

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

QA
ISSUED
7-23-87

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.
One Factory Row
Geneva, OH

Docket No. 30-16055

License No. 34-19089-01

ORDER MODIFYING LICENSE, EFFECTIVE IMMEDIATELY,
AND 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) pursuant to 10 CFR Part 30. The license authorizes possession and use of 150,000 curies of cobalt-60 as solid metal, 150,000 curies of cobalt-60 in sealed sources, and 40,000 curies of cesium-137 in the manufacture, installation and servicing of radiography and teletherapy devices. The license further authorizes the installation, servicing, maintenance, and dismantling of radiography and teletherapy units. The license, originally issued on November 2, 1979, was renewed on June 25, 1986, with an expiration date of October 31, 1986. A timely renewal application has been submitted.

II.

Licensee's teletherapy source fabrication facility is located at 1020 London Road in Cleveland, Ohio ("the London Road facility" or "facility"). Based on surveys conducted in October 1985 and August 1986, contamination and radiation levels at the London Road facility have been found to be excessive and increasing.

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15 pp

Advanced Medical Systems, Inc.

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On October 21-24, 1985, at the request of the NRC staff, representatives of the Radiological Site Assessment Program of Oak Ridge Associated Universities (ORAU) performed an evaluation of the fire protection and operational radiation safety problems at the London Road facility. In addition, ORAU performed confirmatory measurements and onsite/offsite sampling to determine the radiological status of the site and the immediate environment.

On February 20, 1986, NRC Region III representatives met with representatives of AMS at the London Road facility. The meeting included a discussion of the findings and recommendations in ORAU's evaluation report and a discussion of immediate actions that should be taken to protect the public health and safety. Among the concerns expressed by NRC representatives at the meeting were excessive contamination throughout the facility, excessive accumulation of radioactive material, a high potential for serious personnel exposure if operations continue as in the past, and decontamination costs estimated at approximately \$1 million with no firm commitment from AMS that funding will be available.

On March 7, 1986, the NRC staff requested that AMS submit plans to clean up its radioactive waste, decontaminate its hot cell area, and decontaminate its solid and liquid waste storage areas in the basement of the London Road facility. On April 16, 1986 AMS submitted a letter to the NRC on the status of its cleanup of radioactive waste and a general statement about plans for obtaining a contract for decontamination. The NRC staff informed AMS by letter dated May 6, 1986 that

its April 16 response was inadequate. On May 29, 1986 AMS submitted a letter to the NRC indicating the status of its radioactive waste cleanup and providing further general statements about plans to contract for decontamination. Attached to the letter was a generic decontamination plan with no specific schedules for cleanup.

Due to AMS' failure to submit an adequate decontamination plan for the London Road facility as requested in March 1986 by the NRC staff, the NRC on June 25, 1986 issued Amendment No. 8 to AMS' license requiring AMS to submit, within 60 days, a decontamination plan for the facility (License Condition No. 15.A) and copy of a contract for decontamination by a qualified health physics organization.

On July 24, 1986 AMS submitted to the NRC a contract with Rad Services, Inc. to perform decontamination of the London Road facility. The contract contained a schedule for providing the decontamination plan.

On September 5, 1986, Amendment No. 9 was issued extending the time under the AMS license for submittal of the decontamination plan to the NRC. On September 10, 1986, AMS submitted to the NRC a decontamination plan dated September 8, 1986 (Plan), with schedules for decontamination of the London Road facility.

On October 23, 1986 the NRC issued Amendment No. 10 to the AMS License. Pursuant to that license amendment and Conditions 16 and 19.E of AMS'

current license, the initiation of decontamination activities at the London Road facility was required, in accordance with the Plan, by December 22, 1986. Conditions 15.A, 19.C, and 20 in Amendment 10 incorporate AMS' commitments to redesign, reconstruct, and upgrade its facility.

By letter dated December 23, 1986, a day after the decontamination implementation deadline, AMS requested that Condition 16 "be placed in abeyance to be reconsidered following reconciliation of the [NRC's] suspension Order of October 10, 1986." The October 10th Order suspended AMS' authority under its license to install, service, maintain, or dismantle radiography or teletherapy units. The NRC responded, by letter dated February 11, 1987, that it does not consider the Order to be a basis for modification of the license and that any relaxation of the time frames of AMS' decontamination effort must be submitted as an application for a license amendment.

By letter dated March 20, 1987, AMS requested that Condition 16 be revised to provide that AMS shall initiate decontamination of the London Road facility, in accordance with its Plan, by March 1, 1988. AMS cited lack of available profits from its business, due to the suspension of AMS' service license from October 10, 1986, until February 2, 1987, as the basis for its request. AMS stated, "We anticipate that profits, necessary to resolve the accumulated deficit since October 10, 1986 and to provide sufficient profits to finance continuation of the decontamination program, will be available, at the earliest, by March 1, 1988." Region III staff discussed the March 20, 1987, proposal with AMS staff during a site visit on April 2, 1987. Subsequent to that visit, AMS supplemented the March 20, 1987, request with a letter dated

April 10, 1987, proposing an alternative schedule for implementation of the decontamination program, which would still defer initiation of decontamination of the most contaminated areas until March 1, 1988, contingent upon profitability of the company. To date, AMS has not made substantial progress on any of the decontamination activities pursuant to the Plan required under its license.

III.

ORAU's site evaluation of the AMS London Road facility in October 1985 and surveys performed by RAD Services, Inc, an AMS contractor, in August 1986 indicate that a general degradation of radiological conditions has continued, resulting in a significant potential for unnecessary radiation exposures for workers at this facility as evidenced by the following:

1. In the basement, general area radiation levels have remained very high (500-10,000 mR/hr); contamination levels have increased significantly (from 40,000 dpm/100 cm² to 1,500,000 dpm/100 cm²). The liquid waste room general area is on the order of 300 R/hr with some areas as high as 1000 R/hr.
2. On the first floor, general area radiation levels in the Isotope Shop Area (ISA) showed substantial increases from 1985 to 1986 (up to 400% increase). The ISA showed levels of 1.5 - 54.0 mR/hr in 1985, and 2.0 - 180.0 mR/hr in 1986 (the average radiation level in the ISA, a relatively high traffic area, was 15 mR/hr). Contamination levels have increased from a maximum of 90,000 dpm/100 cm² in 1985 to 500,000 dpm/100

cm² in 1986. Radiation levels in the hot cell have been measured at 80 R/hr during routine maintenance procedures and irradiated pellet deliveries. The hot cell entry area (decontamination room) is extremely contaminated due to recent source manufacturing operations and accumulation of solid radioactive waste. A licensee survey performed on April 2, 1987 during an NRC site visit revealed gross floor contamination in excess of 1,000,000 dpm/100 cm².

3. The area of concern on the second floor is the cell machinery/filter room, which houses the exhaust ventilation system, cell-crane equipment, and back-up power supplies. The exposure rate outside the restricted area exhaust ventilation room exceeds 80 mR/h in some areas due to contamination on the HEPA filter. During the 1985 ORAU audit, the exposure rate at the hot cell filter was 3.0 R/h. These exposure rates are excessive, and severely limit the time accessibility to this room for routine maintenance (filter exchange, generator and battery checks, etc.). The filter room and surrounding areas are locked and controlled as restricted areas.

IV.

Despite repeated efforts by the NRC to get AMS to take steps to initiate meaningful decontamination efforts at the facility and modify the facility to minimize contamination, AMS has failed to take such steps and there is no assurance that AMS will initiate meaningful decontamination effort by March 1988. Notwithstanding the issuance of license amendments requiring initiation of

decontamination, redesign, reconstruction, and upgrading of the facility, to date efforts have been minimal and contamination and radiation levels remain excessive and are increasing.

On the basis of the above and after NRC review of licensee activities onsite, it is apparent that since December 22, 1986, AMS has been operating and continues to operate in noncompliance with Conditions 15.A, 16, 19.C, 19.E and 20 of its license in that it has failed to initiate the required activities at the London Road facility. Consequently, the NRC lacks reasonable assurance that decontamination, redesign, reconstruction and upgrading of the licensee's London Road facility will be initiated and completed in an orderly and timely fashion to assure that the health and safety of the public, including licensee's employees, will be protected. Accordingly, the public health, safety and interest require that those efforts commence forthwith. For these reasons and pursuant to 10 CFR § 2.201(c), no prior notice is required.

V.

In view of the foregoing, and pursuant to Sections 81, 161b, 161i, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 34-19089-01 IS MODIFIED AS FOLLOWS:

- A. By August 31, 1987, AMS shall commence decontamination of the London Road facility in accordance with License Condition Nos. 16 and 19.E of its license.

- B. Decontamination of the London Road facility shall be accomplished in accordance with the schedule described in Sections 4.0.1 through 4.0.10 of the Plan submitted with AMS' letter dated September 10, 1986, with completion dates keyed to a program initiation date of August 31, 1987.
- C. By August 31, 1987, AMS shall commence the redesign, reconstruction, and upgrading of the London Road facility and the other activities required by License Condition Nos. 15.A, 19.C and 20, specifically the plan described in the attachment to AMS' letter dated May 29, 1986.
- D. The activities required in C above shall be accomplished in accordance with the schedule described in the attachment to AMS' letter dated May 29, 1986, with completion dates keyed to a program initiation date of August 31, 1987.

VI.

The licensee or any other person adversely affected by this Order may request a hearing within twenty days of its issuance. Any answer to this Order or request for hearing shall be submitted to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies shall also be sent to the Assistant General Counsel for Enforcement at the same address and the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which the petitioner's interest is adversely affected by this Order and shall address the criteria

set forth in 10 CFR 2.714(d). Upon the failure of the licensee to answer or request a hearing within the specified time, this Order shall be final without further proceedings. AN ANSWER TO THIS ORDER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

If a hearing is requested by the licensee or a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

VII.

While alleged lack of profits does not excuse noncompliance with the conditions of an NRC license, lack of financial ability to comply with NRC requirements may require further NRC action. Therefore, further information is needed to determine whether the Commission can have reasonable assurance that in the future the licensee will conduct its activities in accordance with the Commission's requirements and expeditiously conduct required decontamination, redesign, reconstruction, and upgrading of its facilities and programs.

Accordingly, to determine whether the license should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the licensee is required to submit to the Regional Administrator, Region III, the following information in writing and under oath or affirmation, pursuant to Sections 161c and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Part 30:

A. Provide within 30 Days of receipt of this Order:

1. Copies of AMS' annual financial statements, including but not limited to, balance sheets showing all assets and liabilities and profit and loss statements, for the previous three years.
2. Copies of AMS' quarterly financial statements, including but not limited to, balance sheets showing all assets and liabilities and profit and loss statements, for the previous four quarters.
3. Copies of AMS' annual federal tax returns for the previous three years.
4. A listing of the names of all owners of record of the stock of AMS owning at least 10% of the stock, indicating each owner's address and the number of shares owned.
5. A listing of any planned or projected AMS fabrication of teletherapy or radiography sources for domestic or foreign use within the next 6 months, including the number and activity of the sources to be produced and anticipated date of production.

B. Provide a report every 30 days beginning October 15, 1987 addressing:

1. The progress that has been made toward carrying out the Plan during the past calendar month and the radiation dose received by each worker. In the event that a milestone date set forth in the licensee's May 29, 1986 or September 10, 1986 letters, as modified by this Order, is not met during the period covered by the report, the report shall indicate: (1) the date by which the licensee expects to accomplish the activity, (2) the reason for the licensee's failure to meet the milestone date, and (3) the impact that the failure to meet the milestone date will have on the Plan and schedule.
2. The actions under the Plan that the licensee expects to accomplish within the next 30 days.
3. The financial resources available to the licensee during the period covered by the report, including but not limited to revenue, costs and expenses, net losses or profits, and sums expended during the period on decontamination of the London Road facility.

FOR THE NUCLEAR REGULATORY COMMISSION

James M. Taylor
Deputy Executive Director
for Regional Operations

Dated at Bethesda, Maryland
this day of July 1987.

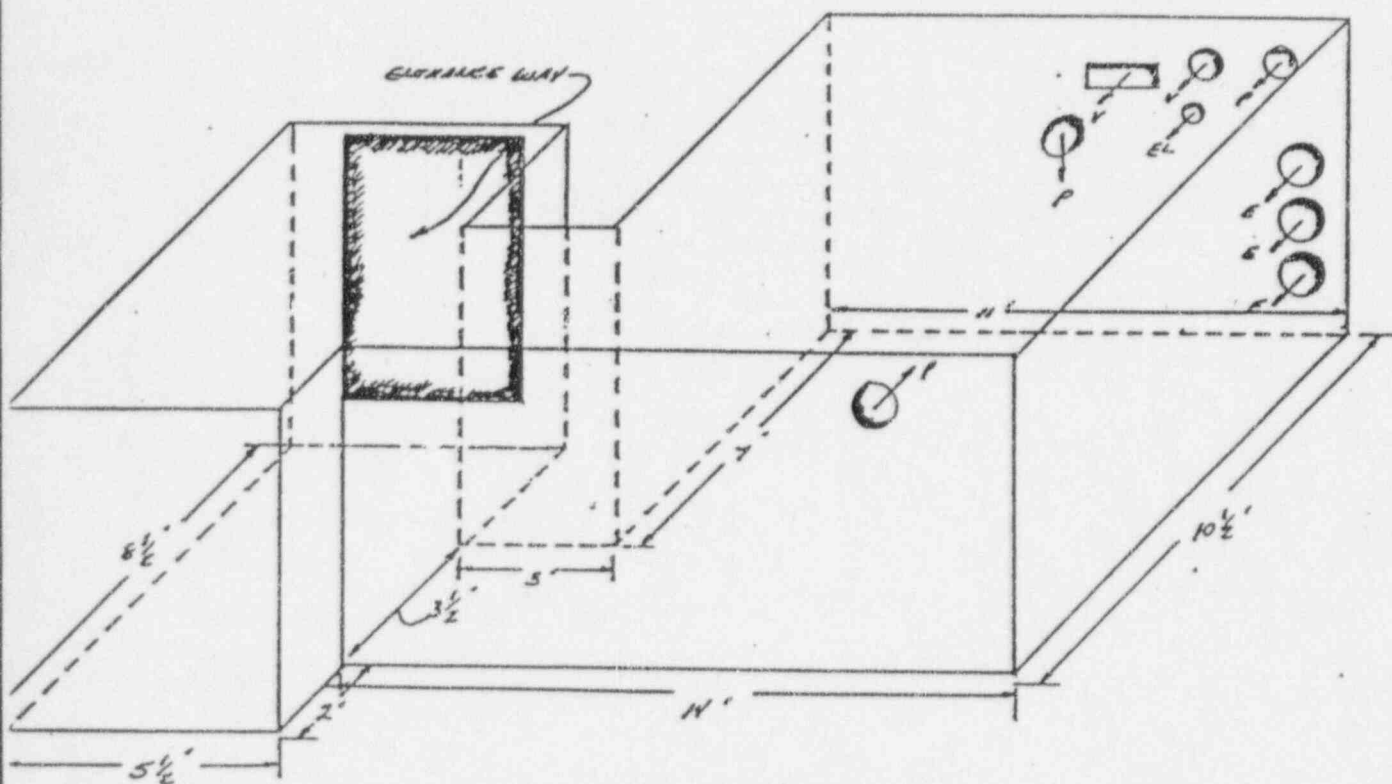
ADVANCE MEDICAL SYSTEMS, INC.
SECTION C
ISOLATION OF W.H.U.T. ROOM
8 FEBRUARY 1988

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.



SECTION G - FIGURE 1
PENETRATION/ROOM DIMENSIONS

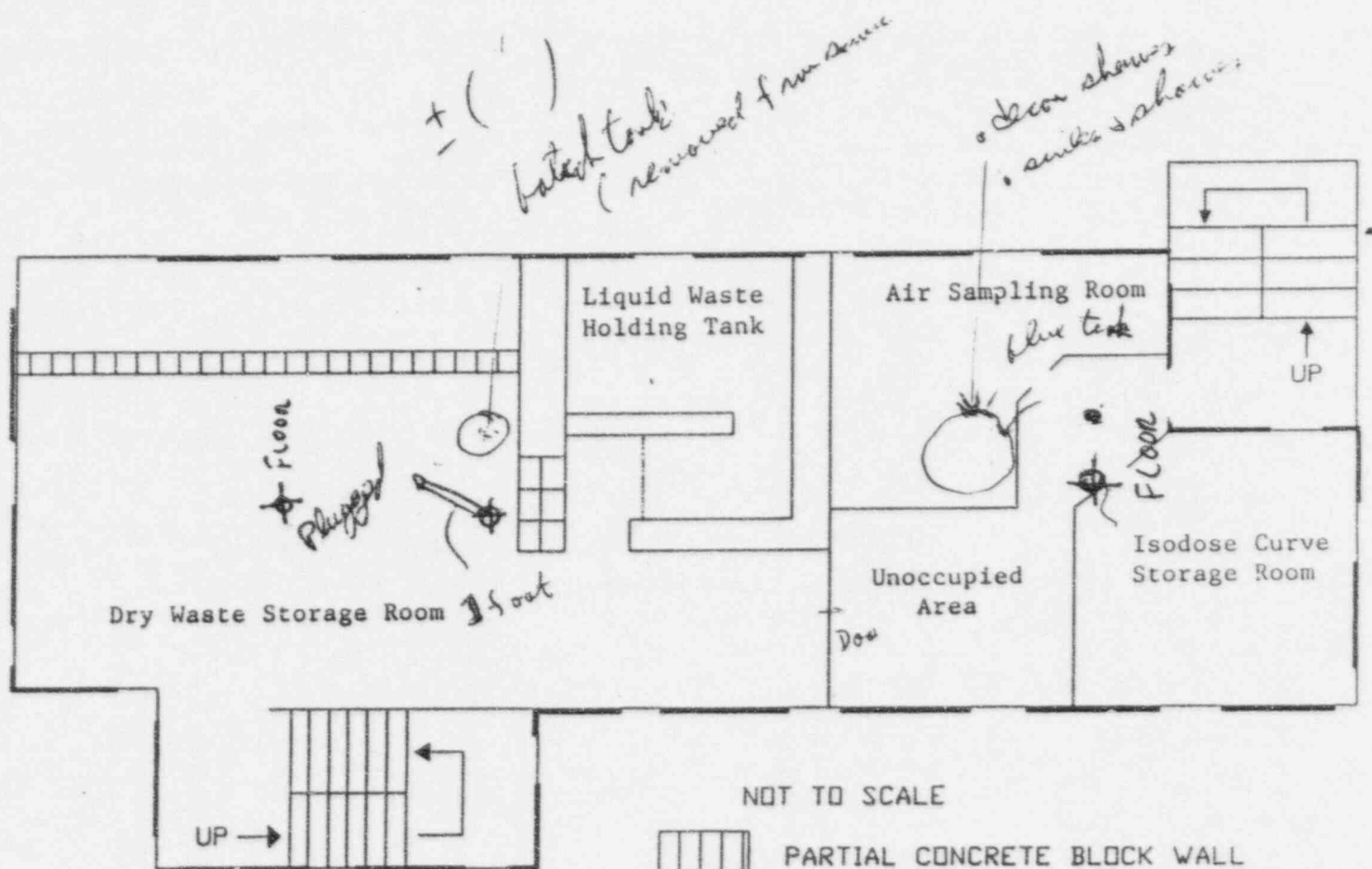


V VENTILATION PEN
P PIPE PEN
EL ELECTRICAL PEN
E EMPTY PEN



AMS8

55



+ ()
bashed tank
(removed from same)

• decou shows
• sinks & showers

Floor
Plugged

blue tank

Floor

Dry Waste Storage Room

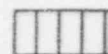
Liquid Waste Holding Tank

Air Sampling Room

Unoccupied Area

Isodose Curve Storage Room

NOT TO SCALE



PARTIAL CONCRETE BLOCK WALL



12" WALL (ACTS AS OVERFLOW BASIN FOR HOLDING TANK)



AREA WITHIN THIS BOUNDARY IS DESIGNATED AS A RESTRICTED AREA BY THE LICENSEE

25%
50%
den/10002
may 89

FIGURE 4-3: AMS Facility--Basement

flood may 89

Val ←
Ht of H₂O in basement
↓
determine Val of H₂O

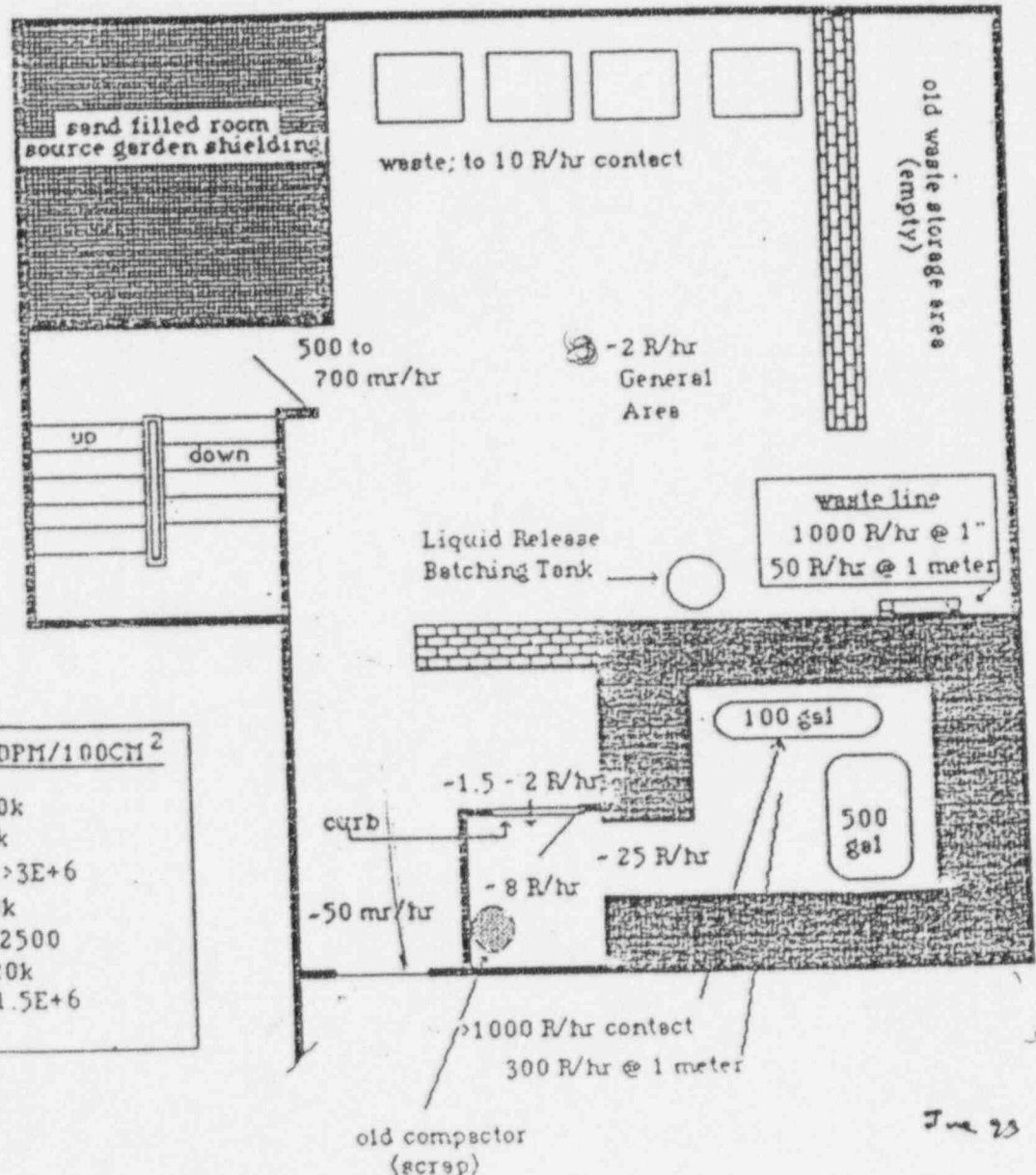
Steve McDemmitt
dealt w/ flood

PRELIMINARY SURVEY WEST BASEMENT

Surveyed by: P Gianutsos & T Spohn
Date and Time: Aug. 21/22, 1986

Survey Instruments R0-2a #003 Lud 177
1345 Teletector #28921 PRM-6 #2525

Air Sample Concentration: $8.9E-10 \mu\text{Ci}/\text{cm}^3$
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 stairwell landing probably due to past storage of leaking red waste.

June 23