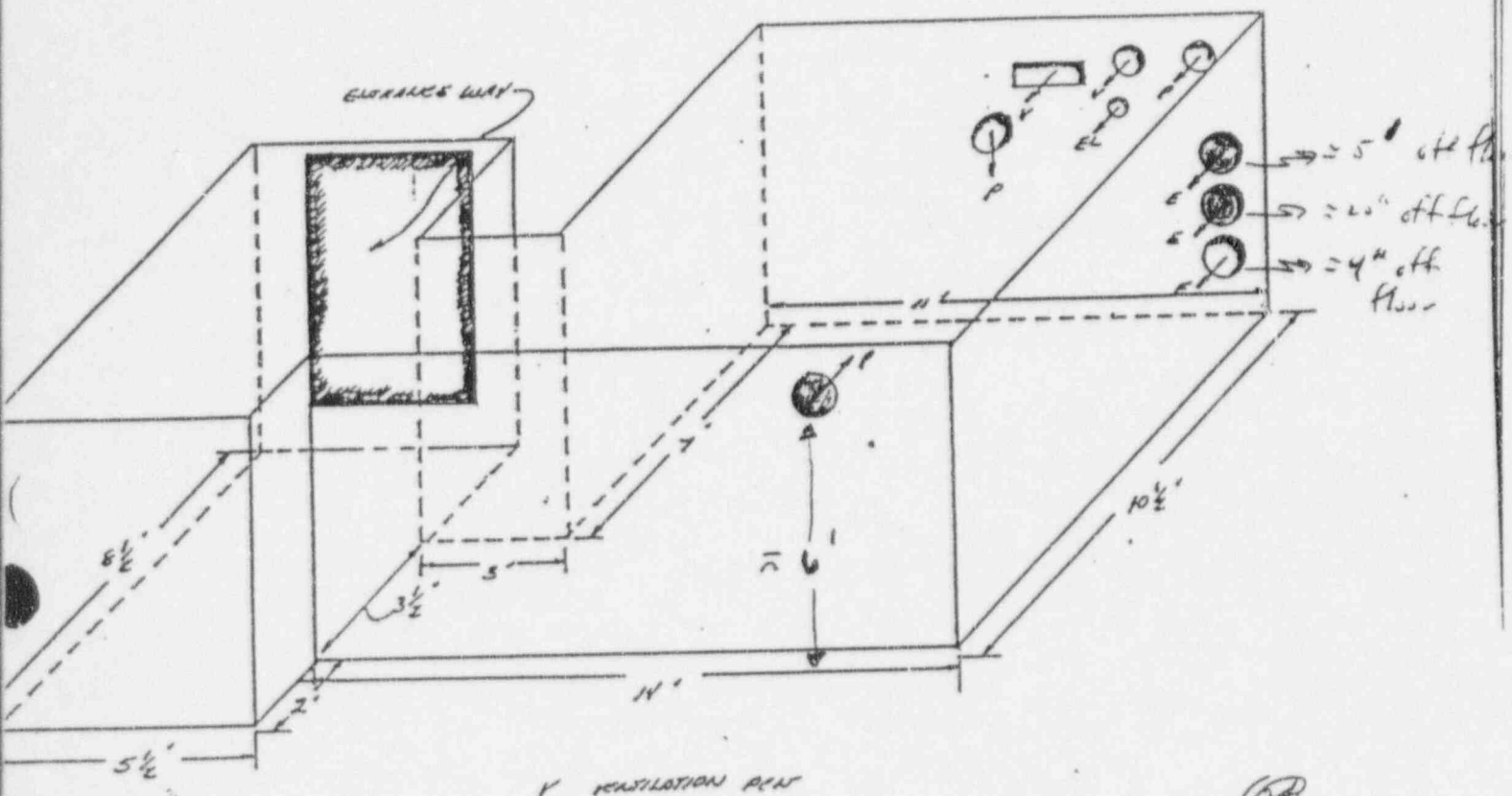
1. 3K	7. 5K	13. 100K
2. 1K	8. 10K	14. 50K
3. 2K	9. 10K	15. 100K
4. 20K	10. 100K	16. 10K
5. 5K	11. 5K	17. 15K
6. 70K	12. 10K	18. 5K



Smears #(11) thru (18) on the blocks as they were being moved.

SECTION G - FIGURE 1

PENETRATION/ROOM DIMENSIONS



V VENTILATION PEN

P PIPE PEN

EL ELECTRICAL PEN

E EMPTY PEN

Dulsi

ADVANCED MEDICAL SYSTEMS, INC. HISTORY OF LICENSED OPERATIONS

D110

TABLE OF CONTENTS

ADVANCED MEDICAL SYSTEMS, INC. (AMS) HISTORY OF LICENSED OPERATIONS

LICENSED ACTIVITIES:

The NRC first issued a license to AMS in November 1979, following a review of their submitted application by NRC Headquarters. The licensed operation, facilities and equipment were previously owned and operated by Picker Corporation since the 1950s. The license authorized AMS to manufacture sealed sources containing significant amounts (thousands of curies) of radioactive cobalt-60 to be placed in teletherapy units. The teletherapy units are used in medical facilities to treat cancer patients. The license also authorized AMS to service and repair the teletherapy units. From 1979 to 1985 the licensee actively manufactured sealed sources for distribution to medical licensees.

INSPECTION/ENFORCEMENT ACTIVITIES:

Since the AMS license was first issued, the NRC has conducted 25 routine and special inspections of AMS licensed activities. On October 21-24, 1985, Oak Ridge Associated Universities (ORAU), accompanied by NRC personnel, performed an evaluation of the fire protection and operational radiation safety programs at the AMS facility. During this evaluation, random facility and environmental (on and off site) samples were collected and analysed. The environmental samples consisted of soil,

vegetation, standing liquid (storm drains, roof, etc.), sediment (sewer and storm drains), sewer discharge, and other miscellaneous samples. Direct radiation measurements were also performed. No detectable offsite cobalt-60 concentrations were found; however, a few sediment, soil, and vegetation samples displayed detectable cobalt-60 on AMS property. Sediment collected from certain storm drains on AMS property contained low, but detectable, cobalt-60. The 1985 ORAU report concluded that the cobalt-60 concentrations detected posed no hazard to the public or environment.

During December 4, 1986, to February 13, 1987, a special inspection was performed to assess AMS' radioactive liquid waste releases to the sanitary sewer. The inspection included a review of records of the volume and concentration of the waste released, interviews of AMS personnel, and the performance of independent radiation surveys of the sanitary sewer. Other inspections before and after this special inspection also examined effluent releases. As a result of these inspections, the NRC did not identify any releases in excess of regulatory limits.

DECONTAMINATION ORDER AND DEMAND FOR INFORMATION:

On July 23, 1987, AMS was issued an Order Modifying License, Effective Immediately, and Demand for Information. The Order

required AMS to commence decontamination of their London Road facility by August 31, 1987. In addition, a Demand for Information requiring AMS to submit financial information was issued.

REMOVAL OF MANUFACTURING AUTHORITY:

After an extensive decontamination project, from 1987 to 1991, manufacturing operations were sporadic with few sources fabricated. On May 31, 1991, due to the loss of AMS' qualified manufacturing personnel, the license was amended to remove the licensee's authority to manufacture sealed sources. The AMS license currently authorizes only service operations and routine health physics activities.

OFF-SITE CONTAMINATION ISSUES:

In February 1988, an AMS contractor identified contamination in the main sewer outside of the licensed facility on AMS property. This contamination was confirmed by the NRC during an onsite inspection and resulted in enforcement action. The material found was localized and rendered immobile by cementing it in place at the bottom of the sewer. This situation does not pose a significant health hazard to the public since the contamination has been isolated and contained.

In April 1991, the NRC identified radioactive cobalt at the Northeast Ohio Regional Sewer District (NEORSD), Southerly Plant. Direct surveys and sludge samples were taken by NRC during a May 1991 inspection. Also, at the request of the NRC, Oak Ridge Institute for Science and Education (ORISE) conducted a radiological characterization survey of NEORSD during the periods of September 16-25, 1991, and March 16-26, 1992. While these surveys indicated the presence of low-level cobalt-60 contamination, there was no indication of significant radiation exposure to the public because of the isolated and secured location of the contamination. The NRC is currently working with the NEORSD to determine appropriate remediation.

RADIOACTIVE MATERIAL INVENTORY ISSUE:

License Condition 14 of Amendment No. 14, which became effective on January 26, 1988, required that AMS conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under their license. During an NRC inspection conducted at AMS on January 23-26, 1990, nine (9) violations of NRC requirements were identified. Among those violations identified was AMS' failure to conduct a physical inventory every 6 months during the period January 1988 through January 26, 1990, to account for all sources and/or devices received and possessed under their license.

With regard to the violation described above, the NRC understood from AMS statements made during the March 27, 1990, enforcement conference conducted in Cleveland, Ohio, that such an inventory was underway and was to be completed by the end of 1990. However, after numerous letters, telephone conferences, and licensing actions concerning the completion of a physical inventory, AMS to date has not completed a physical inventory to account for all the radioactive material possessed under their license. For this reason Region III is proposing to issue AMS a Demand For Information, requiring AMS to respond in writing and under oath or affirmation, information that demonstrates why enforcement action in the form of daily civil penalties until the date of inventory completion, should not be taken.

NMSS INVOLVEMENT WITH AMS:

Region III has coordinated all major issues regarding AMS with NMSS and other offices in headquarters. These issues start with escalated enforcement action in 1983, the issuance of the 1987 Order and Demand for Information, to the current proposed Demand for Information. Attached to this history of AMS operations are various documents and chronologies that outline the multitude of actions involving AMS, Region III, and various NRC Headquarters' offices (see table of contents).

FUTURE REGION III STRATEGY CONCERNING AMS CLEANUP WITH NMSS INVOLVEMENT:

1. Maintain pressure on AMS to complete physical inventory to assure that all radioactive material possessed by them is accounted for. This should be accomplished through the issuance of a Demand for Information, as previously described, with NMSS input.

2. Encourage AMS to transfer their sealed source and bulk cobalt-60 inventory to other licensed facilities. This can be accomplished by maintaining strict regulatory control over their licensed activities through frequent inspections and strong enforcement action for violations of regulatory requirements. All escalated enforcement actions will be coordinated through NMSS and OE Headquarters.

3. Before December 31, 1994, AMS will be required to submit an application for license renewal. With this application, AMS will need to provide NRC with a Decommissioning Funding Plan (DFP), Cost Estimate and financial instrument to cover costs of decommissioning. Their submission will be coordinated through NMSS for technical assistance. If the AMS DFP and Cost Estimate

is found to be deficient, strong enforcement action should be taken to ensure that proper funds are available for clean-up of the AMS facility. This may require NRC to Order AMS to utilize a qualified contractor to perform a site characterization and work cost estimate for the decommissioning of their facility.

Draft

PICKER CORPORATION AND ADVANCED MEDICAL SYSTEMS

INSPECTION AND ENFORCEMENT HISTORY

Picker X-Ray Corporation (License No. 34-07225-09)

License issued 1959; Terminated 1979

Inspection Date(s)	Findings
June 1963	NOV issued for failure to: (1) evaluate airborne concentrations in hot cell; (2) equip high radiation area in hot cell with control device to reduce radiation level; and (3) maintain records of personnel monitoring results (Inspection Report not in file).
May 1965	Clear 591 issued (Inspection Report not in file).
August 1965	Clear 591 issued (Inspection Report not in file).
September 1965	No violations; method of inspection correspondence unknown (no report or other inspection documentation located in file).
February 1966	NOV issued for failure to equip high radiation area in basement with control device to reduce radiation level. Narrative inspection report indicates that this was the seventh inspection of the licensed program. Report described the hot cell ventilation filtration system but did not discuss airborne effluent releases. Inspection report stated that the Licensee's total water usage in 1965 was about 1.8 E 10 ml. Average liquid effluent concentration to the sanitary sewer was 1.3E-5 mCi/ml. Total activity released to the sewer system in 1965 was 0.23 curies.
September 1966	Clear 591 issued (Inspection Report not in file).
April 1967	Clear 591 issued (Inspection Report not in file).

Advanced Medical Systems, Inc. (Licenses No. 34-19089-01; No. 34-19089-02; and No. SUB-1379 (subsequently all incorporated into one -01 license))

Inspection Date(s)	Findings
April 29-30, 1980	Routine inspection of AMS field service activities at client hospital in Region I. No violations.
September 8-9, 1980	Initial routine inspection at AMS facility. Clear letter issued. Average stack effluent release for the period Nov 1979 through August 1980 was 3E-15 uCi/ml (Limit = 3E-10). Report specified that sanitary sewer disposal releases occurred between May 15, 1980 through June 11, 1980, totaling 3.8 mCi. All release concentrations within limits. No other information provided.
January 6, 1982	Routine inspection. Clear letter issued. Average stack effluent releases for 1980 and 1981 were 9E-15 and 5E-15, respectively. Total activity released to sewer in 1980 and 1981 was 10.6 and 15.62 mCi, respectively. All release concentrations within limits.
March 1-3, 1983	Special inspection to review overexposure incident. NOV issued for: (1) 4.3 rem whole body overexposure; (2) improper reading of dosimeter; (3) failure to wear extremity monitor and evaluate dose to hands; and (4) leak test a source at required intervals. $4,000 CP issued and paid.
July 16-17, 1984	Routine inspection. NOV issued for: (1) radiation levels in excess of unrestricted area limits; and (2) failure to post the high radiation area on the roof. Max stack effluent release during 1983 was 2E-19 and for 1984 through June was 9.5E-15. Total activity released to the sanitary sewer in 1983 and 1984 through June was 59.1 and 18.7 mCi, respectively. All release concentrations within limits.

September 24-25, 1984	Special inspection to review allegations related to an overexposure and service activities. Allegations not substantiated. Clear letter issued.
February 21-22, 1985	Special inspection to review overexposure incident. NOV and proposed CP issued for: (1) 2.9 rem whole body overexposure; (2) inadequate surveys of hot cell prior to entry; (3) inadequate reading of dosimeters and (4) failure to calibrate dosimeters at required frequencies. ORDER modifying license required use of alarming dosimeters and related measures for cell entries. CP imposed on May 30, 1989, after OI investigation into falsification of NRC Form-4. AMS requests hearing re:CP on June 20, 1989 (Feb 1985 inspection report not in file).
October 21-24, 1985	ORAU radiological and fire protection assessment of AMS facility made at NRC request. Assessment did not include a detailed evaluation of AMS sewer releases; however, indications of small amounts of cobalt-60 in the storm drain sediment were identified (1.7 pCi/gram). Surveys of roof area revealed low level roof gravel contamination near the stack indicating past releases of materials from the stack. In onsite areas south to southeast of the facility, detectable cobalt-60 concentrations were identified in a few sediment, soil, and vegetation samples. This would also indicate either stack releases or physical transfer of materials outside of the building. Cobalt-60 was also detected in storm drains at the loading dock areas and east end of the building perimeter. In addition to the cobalt-60 contamination, cesium-137 was identified in the areas of the roof and in sediment, vegetation, and soil. ORAU concluded that the levels identified did not pose any hazard to the public or environment (Enclosure I). Also, the stack sampling system was found to be non-isokinetic and not compatible with ANSI standards.
September 17 - November 12, 1986	Special inspection to review allegations related to unlicensed service engineers. Some allegations substantiated. Six service related violations identified, including licensed service activities conducted by

unqualified persons. ORDER suspending service activities issued October 10, 1986. ORDER relaxed on February 2, 1987 and rescinded December 3, 1987, following AMS program changes.

October 10, 1986 - March 4, 1987 and OI Investigation on October 15, 1986 - March 10, 1989

Supplemental inspection to followup on information obtained during September 17 - November 12, 1986 inspection, regarding Sodeco timer failures.

NOV (SLIII; no CP) issued December 27, 1989 for 10 CFR 21 related problems.

December 4, 1986 - February 18, 1987

Special inspection to review allegations pertaining to sanitary sewer releases. Allegations not substantiated. Clear letter issued.

Licensee records showed that max daily and monthly concentrations released to the sanitary sewer were within limits. Total cumulative activity released to the sewer system on an annual basis was as follows:

1980 = 10.6 mCi	1984 = 29.6 mCi
1981 = 15.6 mCi	1985 = 45.8 mCi
1982 = 5.1 mCi	1986 = 51.2 mCi
1983 = 59.1 mCi	1987 thru Feb 11 = 2.9 mCi

April 29-30, 1987

Special inspection at Northeast Ohio Regional Sewer District (specific plant unknown), in response to TI 2800/9, "Reconcentration of Radionuclides in Sanitary Sewer System." Inspector sampled untreated settled soils and treated dry waste; no activity detected by Region III lab analysis.

May 22, 1987 and May 27, 1987

Special inspection of service activities at two AMS client medical facilities. No violations identified. Memo to file issued.

July 23, 1987 Decontamination ORDER

December 11 and 14, 1987 and January 27, 1988

Special inspections of decontamination status. No violations identified. Effluent release activities not discussed in the memos to file describing the areas inspected.

April 13, 1988	Special inspection to review sewer system contamination identified by Nuclear Support Services during facility decon. NOV issued for exceeding unrestricted area radiation level limits. Radiation levels measured up to 80 mrem/hr at bottom of sewer pipe directly below manhole. Sewer sediment smear measured 122,000 dpm/100cm². Water and sludge samples from AMS sewer system yielded 9E-6 and 6E-2 uCi/ml, respectively.
November 7, 1988	Special inspection of decontamination status. No violations identified. Effluent release activities not discussed in memo to file documenting the areas inspected. The inspector's trip report indicated that the manhole had been decontaminated "to the extent possible" and the licensee had applied a layer of concrete over the residual contamination to reduce radiation levels.
November 14-18, 1988	Routine inspection. NOV issued for failure to: (1) conduct field audits of service engineer work and audits of the service program; and (2) amend the license to reflect management changes. Inspection Report stated that the average stack effluent releases for 1987 and 1988 were well below the 3E-15 uCi/ml limit. (Note: limit is actually 3E-10.) Report stated that no liquid waste is being released presently. The WHUT room has been isolated. Total activity released to the sewer in 1986-1988 was 35.6 mCi, 3.83 mCi, and 0.46 mCi, respectively. (Note: Inspection Rpt No. 87-001 indicates that 51.2 mCi was released in 1986, not 35.6 mCi.
November 14-17, 1988	ORAU conducted a radiological assessment of the AMS facility as a followup to the 1985 assessment. This assessment included radiation surveys and sampling of the AMS sewers. Radiation surveys in the interior of the manhole on AMS' property revealed radiation levels between 4 and 20 mR/hr (average 4-5 mR/hr). These radiation levels remained a concern relative to the NRC limits for unrestricted areas. The manhole was still posted and restricted. Sediment and water samples were also collected from that manhole and analyzed. The concentration of cobalt-60 in the sewer sediment was 6.4 E-4 uCi/g and the concentration in the water collected in the manhole was 1.5 E-7 uCi/ml.

No direct radiation levels above background and associated with environmental contamination could be identified outside the facility. Soil samples taken showed cobalt-60 contamination well below releasable concentrations. Cesium-137 contamination was not detected above background. No significant levels were found in storm water, but a sediment sample taken in a storm sewer near the loading dock revealed 1.6 E-5 uCi/g of cobalt-60.

ORAU concluded that radiological conditions outside the AMS facility were generally at or near background levels and, although some concentrations of cobalt-60 were identified in soil and sediment, the levels did not pose any environmental concern (Enclosure II).

January 23-26, 1990

Routine radiological and fire protection inspection. NOV (SLIII problem, no CP) issued with nine violations, including failure of the emergency generator to autostart; conduct physical inventories; perform bioassays; and maintain adequate high radiation area access controls.

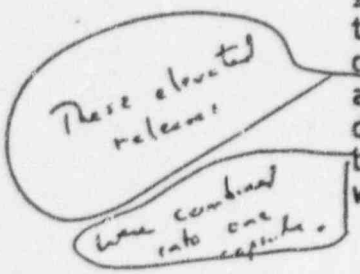
Licensee stack monitoring analysis records indicate that the concentration of effluents released to the environment was about 5.5 E-11 uCi/ml, averaged over calendar year 1989; this is about 18% of 10 CFR 20.106 (3E-10) limit. The majority of the 1989 release occurred during November 1989, when an effluent concentration of 4.9 E-10 uCi/ml was released between November 9 and November 29, 1989. The licensee attributed the elevated release in November 1989 to hot cell operations, when five depleted cobalt-60 sources were cut open to consolidate their bulk constituents into one larger capsule. Although the stack monitoring system appears to be isokinetic, several unresolved items associated with the monitoring system were identified.

Small volumes of liquid radwaste are occasionally generated from the licensee's two decontamination showers and three sinks. This waste is collected in a small (approximately 200 gallon) holdup tank located in the basement and batch released to the sanitary sewer system. Waste water is mixed and analyzed, as delineated in ISP-12, prior to release. Licensed records indicated the last planned release of liquid radwaste was on January 25, 1989 and consisted of 136 gallons containing 67 uCi of cobalt-60. This release concentration is about 14% of applicable 10 CFR 20.303 limit.

On May 25, 1989, heavy rains caused a sewer backup that flooded the basement of the licensee's London Road facility, a contaminated area, with about 2E7 milliliters of water (about 5300 gallons). The water apparently entered the

	basement through a floor drain. The water was sampled and analyzed by the licensee and allowed to drain back into the sewer system through the floor drain. Licensee records showed that the release concentration was about 16% of applicable 10 CFR 20.303 sanitary sewer disposal limits.
June 11, 1990	Findings of the ORAU 1985 and NRC 1990 fire protection assessments were combined into a Fire Protection Safety Evaluation Report and transmitted to the licensee. Although no violations were identified, the assessments identified several weaknesses in the licensee's fire protection capabilities.
July 16-17, 1991	Routine inspection of the licensee's hot cell ventilation system replacement project and of selected outstanding issues. NOV issued for repeated failure of the emergency generator to autostart. Concerns with the ventilation system's operability and testing were also noted. No liquid effluent discharges were made since the previous inspection in January 1990. Licensee stack monitoring analysis records showed that the concentration of cobalt-60 effluent released to the environment was about 5.75 E-12 uCi/ml, averaged over calendar year 1990 and 7.25 E-12 uCi/ml for 1991, averaged monthly through July 15, 1991. These concentrations are less than 3% of the 10 CFR 20.106 limits.
August 27, 1991	Radiological surveys of NEORSD's Easterly Wastewater Treatment Plant. The surveys consisted of direct radiation level measurements in and around the plant, including process piping and collection vessels where wastes are handled or processed. No radiation levels above natural background were noted.
April 7-8, 1992	Special (AIT) inspection to review material accountability problems. No violations were identified; however, significant material accountability and inventory problems were noted.
September 30 - October 2, 1992	Special inspection to review concerns associated with the radiological conditions in the hot cell. No violations identified; however, several concerns related to the hot cell's radiological condition, operating history, and design were noted.

Licensee stack monitoring analysis records showed that the concentration of cobalt-60 effluent released to the environment was about 5.75 E-12 uCi/ml and 5.5 E-12 uCi/ml, averaged over calendar years 1990 and 1991, respectively. The average concentration for 1992 through September 29, 1992, was 1.4 E-12 uCi/ml. These concentrations are less than 5% of the 10 CFR 20.106 limits. Elevated released occurring during specific, two to four week periods in 1990 and 1991, were found to coincide with hot cell cleaning ~~decontamination~~ activities and ~~during combining of source bulk lots~~. These elevated short term releases were also within 10 CFR 20.106 limits.



January 19-20, 1993

Routine inspection to review teletherapy service and installation activities. No violations or significant problems identified.

April 19, 1993

Routine inspection to review physical inventory operations. No violations identified. Source garden inventory complete; however, hot cell inventory cannot be completed until a storage plug lifting ring is repaired.

Stack air sample analysis frequency was increased to weekly during the hot cell decontamination activities conducted in preparation for the physical inventorying. During the January 21, 1993 - February 24, 1993 period, the maximum stack effluent release was 7E-12 uCi/ml.

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4871 TWX 4332-136 ATC UI FAX (216) 466-0186

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To John Madera	From Sherry Stein
Co. USNRC	Co. AMS
Dept.	Phone #
Fax # 708/790-5183	Fax # 216/466-0186

May 17, 1993

Mr. John Madera
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Madera:

In response to your request for a status of our physical inventory, we offer the following:

As previously indicated in our letter of April 16, 1993, the physical inventory of the source garden was completed by March 31, 1993, with the completion of the inventory of the rear hot cell plug following shortly thereafter. In addition, on April 5, 1993, four (4) cesium sources were shipped to J. L. Shepherd & Associates, and nine (9) cobalt^{60} sources were shipped to Southwest Research Institute for J. L. Shepherd.

As you are well aware, although AMS' inventory records of sources received by us are properly maintained, the records inventory carried over from Picker was incomplete and never verified by them. We have, thus, been diligently working to make our records as complete as possible.

We can verify that the records indicated that we had sixty-three (63) competitive sources prior to commencing the physical inventory, and we physically verified our possession of sixty-three (63) competitors' sources. Two (2) of these sources have since been shipped to Southwest Research Institute.

Our records also indicated that we possessed fifteen (15) AMS sources, all of which have been physically verified and eighty-one (81) Picker sources (including Picker wafer sources). We have physically verified eighty-one (81) Picker sources. Two (2) Picker and five (5) AMS sources have since been shipped to Southwest Research Institute.

The ten (10) bulk lots listed as being contained in the garden have all been verified. Of the fourteen (14) bulk lots listed as, at one time, being contained in the hot cell in sixteen (16) capsules, nine (9) have been physically verified, with the remaining seven (7) listed as potentially being contained in the front cell plug. AMS cannot state for certain if these bulk capsules are in fact inside the front plug for the following reasons: First, their contents may have been used in the fabrication of other sources; and second, four (4) bulk lots, B449 (Capsule No. II), B450 (Capsule No. I), B453 (Capsule No. XXIII), and standard (Capsule No. SK-84, containing eighteen (18) curies of wafer source material) do not specify which lots were combined to fill them.

With respect to the cesium^{137} sources, AMS' records based on actual physical inventories previously performed, indicated that AMS possessed nine (9) sources, two (2) of which were previously taken by J. L. Shepherd, four (4) of which were shipped to J. L. Shepherd in April, and three (3) of which are scheduled to be shipped to J. L. Shepherd shortly. AMS will not remove cesium^{137} from its license until after the contents of the front cell plug have been verified, since one source possessed by Picker in 1977, CS-10, does not have a disposition record. Although it was never indicated as being in AMS' possession, Picker records are incomplete and AMS cannot thus verify at this time that once it ships the three (3) sources to J. L. Shepherd that it will no longer be in possession of any cesium sources.

With respect to the front cell plug, since early-April, 1993, AMS has been diligently trying to remove it so that its contents may be physically verified. This process has included replacing the lifting ring on its lid so that it could be removed. AMS also attempted several applications of WD-40, a penetrating lubricant, in an attempt to dislodge the floor plug from its receptacle. This was done because it was suspected that a corrosion level might have developed between the plug and its receptacle. From what we can determine from speaking with former AMS and Picker employees, the front plug has been inoperable since at least the mid-1980's. AMS has sought help from current and former Picker and AMS employees as well as from outside consultants including Alaron, Science and Technology, Inc., and J. L. Shepherd & Associates. So far all recommendations for remote removal have proven unsuccessful. Although AMS is continuing to actively seek assistance from outside consultants, it appears that removal of the front plug may require a physical entry into the cell to dislodge the plug. At present, although the cell has been cleaned to the point where the inventory could be conducted, its levels do not permit such a physical entry.

AMS does plan to make another shipment of cobalt^{60} and cesium^{137} sources as soon as the containers used to make the previous shipments have been returned. Some of these containers are expected to be received back from Southwest Research Institute by May 20, 1993. The removal of additional sources from the garden will permit the sources currently stored in the cell to be transferred to the garden. Once that shipment has been made, AMS will recommence cleaning the cell so that an entry may be made. In the meantime, AMS is continuing to actively pursue outside assistance in finding a means to dislodge the cell plug remotely. It is not practical, however, to expect that the removal and physical inventory of the front cell plug will be accomplished by June 1, 1993, since this is not possible without exposing the individuals attempting to remove the plug to extreme health and safety risks.

The plug in its present condition is secure and does not pose a health or safety risk to employees or the public.

At this point, it is difficult to determine an exact time frame for removal of the front floor plug. Based on discussions with consultants, we have been unable to determine a safe and effective method for withdrawal of the front plug. Since the only apparent method for removal of the front plug is a complete clean up of the hot cell to allow entry into the hot cell, some prior actions must be completed.

First, the cobalt sources in the garden must be removed to allow space for the sources in the rear plug. Second, the sources in the rear plug must be placed in the garden. Third, the hot cell and decon room must be decontaminated to the greatest extent possible. Finally, techniques must be devised and evaluated to determine how the front plug can be removed.

The first two steps should be completed by mid-June, 1993. The hot cell and decon room decontamination will take approximately five weeks which takes us, at the earliest, to the end of July, 1993. The final step for evaluation of the front plug cannot be determined at this time based on the information available to AMS. AMS will provide updates to you by mid-August, 1993, as we make progress in resolving this issue. By that time, AMS should have completed an evaluation of the front plug and with the help of consultants, as necessary, been able to determine the necessary course of action.

Finally, a summary of the status of the inventory to date is attached for your convenience.

Sincerely,

SHERRY J. STEIN
Director of Regulatory Affairs

SJS/cs
Attachment

SUMMARY OF PICKER AND AMS INVENTORY RECORDS COMPARED TO PHYSICAL VERIFICATION OF SOURCE GARDEN AND REAR CELL PLUG

INVENTORY RECORDS OF RETURNED SOURCES AND BULK COBALT

AMS SOURCES	15	15 VERIFIED; 5 SHIPPED TO SOUTHWEST RESEARCH INSTITUTE; 10 REMAINING (9,317 CURIES*)
PICKER WAFER AND PELLET	81	81 VERIFIED; 2 SHIPPED TO SOUTHWEST RESEARCH INSTITUTE; 79 REMAINING (11,283 CURIES* INCLUDING 39 WAFER SOURCES TOTALING 2,457 CURIES)
COMPETITIVE SOURCES	63	63 VERIFIED; 2 SHIPPED TO SOUTHWEST RESEARCH INSTITUTE; 61 REMAINING (44,578 CURIES*)
CESIUM^{137}	9	9 VERIFIED; 2 SHIPPED TO J. L. SHEPHERD PRIOR TO INVENTORY; 4 SHIPPED TO THEM FOLLOWING CELL INVENTORY; 3 SCHEDULED TO BE SHIPPED SHORTLY (3,367 CURIES*)
BULK COBALT CAPSULES IN GARDEN	10 LOTS LISTED IN 13 CAPSULES	ALL 13 CAPSULES VERIFIED (3,552 CURIES*)
BULK COBALT CAPSULES IN CELL	14 LOTS LISTED IN 16 CAPSULES (AS BEING STORED IN THE CELL AT ONE TIME)	9 CAPSULES PHYSICALLY VERIFIED; 7 LISTED AS HAVING ONCE BEEN IN THE FRONT PLUG (ESTIMATED MAX. CURIES 13,398*)
BULK COBALT IN GE-500 CASK	10,793 CURIES AS OF 4/1/93	10,793 CURIES AS OF 4/1/93

*CURIES CALCULATED AS OF 4/1/93

TOTAL CESIUM^{137} SEALED SOURCES VERIFIED IN AMS' PRESENT POSSESSION: 3 TOTALING 3,367 CURIES AS OF 4/1/93. TOTAL COBALT^{60} SEALED WAFER AND PELLET SOURCES VERIFIED IN AMS' PRESENT POSSESSION: 150 TOTALING 65,178 CURIES AS OF 4/1/93. TOTAL BULK COBALT^{60} INCLUDING 7 SUSPECT CAPSULES: 27,743 CURIES AS OF 4/1/93. AMS IS THUS WELL BELOW ITS CESIUM^{137} AND COBALT^{60} LICENSE LIMITS, BUT WILL NOT CUT DOWN ITS LICENSED AMOUNTS UNTIL AFTER THE CONTENTS OF THE FRONT PLUG HAVE BEEN PHYSICALLY VERIFIED.

SJS/cs
5/17/93

DRAFT
6/1/93

Docket No. 030-16055

License No. 34-19089-01

Advanced Medical Systems, Inc.

ATTN: Ms. Sherry Stein, Director

Regulatory Affairs

1020 London Road

Cleveland, OH 44110

SUBJECT: DEMAND FOR INFORMATION

Dear Ms. Stein:

This refers to the Advanced Medical Systems, Inc. (AMS) radioactive material inventory requirement described in License Condition 14.C. of NRC License No. 34-19089-01. We are concerned that AMS has not yet completed the required physical inventory of all radioactive material possessed under its license. License Condition 14.C required such inventory to be complete on or before June 1, 1993. This has been a subject of considerable discussion and exchange of correspondence between AMS and NRC staff. We recognize that AMS has made progress toward the completion of the required physical inventory. Notwithstanding, these efforts were not sufficient to meet the requirements for completion of the inventory and assuring us that all radioactive material is accounted for.

Attached is a Demand for Information which documents the communications and past actions by AMS, and which identifies the information required to determine whether the Commission can expect to receive an adequate radioactive material inventory and if not, whether AMS should be subject to escalated enforcement action.

If AMS does not satisfactorily respond to this Demand for Information the NRC will consider taking escalated enforcement action in the form of civil penalties of $1,000 for each day the physical inventory is not completed. The NRC Region III contact is Roy J. Caniano, Chief, Nuclear Materials Safety Branch, (708) 790-5500.

Questions concerning this Demand should be addressed to the contact person named above.

The information gathering directed by this letter was approved by the Office of Management and Budget (OMB) as required by the Paperwork Reduction Act of 1980, (44 U.S.C., 3501 et seq.), OMB approval number 3150-0017, which expires March 31, 1996.

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

Sincerely,

J. Martin

Regional Administrator

Enclosure: Demand for
Information

cc w/enclosure:
SECY
CA
S. S. Stein, President
H. Thompson, DEDS
J. Sniezek, DEDR
J. Lieberman, OE
L. Chandler, OGC
J. Goldberg, OGC
R. Bernero, NMSS
R. Cunningham, NMSS
Enforcement Coordinators
RI, RII, RIV, RV
F. Ingram, GPA\PA

D. Williams, OIG

B. Hayes, OI

V. Miller, SP

E. Jordan, AEOD

OE:ES

OE:Chron

OE:EA (2)

State of Ohio

RAO:RIII

SLO:RIII

PAO:RIII

IMS:RIII

bcc w/enclosure:

PUBLIC

RIII	RIII	RIII	RIII	RIII	RIII	RIII	RIII.
Madera/jaw	McCann	Caniano	Norelius	Berson	DeFayette	Miller	davis

DRAFT

UNITED STATES

NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Advanced Medical Systems, Inc.	)	Docket No. 030-16055
1020 London Road	)	License No. 34-19089-01
Cleveland, Ohio 44110	)	EA _____

DEMAND FOR INFORMATION

I.

Advanced Medical Systems, Inc. (AMS or licensee) is the holder of Byproduct Material License No. 34-19089-01 issued by the Nuclear Regulatory Commission (the NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes possession and use of 150,000 curies of cobalt-60 as solid metal for storage and training of licensee personnel in the manufacture of NRC approved sealed sources, 150,000 curies of cobalt-60 and 40,000 curies of cesium-137 in NRC approved sealed sources for installation and removal from radiography and teletherapy devices; and for storage only of 15,000 curies of cobalt-60 as non-approved sealed sources already in the licensee's possession prior to

renewal of its license on December 13, 1989. The license further authorizes the installation, servicing, maintenance, and dismantling of radiography and teletherapy units. The license was originally issued on November 2, 1979 and was last renewed on December 13, 1989, and is due to expire on December 31, 1994.

II.

License Condition 14 of Amendment No. 14, which became effective on January 26, 1988, required that AMS conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. During an NRC inspection conducted at AMS on January 23-26, 1990, nine (9) violations of NRC requirements were identified. Among those violations identified was AMS' failure to conduct a physical inventory every 6 months during the period January 1988 through January 26, 1990, to account for all sources and/or devices received and possessed under the license.

With regard to the specific violation for failure to conduct physical inventories of radioactive material, the NRC understood from AMS statements made during the March 27, 1990, enforcement conference conducted in Cleveland, Ohio, that such an inventory was underway and was to be completed by the end of 1990. During the Enforcement Conference AMS discussed the difficulties

inherent in performing a physical inventory at six month intervals. The NRC staff understood that AMS would propose, in a request for a license amendment, an alternative means of assuring that the location and amount of licensed material would be accurately known. However, as stated in our July 26, 1990 Notice of Violation (NOV), AMS was required to conduct six month physical inventories to comply with NRC license conditions and regulations unless specific relief was requested and received in the form of a license amendment.

By letter dated October 3, 1990, in response to the July 26, 1990 NOV, AMS stated that the physical inventory was suspended indefinitely on September 21, 1990, due to the employment termination of its Radiation Safety Officer (RSO) and source handler. The required physical inventory was postponed pending the arrival of the new RSO and the training of other isotope technicians. During the period between September 21, 1990, and April 17, 1991, the date the AMS license was amended to add a new interim RSO, AMS retained the services of the previous RSO for service operations only.

The new RSO was fully trained and able to carry out physical inventory operations by the end of May 1991. The AMS license was amended on May 31, 1991, to authorize the new RSO and to remove authority for manufacturing sealed sources other than for training purposes. The removal of sealed source manufacturing authority was initiated because of the employment termination of the only AMS qualified source handler and fabricator.

During the period between May 1991 and early 1992, the newly appointed RSO was involved with training, hot cell ventilation system replacement, and the preparation of the AMS Decommissioning Funding plan cost estimate, required by 10 CFR 30.35. Consequently, little time was devoted to the completion of the required physical inventory.

In early 1991, AMS terminated the employment of the RSO. On March 13, 1992, AMS amended its NRC license to add another new RSO for service operations and routine health physics activities. Again, the physical inventory was postponed due to the training requirements for the new RSO and the completion of the hot cell ventilation redesign and replacement project.

After numerous letters and telephone conferences between NRC and AMS concerning the importance of the completion of a physical inventory to account for all radioactive material possessed by AMS, Condition No. 14 of the AMS license was amended on May 8, 1992 to reflect new inventory requirements. This condition outlined various milestones with completion dates that AMS had to meet to complete the required physical inventory of the remaining radioactive material possessed under the license by March 31, 1993.

From the issuance of the May 8, 1992 amendment described above to March of 1993, AMS was unable to complete the required inventory. Resources were directed to other areas including: (1) personnel changes; (2) hot cell ventilation system redesign and replacement; (3) training of new personnel; and (4) hot cell decontamination projects.

AMS requested an extension to the March 31, 1993 inventory completion date required by License Condition No. 14 of their license by letter dated March 30, 1993. The March 30, 1993 letter stated that one of the floor plugs in the hot cell covering a sealed source storage well had a broken lifting device. In order to repair this device and complete the inventory inside the hot cell, the hot cell would need to be cleaned completely. This operation, according to AMS, would require a two month extension to the March 31, 1993 required inventory completion date. Therefore, AMS requested in their March 30, 1993 letter, a license amendment to allow for the completion of the sealed source inventory by June 1, 1993.

On April 19, 1993, NRC Region III amended the AMS license to extend the required date for completion of a physical inventory of all radioactive material possessed under NRC License No. 34-19089-01 to June 1, 1993. The NRC cover letter to this amendment stated that AMS had not allocated appropriate resources and/or included in its planning, sufficient time to allow for such contingencies, which resulted in another amendment request to extend the completion date. While granting the amendment request, the letter stated that the NRC did not intend to grant any further extensions of the inventory completion date. Further, it stated that failure to complete a physical inventory on or before June 1, 1993, would result in our consideration of escalated enforcement action. AMS submitted to NRC by letter dated May 17, 1993, a status report on their inventory. This status report indicated that AMS was again experiencing problems with the front floor plug of the hot cell storage well. The report stated that it would not be

practical to expect that removal and physical inventory of the front cell plug would be accomplished by June 1, 1993, since this would not be possible without exposure of individuals attempting to remove the plug to extreme health and safety risks. The May 17, 1993 report outlined four actions to be completed before hot cell entry could be attempted to dislodge the floor plug. First, the cobalt sources in the garden must be removed to allow space for the sources in the rear plug. Second, the sources in the rear plug must be placed in the garden. Third, the hot cell and decon room must be decontaminated to the greatest extent possible. Finally, techniques must be devised and evaluated to determine how the front plug can be removed.

AMS stated that the first two steps should be completed by mid-June, 1993. The hot cell and decon room decontamination will take approximately five weeks to the end of July, 1993. AMS further stated that the final step for evaluation of the front plug cannot be determined at this time. AMS stated they would provide updates to NRC by mid-August, 1993, as they make progress in resolving this issue. By that time, AMS should have completed an evaluation of the front plug and with the help of consultants, as necessary, be able to determine the necessary course of action.

This summary demonstrates that AMS was in violation of its inventory requirements since at least January 26, 1988 to May 8, 1993. This was identified to AMS during an inspection in January 1990. License modifications since May 8, 1992 required the completion of the inventory by June 1, 1993, and to date this requirement has not been met. Repeated efforts by the NRC

through routine enforcement and licensing actions have not resulted in compliance with the requirements by AMS. The lack of a physical inventory raises questions as to the accurate knowledge of the location of large quantities of cobalt-60 and cesium-137 which may demonstrate a matter of significant safety concern. We recognize that AMS has made an effort ~~and has made progress~~ to complete the inventory. However, these efforts were not sufficient to meet the requirements for completion of the inventory, and assuring us that all radioactive material is accounted for. Thus it is imperative that escalated enforcement action be considered to ensure timely completion of this physical inventory and confirm what radioactive material is in AMS' possession.

III

Accordingly, pursuant to Sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and 10 CFR Part 30, the Licensee is required to submit to the Regional Administrator, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, information that demonstrates why enforcement action in the form of daily civil penalties until the date of inventory completion, should not be taken. In submitting this information, the licensee may address, among other things, the following:

A. Reasons why appropriate resources were not committed to the completion of the inventory since January 1990. The following issues should be addressed:

- The date when the inventory was actually started.

- Why contractors were not obtained to assist in meeting license commitments. If contractors were utilized, include specific dates and contractor visits onsite to evaluate or assist in the inventory and verify that monies were expended for contractor support (provide copies of contracts and statements of work).

B. Plans for completing the inventory, including provisions for the allocation of resources and specific timetables, i.e., name(s) of contractor, copies of contracts, and statements of work. Also, describe the root cause(s) for not meeting past commitments and what has been done to assure current plans address the root cause(s) and will be successful.

Copies of your response to this Demand also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and Assistant General Counsel for Hearings and Enforcement at the same address.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this day of , 1993

Advanced Medical Systems, Inc.

1. Site Identification

Advanced Medical Systems, Inc.
Cleveland, OH
License No.: 34-19089-01
Docket No.: 030-16055
License Status: Active
Project Manager: D. Sreniawski, Region III
LLWM Monitor: D. Orlando

2. Site and Operations

Advanced Medical Systems, Inc. (AMS), manufactures cobalt-60 (Co-60) and cesium-137 (Cs-137) sources for use in medical teletherapy devices and radiography machines. Poor radiation safety practices in plant operations have led to serious contamination of the facility. A 1985 survey by Oak Ridge Associated Universities (ORAU) found surface contamination in a hot cell, the ventilation system, the dry waste storage area, the liquid waste area, and the holding tank and piping. No offsite contamination was found. However, some detectable activity was found in sediments, soil, and vegetation in the southern portion of the AMS property. ORAU believed that this contamination resulted from stack effluent releases. Per a July 1987 Nuclear Regulatory Commission (NRC) order, the licensee has cleaned-up the site, with the exception of a holdup tank room, to contamination levels suitable for continuing operations. Exposure rates of 2000 Rem per hour at 30 centimeters have been measured in the holdup tank room making the activity level too high to compel cleanup at this time. NRC gave AMS permission to seal and monitor this room until radiation levels are low enough to permit decontamination.

Currently, AMS plans to continue sealed source manufacturing operations and does not plan to decommission the facility soon. During the next

showed Co-60 levels up to 150 pCi/l and sediment samples showed up to 640 pCi/g. No Cs-137 was detected. AMS completed cleanup to activity levels suitable for continued operation in 1989. Unrestricted release criteria were not used. The holdup tank room remains sealed and cleanup of this room will be evaluated during the license renewal in December 1994.

3. Radioactive Wastes

The contaminated material at the AMS facility consists of equipment and concrete contaminated with Co-60. There is also some Co-60 contaminated sludge in sewer piping. The concrete and equipment contain a wide range of activity levels with relatively low exposure rates up to 2000 R/hr in the holdup tank room. Activity levels for the contaminated sludge are relatively low with exposure rates up to 20 mR/hr. In addition Co-60 pellets, used to manufacture sealed sources, may be present. The licensee is not currently using Cs-137, and the bulk of this isotope is in the form of sealed sources that were returned from customers. These sources are stored in a sealed source storage vault in the isotope shop.

4. Description of Radiologic Hazard

The principal hazards associated with the AMS facility are direct exposure, inhalation, ingestion, intrusion, and ground water contamination. No immediate threat to the public health and safety exists. Direct exposure has been significantly reduced by the licensee's previous cleanup activities. Access to the high exposure rates and contamination in the holdup tank room is prohibited by a concrete block wall. Sufficient shielding exists to reduce exposure rates to less than 30 mR/hr outside the holdup tank room. Inhalation and ingestion of radioactive material is minimized by high efficiency particulate air filter (HEPA) filtered ventilation systems and by protection of the hot cell and sealed rooms. Intrusion into the facility is unlikely because the facility is protected as a restricted area. Offsite ground water samples show Co-60 levels at or just above background.