501 Summit · Yankton · South Dakota 57078 · Phone 605/665-9371

SACRED HEART Hospital

professional care with a personal touch

1/9/91

Dear Sirs:

Enclosed is the response to the violations license #40-01683-01 that the Department of Nuclear Medicine at Sacred Heart Hospital were sited for on the N.R.C. inspection of 10/24/90. I believe that we have corrected all the discrepancies and are now in line with the N.R.C. regulations.

If any questions or further concerns, please contact Kevin Pistulka RT(R) or Bob Ellingson RT(R) at Department of Radiology, Sacred Heart Hospital, Yankton, SD, 57078.

Thank you for your consideration on this matter.

Sincerely,

Kevin Pistulka RT(R)

Kevin Pistulka RT(R)
Director of Radiology

IE07
1/1

A member of the Benedictine Health System

REPLY TO NOTICE OF N.R.C. VIOLATIONS - LICENSE #40-01683-01

In regards to violation #1 - 10 CFR 35.50 (b) (3) - Sacred Heart Hospital Department of Nuclear Medicine neglected to test the dose calibrator for linearity to below a level of 10 microcuries.

CORRECTIVE ACTIONS TAKEN: Enclosed is ar amendment request to N.R.C. for license #40-01683-01 to begin the use of an Attenuator Kit. This will enable the Department of Nuclear Medicine to conduct the test over a range of activity as low as 10 microcuries. (See attached amendment request Exhibit A)

With implementation of new procedure, the Linearity testing will be scheduled on a quarterly basis.

Compliance will be achieved by February 1, 1991.

In regards to #2 - 10 CFR 35.51 (a) (2) - Sacred Heart Hospital Department of Nuclear Medicine did not calibrate the Victoreen Model 592B and Nuclear Chicago 2612 survey instruments using two separate readings on each scale of use during calibrations in October, 1988, and November, 1989, for Victoreen instruments and July, 1989, for Nuclear Chicago instruments.

Department of Nuclear Medicine failed to calibrate the Nuclear Chicago instruments such that the indicated exposure rate differed from the calculated exposure rate by less than 20% or to attach a correction chart or graph to the instrument when indicated exposure rates varied as much as 10% from the calculated value for calibrations done in June, 1988, and July, 1989.

CORRECTIVE ACTION TAKEN: The Nuclear Chicago survey instrument Model 2612 has been replaced with a Victoreen Survey and Count Meter Model 190 (See enclosed Exhibit B). Department of Nuclear Medicine has also signed an agreement to have Victoreen calibrate both the Victoreen Model 592B and Survey and Count Meter Model 190. This new agreement will assure compliance with N.R.C. Regulations.

Compliance will be achieved by Februery, 1, 1991.

In regards to violation #3 - 10 CFR 35.70 (h) - Sacred Heart Hospital Department of Nuclear Medicine did not retain a record of each radiation survey which included a plan of each area surveyed, the Trigger level established for each area, the detected dose rate at several points in each area expressed in mr/hr, and the instrument used to make the survey.

CORRECTIVE ACTION TAKEN: Department of Nuclear Medicine has implemented new records that include a plan of each area surveyed and trigger levels for each area have been established. Detected dose rates are now being expressed in mr/hr and we are documenting the survey instrument used. (See Exhibit C)

Compliance has bee achieved as of January 2, 1991.

In regardss to violation #4 - 10 CFR 35.92 (b) - Sacred Heart Hospital Department of Nuclear Medicine did not include the following: 1. Notation of the survey instrument used for disposal surveys. 2. Background or waste container surface dose rate at the time of disposal. The Department of Nuclear Medicine had instead recorded "Background".

CORRECTIVE ACTION TAKEN: Procedure for recording disposals has been established that includes the notation of what survey instrument is used, the background dose rate, and the container surface dose rate will be recorded in mr/hr. (See Exhibit D1 and D2)

Compliance has been achieved as of January 2, 1991.

In regards to violation #5 - 10 CFR 35.200 (b) - Sacred Heart Hospital Department of Nuclear Medicine failed to prepare reagent kits in accordance with the manufacturer's instructions. Section 35.200 (c) (1) specifies, in part, that a licensee may depart from the manufacturer's instructions in preparing reagent kits provided that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient or for a radiopharmaceutical.

The manufacturer's instructions for the macroaggregated albumin reagent (MAA) used by the licensee specifies that each vial be reconstituted with 20-50 millicuries of technetium-99m and that the recommended number of particles per single injection be 200,000-700,000.

During the period August through October, 1990, the Sacred Heart Hospital Department of Nuclear Medicine had reconstituted the reagent kit using less than 20 millicuries of technetium-99m and had injected as many as 2 million particles per single injection.

CORRECTIVE ACTION TAKEN: A new procedure has been implemented to insure patients receive a maximum of 700,000 particles per injection. Each vial contains from 3.6-6.5 million particles. Prior to use, in uses where our total activity available is below 20 mCi, the vial will be reconstituted with 5 ml of normal saline. Then, depending on the amount of activity available, a fraction of the 5 ml will be withdrawn and discarded to match the fraction of activity we have that is below 20 mCi. For example, if we only have 15 mCi of activity which is 25% below the 20 mCi minimum then 25% (or 1.25 ml) of the reconstituted 5 ml solution will be withdrawn and discarded. The available activity will be injected into the remaining solution and the total volume calculated. A fraction of this will be used to give a dose of 3-5 mCi and the range of particles should be 200,000-500,000 per injection. For purposes of calculation, the vial will be assumed to have 5 million particles initially. (A chart will be available to guide the technologist in this procedure. See Exhibit E.)

Compliance has been achieved as of January 2, 1991.

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SACRED HEART Hospital

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EXHIBIT A

Gentlemen:

Please amend our license to allow our dose calibrator to be checked for dose linearity with the model 086-507 Lineator manufactured by Atomic Products Corporation. Test results will be maintained in forms similar to those provided in the manufacturers operation manual. The test will be performed as per the operation manual. All corrective actions will be made.

NRC or State License #: 40-01683-01

Facility: Sacred Heart Hospital

Address: 501 Summit

City: Yankton State: SD Zip: 57078

Contact: Bob Ellingson RT(R), Nuclear Medicine Supervisor

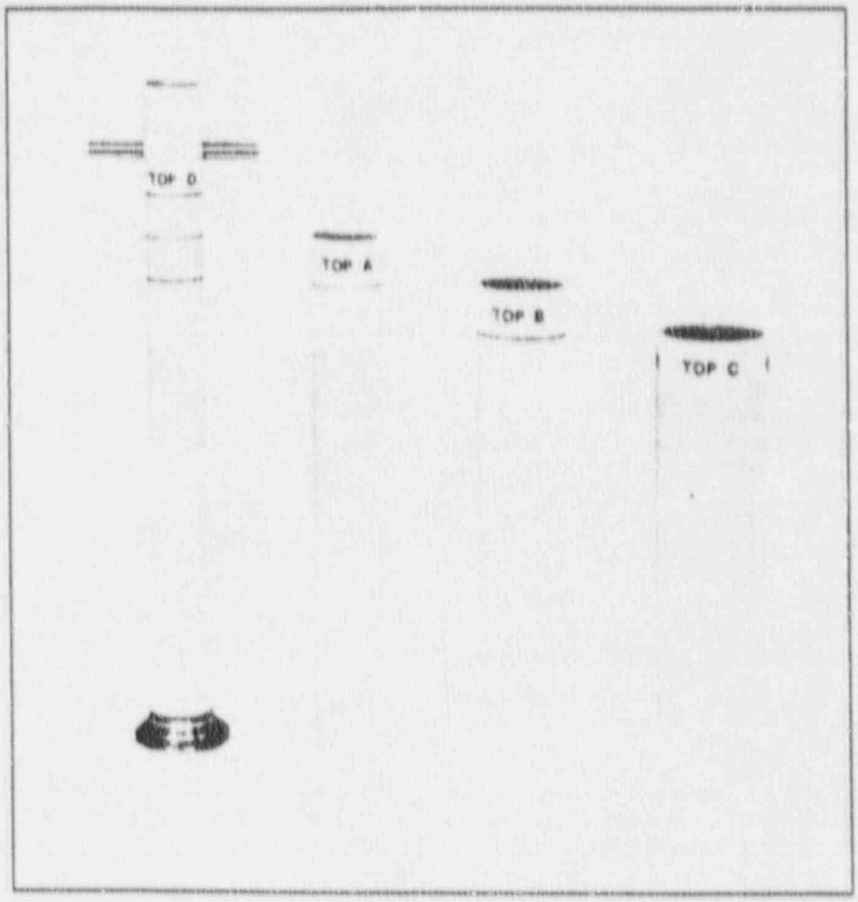
Kevin Pistulka RT(R), Director of Radiology

John M. Wells, MD

Phone: (605) 665-9371 Ext. 150

OPERATION MANUAL

EXHIBIT A



The Lineator (#086-507)

Atomic Products Corporation

ATOMLAB DIVISION • ESTABLISHED 1949

BROOKHAVEN R & D PLAZA, P.O. BOX 702, SHIRLEY, NEW YORK 11967-0917
TEL #: (516) 924-9000 • FAX #: (516) 924-9241
TELEX #: 797536 • ANSB: ATOMLAB CTOH

THE LINEATOR

Introduction:

The Lineator is a simple device for testing linearity and dynamic range of isotope calibrator instruments. Its use simplifies compliance with the Nuclear Regulatory Commission Appendix B of Regulatory Guide 10.8, 10 CFR, October 1986, and various state requirements.

The Nuclear Regulatory Commission, and other licensing agencies typically require a license amendment before use of the Lineator is authorized. A sample license amendment form is included in these instructions as Appendix A. This form should be transferred to your stationary, signed by authorized personnel, and sent to the appropriate agencies with any required fees. When the amendment is received use of the Lineator is authorized. Note that the NRC Regulatory Guide 10.8 Appendix B dated October 1986 requires a test of calibrator linearity at installation and quarterly thereafter. State and local requirements may differ. The Lineator may be used for this quarterly calibration. The concentration of Mo-99 should be less than .1 μCi per mCi of Tc-99m.

The Lineator consists of four tubes, three of which are lead-lined, which can be arranged concentrically. The smallest diameter tube is labeled 0 and is used to contain and position a source of Technetium 99m of the maximum activity to be measured in the dose calibrator in normal service. The lead-lined tubes, labeled A, B and C, slide over the central tube, and are used singularly, or in combination. Each of these outer tubes absorbs some of the radiation from the source and reduces the *effective* source activity seen by the dose calibrator. Use of the lineator thus allows the operator to simulate a total of eight different source strengths with only one source. The effective reduction increases from tubes A to B to C, and is affected slightly by the shape of the source used, and by the characteristics of the isotope calibrator.

The principle operation of the Lineator is reproducibility over a wide dynamic range, rather than absolute calibration. Initially the linearity of the dose calibrator must be established by conventional means, such as dilution or decay of a Technetium source. The initial calibration using the Lineator then establishes the effective reductions in activity (ratios of activity with lead tubes(s) inserted relative to source in central tubes alone). All subsequent use of the Lineator will show the same effective ratios unless:

a. The dose calibrator becomes defective, at which time it must be repaired, or

b. The Lineator components are damaged or replaced. Care should be taken that the bottom end of the Lineator components are not damaged.

Operating Instructions:

1. Remove *all sources* from the region of the calibrator to be tested.

2. Remove the source holder/hanger from the calibrator. Remove the chamber liner, if necessary, to allow insertion of the central Lineator tube, tube 0.

3. Set the calibrator to Tc-99m, check background reading using most sensitive scales. Zero out the background reading or note the value for later calculations. Check zero on all ranges if the unit has ranges. Note that background readings which vary widely may indicate a defective machine or a changing radiation environment which will affect the calibration.

4. The Lineator is designed for use ONLY with Tc-99m. Load tube 0 with a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator). The base is formed to center a 10ml or a 20ml vial. Place the tube in the calibrator chamber with the open end up. Use caution to avoid damaging the calibrator or the Lineator. The source and central tube will stay in place until the calibration procedure is complete.

5. Be prepared to work quickly. Arrange Lineator components, data sheets and clock for ease of operation. A complete calibration requires less than 5 minutes. Completion in 6 minutes introduces only a 1% total error due to decay of Tc-99m.

NOTE: *If linearity test duration exceeds 6 minutes, the procedure should be repeated.*

6. Set the range switch, as necessary, to read the activity to three significant figures, if the dose calibrator has a range switch.

NOTE: *The NRC requires test of linearity from the largest activity to be assayed down to 10 μCi. If the largest activity is greater than about 5 mCi, the linearity test must be done in two steps, using one source of the largest activity, and a second source which is less than 5 mCi.*

— Appendix D —
Work Sheet

Date: _____

Calibrator Serial No.: _____

Operator: _____

Source: _____

Zero (Background) Reading: _____

Range: _____

Start Time: _____

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only		1	1	100
0 + A				
0 + B				
0 + AB				
0 + C				
0 + AC				
0 + BC				
0 + ABC				

Completion Time: _____

Notes: (1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.

(2) Values determined from initial calibration.

(3) % Ratios of Entries: 100 x Col. (1)/Col. (2). If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

— Appendix B —
Initial Calibration Work Sheet

This should be completed and retained for your records.

Date: _____

Calibrator Serial No.: _____

Operator: _____

Source: _____

Zero (Background) Reading: _____

Range: _____

Start Time: _____

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only		1	1	100
0 + A				
0 + B				
0 + AB				
0 + C				
0 + AC				
0 + BC				
0 + ABC				

Completion Time: _____

Notes: (1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.

(2) Values determined from initial calibration.

(3) % Ratios of Entries: 100 x Col. (1)/Col. (2). If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

Calibration Procedures:

Having established the linearity of the calibrator by standard means, an initial calibration provides the factors to be expected for all future linearity checks, so long as the calibrator maintains its linearity and the Lineator components are not damaged.

After performing the steps given in the General Instructions, continue with the following steps, adjusting range switch if necessary to obtain 3 significant figures.

7. Record the time and the initial activity with the source in the central tube, and only the central tube inserted in the calibrator. Use a data sheet similar to or a copy of Appendix B.

8. Place tube A over the central tube and lower gently. Record reading A.

9. Remove tube A and place tube B carefully over the central tube. Record reading B.

10. Insert tube A between central tube and tube B. Record reading AB.

11. Remove tubes A and B, insert tube C. Record reading C.

12. Add tube A. Record reading AB.

13. Remove tube A, add tube B. Record reading BC.

14. Add tube A. Record reading ABC.

15. Record time.

16. Remove and store lineator components. Store source in lead shield.

17. Calculate the eight factors as indicated on the sample work sheet, Appendix C. Divide the value for the central tube only by the value for each reading for each tube combination and enter results in column headed "Present Factors". Be sure *all* readings are in the same units (e.g. mCi or μCi). If this is an initial calibration the factors should be retained for future reference and transferred to a master work sheet similar to a copy of Appendix B, in the column labeled "Initial Factors". Copies of this master work sheet will be used for subsequent calibrations.

NOTE: *If not performing an initial calibration, continue with the following steps.*

18. Divide each entry in "Present Factors" column by corresponding entry in column labeled "Initial Factors". Enter results times 100 in column labeled "Percent Ratio". The ratios should have values near 100.

19. Examine entries in "Percent Ratio" column (3) to be sure that each is within the allowed tolerance limit for the present radioactive material license. For example, if the license allows 5% variation, all the values in the ratio column should be between 95 and 105. If all ratio values are within acceptable range, the calibration is complete and the isotope calibrator has been proven to have acceptable linearity.

If any value of the Percent Ratio is outside the acceptable range, renormalize by finding an average value for all eight percent ratio values and dividing each ratio by this average, then multiplying each by 100.

20. If final reading is greater than 10 μCi make a second source of ~1 mCi and repeat.

If still beyond tolerance, the problem may be due to:

A. Changing background conditions, including activity in nearby patients. Stabilize background activity and repeat.

B. Failure to properly subtract background for each reading. Check and repeat procedure if appropriate.

C. Damage to lineator components. Inspect and replace as necessary. Each component may be purchased separately but will require a new initial calibration.

D. A defect in the dose calibrator. This requires repair of the calibrator, followed by a demonstration of linearity using conventional methods, and an initial calibration to establish the factors to be expected with future operation with the Lineator.

21. Sign data sheet and retain for future proof of calibration and compliance with regulations.

Atomic Products Corporation

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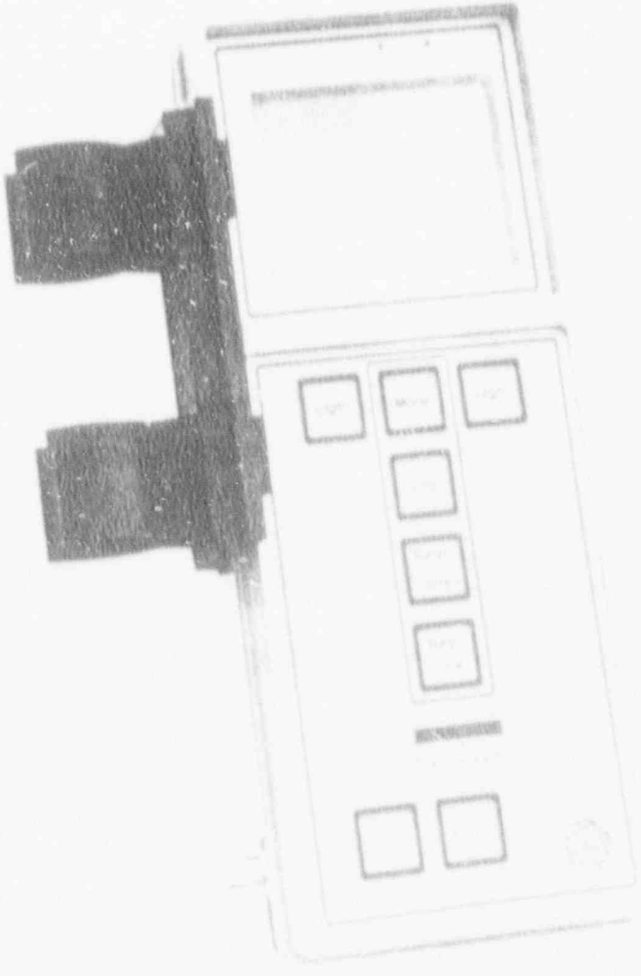
TELEX #: 797566 • ANSB: ATOMLAB CTCH

VICTOREEN

(216) 248-0500
FAX: (216) 248-0504
TWX: 810-421-8287
VICNET™ Customer Service
Modem Access:
(216) 248-9743

Survey and Count Rate Meter Model 190

- Analog/Digital Display
- Data Logging
- Rate Integrate
- Time Integrator
- Backlighted display
- Response time selection
- Error free visual indication
- Reduced exposure to technician
- Auto dose accumulation
- Exposure time verification
- Use in low light areas
- Increase accuracy in counting



SPECIFICATIONS

5608 COCHRAN ROAD, CLEVELAND, OHIO 44139 U.S.A.

VICTOREEN
(216) 248-9300
FAX: (216) 248-9301
TWX: 810-421-8287
VIC-NET™ Customer Service
Bulletin Board:
(216) 248-9043

Survey and Count Rate Meter Model 190

EXHIBIT B

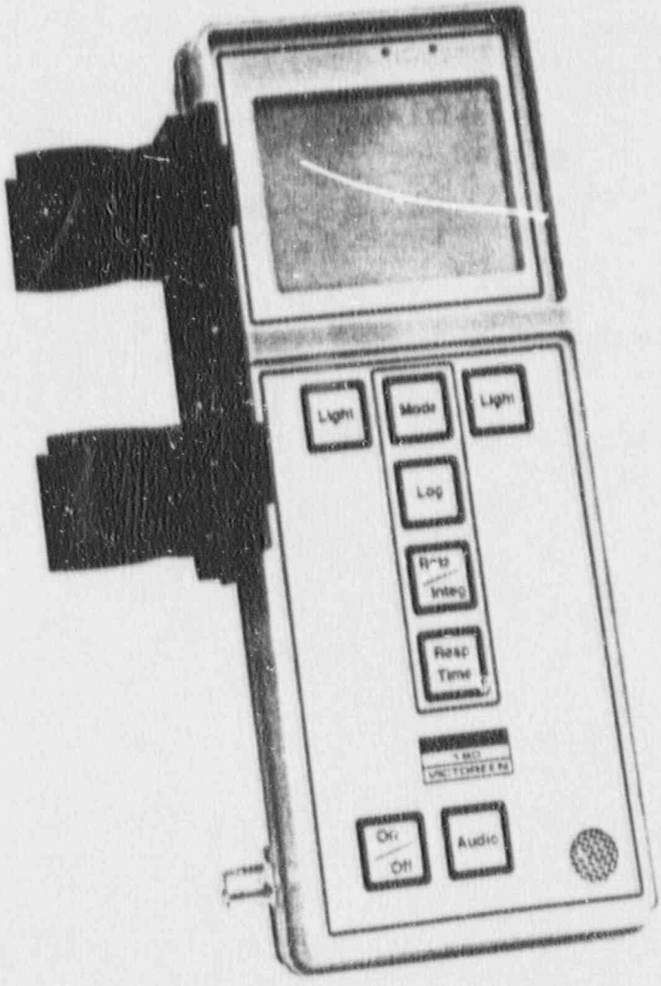
- Analog/Digital Display
- Data Logging
- Rate/Integrate
- Time Integrator
- Backlighted display
- Response time selection
- Error free visual indication
- Reduced exposure to technician
- Auto dose accumulation
- Exposure time verification
- Use in low light areas
- Increase accuracy in counting

The Modal 190 survey meter is an easy to use instrument designed to meet the high tech requirements of health and medical physics applications. It is compatible with GM detector, proportional and scintillation probes operating from 300 to 1300 volts. Depending on probe selection, the Model 190 detects alpha, beta, gamma, or x-ray radiation within an operating range of .001 mR/hr to 1 R/hr or 1 CPM to 1,000,000 CPM. The unit is available with either MHV or a BNC connector, to provide the user versatility in probe selection.

The Model 190 features several user-selectable parameters, entered via the top panel pushbuttons or via computer through an optional infrared communicator. Rate/Integ allows the user to select the mode of display. Mode rolls through and displays the available units for the selected mode of operation. Light activates a background light for a preset time period. Log enters and sequentially labels the displayed data into a data log. Response Time rolls through and displays available response times (3, 6, 12, and 24 seconds) for user selection. Audio allows the user to turn on/off the audio indicator.

Visual indication of selected parameters, as well as measured values, are displayed on the analog/digital display.

The Model 190 with purchased probe is shipped calibrated and ready to use.



** EXHIBIT B **

SPECIFICATIONS:

LCD Display Readout

Dimension: 2.6 inches (wide) x 2.00 inches (high) 6.6 cm (wide) x 5.1 cm (high)

Analog Scale (Bargraph): Fifty one elements arranged in a radius arc. Each element represents 2% of full scale. Scale markings are 0, 2, 4, 6, 8, and 10. Scale length is 2.2 inches (5.6 cm).

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SPECIFICATIONS:

Scale Multiplier: x.0001 to x1 million. Dependent on probe selection and the activated units.

Alpha Numeric Display: 16 characters. Displays digitized average of the bargraph value. Displays operational units such as radiation unit changes, response time changes, data and labels.

Pushbutton Controls:

Mode: Toggles and selects rate units: µR/hr, mR/hr, R/hr, cpm, cps,uSv/hr, mSv/hr, dpm, Bq/cm²; and the complementary units in the integrate mode: µR, mR, R, cts, d, uSv, mSv with the integrated time value in seconds. Battery condition.

Log: Logs data and sequentially labels data points. (Data retrieval requires the Model 190-1A communicator).

Rate/Integrate: Toggles between rate and integrate.

Response Time: Toggles and selects 24 seconds, 12 seconds, 6 seconds, or 3 seconds response time during operation.

Audio: Turns audio on and off. Acknowledges alarm.

Light: Turns back light "ON" for a preset time.

NOTE: Using the Infra-Red communicator, default settings can be programmed into the Model 190. Features and push-buttons can also be locked-out to set up the Model 190 in a user-defined mode of operation.

Temperature Range: –10 °C to 60 °C

Check Source: Natural uranium mounted on case side.

Construction: Molded ABS Plastic, splash-proof case. Probe fits into a side mounted ABS plastic clip.

Case Dimensions: (without probe holder) 9.2 inches (long) x 3.75 inches (wide) x 2.1 inches (deep). 23.4 cm (long) x 9.2 cm (wide) x 5 cm (deep).

Weight: (without probe) 1 lb. 9 oz., 708.7 g.

Accuracy: Within 10% of reading between 10% to 100% of full scale indication on any range, exclusive of energy dependence. Accuracy is probe dependent.

Detector: Accepts GM detectors, scintillation probes, and proportional counters operating at high voltages between 300 volts and 1300 volts.

Adapter Module: Contains calibration data for specified probe. It's available with BNC or MHV connectors. Specify the type of connector with order. (Note: Additional adapter modules can be purchased for use with multiple probes).

Battery Compartment: One (1) to four (4) 9 volt batteries. The unit will operate on 1 battery.

Operating life: Over 200 hours of continuous operation with four batteries.

Humidity: 0 to 95% RH, non-condensing.

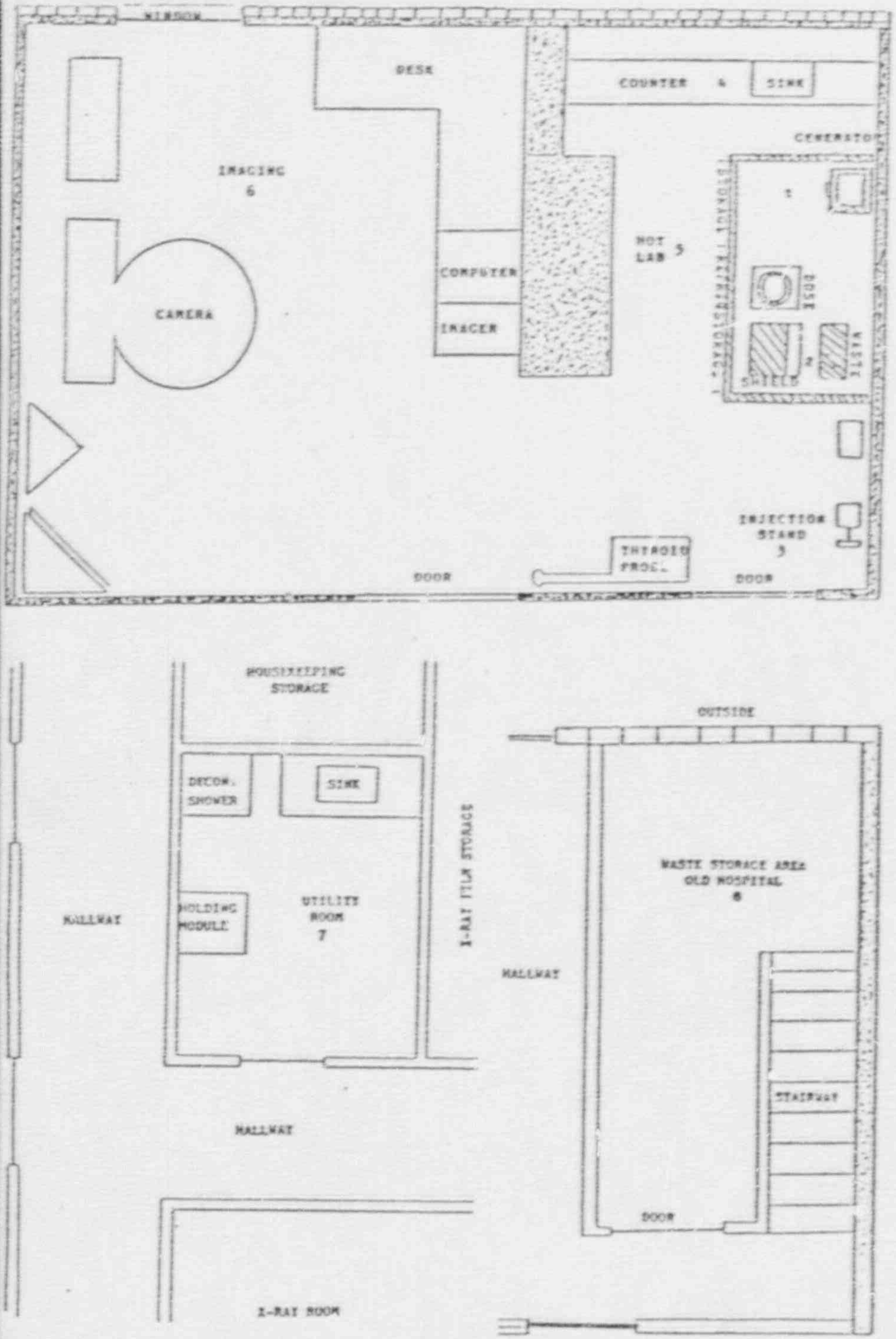
Warm up time: Negligible.

Option: Model 190-1A communicator. For a complete description of software capabilities, refer to the Model 190-1A sheet specifications.

6000 COCHRAN ROAD, CLEVELAND, OHIO 44139 U.S.A.

EXHIBIT C

S.H.H. AREA SURVEY FOR THE MONTH__________ 19__



MR/HR AT LOCATION

DATE	1	2	3	4	5	6	7	8		GM TUBE	SURV METR	INIT
trigger	1.2	1.0	0.1	0.7	0.7	0.1	1.0	0.5				

EXHIBIT D1

S.H.H. DEPT. OF NUCLEAR MEDICINE

RADIOACTIVE PACKAGE RECEIPT LOG								DISPOSAL LOG					
DATE RECIEVED	ISOTOPE	CHEMICAL	mCi	PKG OK?	SUPPLIER	PACKING SLIP #	MR/HR SURFACE	DATE OF DISPOSAL	#190 S.MTR.	#592B S.MTR.	MR/HR BKG.	MR/HR SURFACE	INTL

EXHIBIT D2

S.H.H. DEPT. OF NUCLEAR MEDICINE

RADIOACTIVE WASTE DISPOSAL LOG

ISOTOPE	TYPE OF MATERIAL	DATE SEALED	COLLECTION INTERVAL	DATE OF DISPOSAL	#190 S.MTR.	#592B S.MTR.	MR/HR BKG	MR/HR SURF	INITIALS

EXHIBIT E

PROCEDURE FOR RECONSTITUTING MAA WITH DOSES LESS THAN 20 mCi

Dose available (mCi)	Reconstitute vial with 5.0 ml normal saline. Withdraw and discard (ml)	(Use this number) (to divide total) (volume to get) (volume to use) (for each dose.) Resulting volume adequate for number of doses.
18 mCi	0.5 ml (10%)	5 doses
15	1.25 (25%)	4 doses
12	2.0 (40%)	3 doses
9	2.75 (55%)	3 doses
6	3.5 (70%)	2 doses