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030-30562

Betagen

NRC License No. 20-20993-01
April 28, 1988

Nuclear Regulatory Commission
Medical Academic and Commercial Use Safety Branch
Washington, DC 20555

Dear Nuclear Regulatory Commission:

We are applying for an NRC license to allow us to distribute exempt quantities of 55-Fe, incorporated as internal calibration material in an electronic device pursuant to 10CFR PART 30.15(9). Included with this application is a check for $290.00 as per 10CFR PART 170.31.3.I. Concurrent with this application we are also applying through Region I of the NRC for an amendment to our license for possession of exempt quantities of 55-Fe for redistribution.

As guides for the preparation of these applications we have followed PART 30.15 and PARTS 32.14, 32.15 and 32.16. We anticipate shipping our first instruments in early July, 1988.

If further information is required please contact me at the address below.

Sincerely,

Daniel E. Sullivan

Daniel E. Sullivan
Radiation Safety Officer

jkm

Recv'd 5/2/88

Log May 1 #25
Remitter
Check No. 3765
Amount $290
Fee Category 3I
Type of Fee APP
Date Check Rec'd. 5/4/88
Date Completed 5/10/88
By: S. Kimberley

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I. Description of the Instrument Components.

A. Type of instrument and purpose of the iron 55 (55-Fe) source.

Our company is beginning production of the Betascope 603 Blot Analyzer (the "instrument") which will be sold to the biotechnology industry, including private companies and foundations, academic institutions, government agencies, etc. The instrument will analyze user generated patterns of biological macromolecules radiolabeled with 32-P. A photograph of the instrument as it will be sold is in Appendix A, fig. 1.

The instrument incorporates a modified multiwire proportional counting chamber (the "chamber") to quantify and locate the beta emissions from 32-P placed against an aluminized mylar window on one side of the chamber. On the opposite side of the chamber is located a shutter device enclosing a source containing 100 microCuries(uCi) of 55-Fe (the "source"). This source is used for periodic calibration of the electronics and as a check on the purity of the ionization gas in the chamber.

We anticipate production runs of 100 instruments per year beginning in the summer of 1988.

B. Description of the 55-Fe Source

In the multi-mount format, the 55-Fe sources will not be produced in-house but will be purchased from manufacturers of such materials. The initial supplier of the 55-Fe sources will be NEN-DuPont (Diagnostics Group, 331 Treble Cove Road, North Billerica, MA 01862) catalog number NES400S. The source will be mounted either in the "multi-mount" or the crimp seal disc holder (Appendix A, Fig. 2, a and b).

The 55-Fe is deposited as an aqueous salt solution and dried onto the mylar side of an aluminized mylar disc. The active material is then sealed between another aluminized mylar disc. In the crimp seal mount format, the 55-Fe is electro-deposited on a stainless steel disc and then covered with a disc of aluminized mylar and sealed around the perimeter. Neither of these formats is considered a sealed source and neither has been subjected to any sealed source performance tests. The maximum quantity of 55-Fe per source is 100 microCuries (3.7 MBq) and there is only one source per instrument. This level of 55-Fe activity is defined as "exempt quantity" in 30.71 schedule B. The source, in either the multi-mount or disc holder, is then placed in a shutter device, manufactured by our company, and secured in place by a set screw against the side of the source holder.

C. Description of the shutter device. (Appendix A, fig. 3, a through e).

The device consists of:

*the body, machined out of 3/4" thick aluminum (3" long x 2" high);
*front and back cover plates, 1/8" thick aluminum;
*the shutter, 1/8" thick aluminum;
*a 24 V solenoid to move the shutter and expose the enclosed 55-Fe source to a 1/4" diameter hole in the front plate;
*a spring and tension adjustment screw to maintain the shutter in the closed position when the solenoid is not activated.

D. Mounting the Shutter Device on the Sensor.

The shutter device is mounted on the back plate of the sensor with bolts such that the 1/4" hole in the shutter device front plate aligns with a 1/4" diameter hole in the sensor back plate. A mounted shutter device is shown in Appendix A, figure 4a. The sensor back plate is surrounded by a 1/4" aluminum frame enclosing electronic components. This electronic component area is covered by a perforated aluminum sheet held in place by socket head cap bolts (Appendix A, figure 4b).

E. Mounting the sensor in the instrument.

The sensor with its electronic components and 55-Fe calibration source in the shutter device is mounted horizontally, 55-Fe source on top, and bolted to the instrument frame. An external instrument shell of 18 gauge steel encloses the entire instrument (Appendix A, fig. 1).

F. Labeling.

The 55-Fe Source as obtained from the manufacturer is labeled on the source holder with the manufacturer's name, isotope identifiction (55-Fe), Activity (100uCi) and date of that activity.

If required by the NRC we will affix a tape label to the external surface of the shutter back plate which states: caution: radioactive material, 100uCi 55-Fe, and the appropriate date. Packaging for transport by service personnel will be labeled as described below under "Transport of 55-Fe Sources".

G. Assurance of Proper Source Mounting during Instrument Assembly.

Proper and secure mounting of the 55-Fe source in an instrument during assembly will be assured by:

1) Visual inspection throughout the assembly process.
2) Mechanical testing of the shutter mechanism before and after mounting on the sensor.
3) G-M tube survey of the mounted shutter device, and
4) electronic calibration testing after final assembly.

The assembly personnel complete a check-off list included by the R.S.O. with each 55-Fe source.

II. Testing of Radiation Exposure Levels.

A. Method of Testing.

All of our in-house testing of radiation levels were made with a Geiger-Mueller Tube (G-M tube) on a Ludlum Model 3 survey meter calibrated by Bolton & Galanek (P.O. Box 366, MIT Branch, Boston, MA, 02139). The most recent calibration date is January 6, 1988.

The window of the G-M tube was placed at the indicated distance from the surface being surveyed and the instrument allowed to equilibrate for one minute on the slow response setting before a reading was taken. At low activities (<0.1 mRem/hr.), the meter needle movements were averaged "by eye" over a 15 second period following the 1 minute equilibration time.

B. Exposure Level to the User During Normal Operation.

There is a single opening (15" x 2") in the front panel of the instrument through which a drawer slide mechanism moves (Appendix A, fig. 1). The drawer slide mechanism holds a vacuum hold-down platen on which the user places the samples to be analyzed. When the drawer is closed, the vacuum platen is automatically raised to the window on the bottom side of the sensor. It is in this configuration that the shutter mechanism will periodically be activated to calibrate the instrument prior to sample analysis. The vacuum platen is made of 1/4" thick aluminum and totally covers the aluminized mylar window of the sensor. Thus, during normal operation of the instrument, the 55-Fe radiation is totally enclosed by aluminum shielding, even when the shutter is open to allow 55-Fe X-rays into the sensor for calibration.

No radiation level above background (0.010 to 0.015 mRem/hr) can be detected 1 cm from any surface on the sensor, including the shutter device, when the shutter is open or closed, and when the sensor window is covered by the aluminum vacuum platen. Since the sensor is totally enclosed within the 18 gauge steel instrument shell, the user will receive no radiation from the 55-Fe source during normal operation of the instrument.

It is possible that a user will put his/her hand through the 15" x 2" opening while the drawer is open; (This may be done to retrieve a sample which became stuck in the instrument, for example). Under normal conditions the shutter device will be closed & no 55-Fe X-rays will be entering the sensor from above. If the shutter mechanism is malfunctioning and remains open, the dose rate at the sensor window surface is 0.020 mRem/hr, only slightly above background range (0.01 to 0.015 mRem/hr).

C. Exposure Level during "Abnormal" Conditions.

i. Removal of exterior instrument panels.

There are no user serviceable components inside of the instrument and the instruction manual will explicitly state that the user is not to attempt removal of any panels of the instrument shell. The only panel removeable from the outside is the top panel. Once it is removed, the side panels can be disconnected and removed. As stated above, the only possible exposure to 55-Fe would be 0.02 mRem/hr at the sensor window surface, below the sensor, and this would require a malfunction of the shutter device.

ii. Removal of the shutter device and source from the instrument.

To actually remove the shutter device from the instrument, one would have to 1) remove the instrument top panel, 2) remove the perforated aluminum plate over the sensor back, and 3) remove the shutter device. If this were done, the spring loaded shutter would prevent any radiation from escaping. If the 55-Fe source were removed from the shutter device or the shutter opened to expose the source, radiation exposure would occur.

To determine the maximum radiation exposure under these conditions we have measured the dose rates at various distances from the 55-Fe source in a multi-mount holder: A, outside of the shutter device, and B, inside the shutter device but with the shutter open. These data are presented in Appendix A Table 1.

iii. Damage to the instrument.

The most severe situation likely to be encountered would be if the instrument were to fall off of a laboratory bench. The instrument weighs approximately 180 lbs. and such a fall would severely damage the outer shell and the electronic components, rendering the instrument inoperable. It is highly unlikely that the 55-Fe source would be exposed even with severe damage to the instrument.

III. Quality Assurance and Tracking of 55-Fe Sources.

The Radiation Safety Officer(R.S.O.) will maintain records on all of the 55-Fe sources received from manufacturers, installed in instruments (Instrument Serial #,etc.), or returned to to the manufacturer for any reason.

Upon receipt of the sources from a manufacturer, each source will be visually inspected for obvious damage (eg. tears, unsealed edges, etc.) and the surfaces wipe tested for external contamination. The wipes wil be done with an approximately 1" x 1" square piece of damp filter paper & analyzed by placing the filter paper 1 cm from the window of a calibrated Geiger-Mueller tube. Any obvious visual damage or any external radiation detected in the wipe test will result in rejection of that source and it will be sent back to the manufacturer. Sources which pass the visual inspection and wipe test will be numbered and stored in a steel radiation storage cabinet until installed in an instrument. The locations of the radiation storage cabinet and the assembly areas are indicated in Appendix A, figure 5. An "Assembly Quality Assurance" check-off list will be included with each source. This list will be used by the instrument assembly personnel to record: date, assembler's name, source number, instrument serial number, visual inspection of the source and shutter device, testing of the shutter mechanism, and a radiation survey after the shutter device is mounted on the sensor. The form will be returned to the Radiation Safety Officer for filing.

If during the assembly process, a source becomes damaged or there is reason to believe that a source may have been damaged, the Radiation Safety Officer will conduct visual, G-M tube, and wipe test surveys of the source and potentially contaminated surfaces. A description of the circumstances which led to the situation will be obtained to determine the cause(s) and recommend changes in procedures.

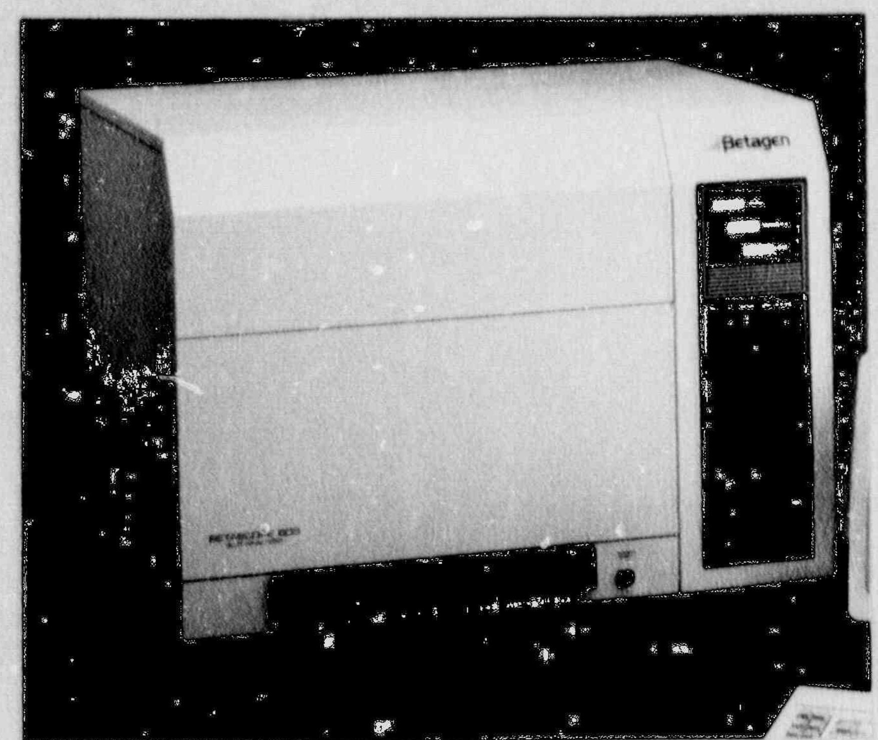
IV. Personnel Training and Monitoring.

All production and technical staff, including in-house and field service personnel, who handle the 55-Fe sources, the shutter device with sources inside, or work on the instruments with the 55-Fe source mounted in place, will be included in the Betagen Radiation Safety Training Program, and will wear a G-1 type radiation dosimeter film badge with monthly reporting. If radiation exposures are recorded, the Radiation Safety Officer will review the situations to see if changes in procedures are required to minimize future exposures. The Radiation Safety Training Program includes mandatory semi-annual seminars covering NRC regulations & the properties and safe handling practices for the isotopes which we are licensed to possess. Assembly and field service personnel who will assemble or periodically need to repair shutter mechanisms or replace outdated 55-Fe sources will be instructed on the paper handing of the 55-Fe source to keep the exposure as low as possible. This includes wearing safety glasses when handling any 55-Fe sources as well as disposable gloves when there is a possibility that a source has been damaged.

V. Transport of 55-Fe Sources.

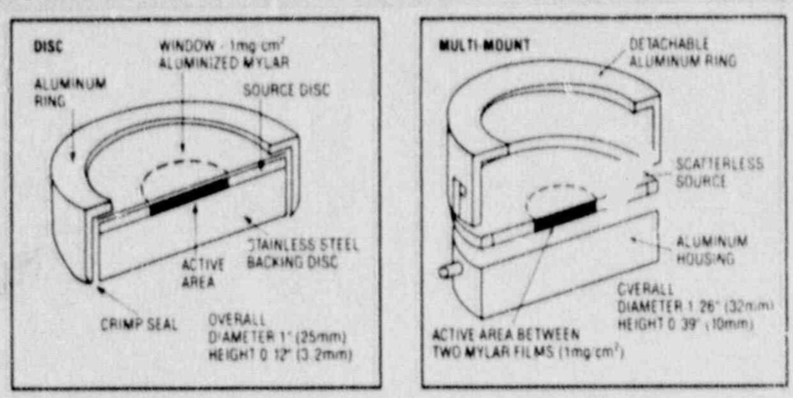
Replacement and out-dated 55-Fe sources will be transported by Betagen service personnel in small plastic boxes with a 1/16" thick aluminum plate over the open face of the 55-Fe source. Our tests have shown that no radiation is detected from a 100uCi 55-Fe source in such boxes. The boxes will have a "Caution Radioactive Material" label on the exterior and a label with "Betagen, Inc., 100 Beaver Street., Waltham, MA 02154, 617-899-3400, 1-800-421-4213." The mount for the source (either a multi-mount or the crimped disc type mount) is labeled by the manufacturer with the manufacturer's name, the isotope, (55-Fe), the activity (100uCi) and the date of the 100uCi activity.

Figure 1.



The Betagen 603 Blot Analyzer showing the instrument in which the 55-Fe calibration source is located. The external dimensions of the instrument are 32.5" W x 27" H x 21.5 "D. The instrument weighs approximately 180 lbs.

Figure 2.



Diagrams of the mounting systems used by NEN-Dupont for holding the 55-Fe source.

Figure 3. NRC Lic.#2020993-01

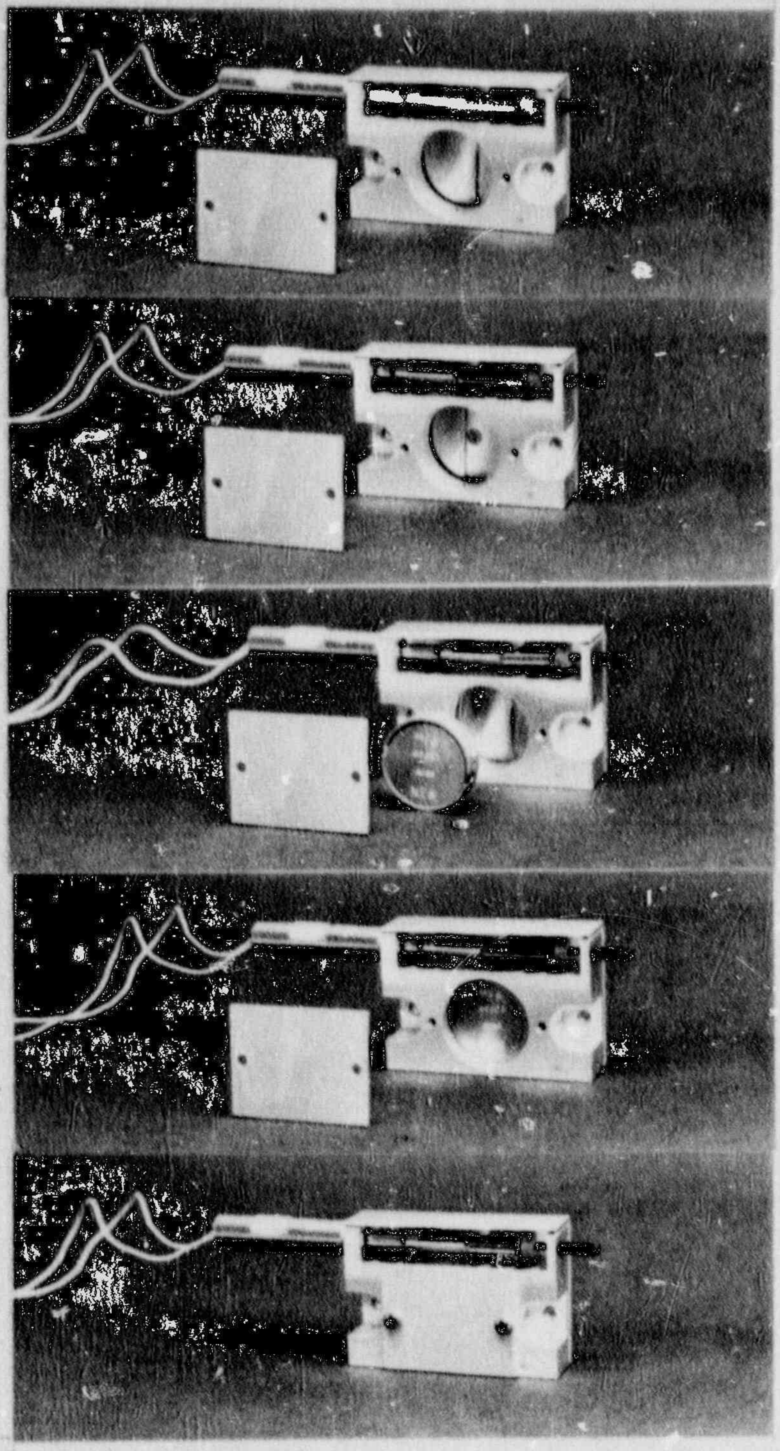
a.

b.

c.

d.

e.



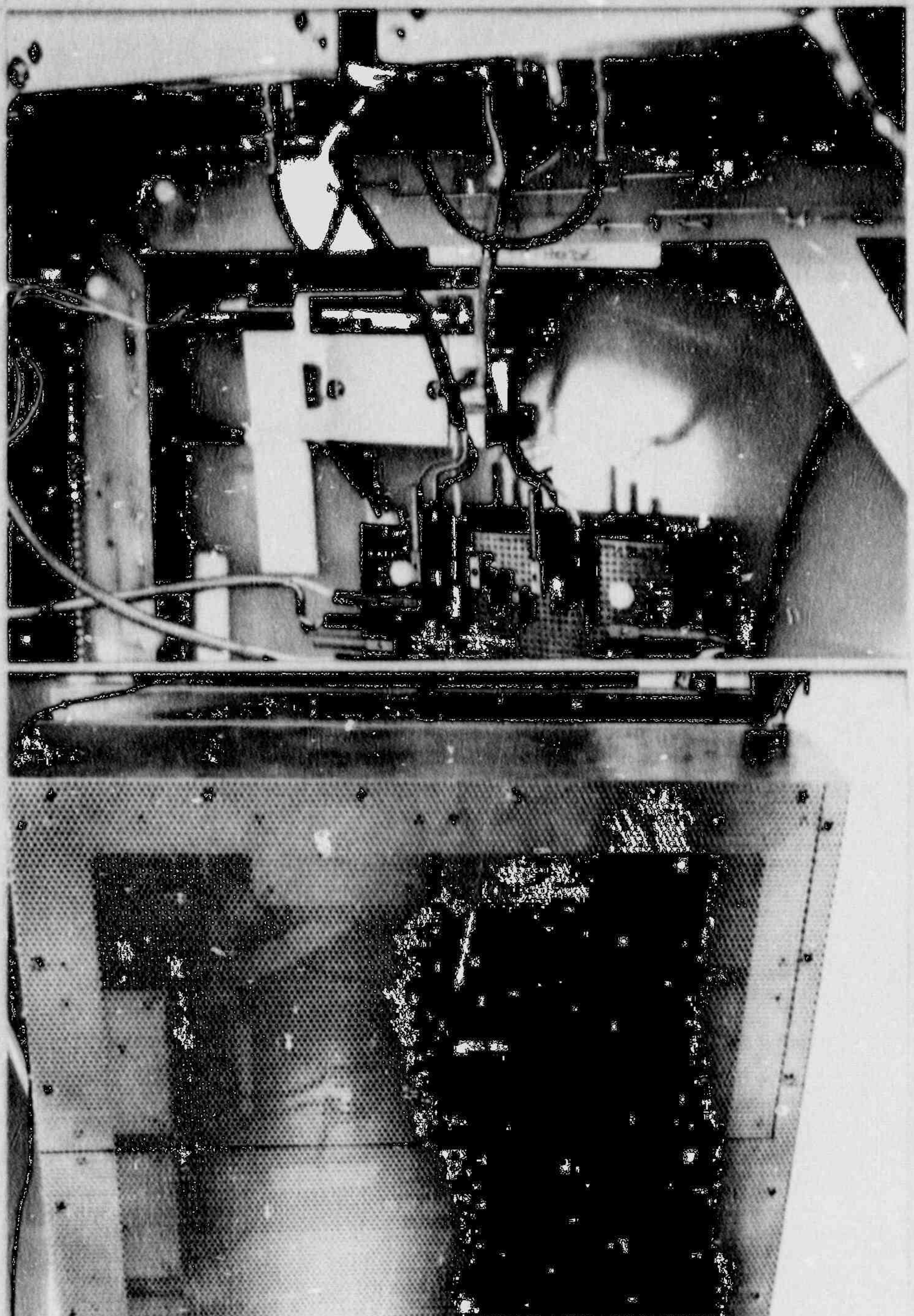
Photographs of the shutter device.

a. back plate removed, shutter closed, no 55-Fe source,
b. as in a, but shutter open, exposing the 1/4" diameter hole in the front plate,
c. as in a, but with NEN-DuPont multi-mount source holder,
d. source holder positioned in shutter device,
e. back plate in place over source holder, as it would appear when mounted in the instrument.

Figure 4.

a.

b.



Mounting the shutter device on the sensor.

A. shutter device located on sensor back wall in the electronics component area.

B. electronics component area covered with perforated aluminum sheet.

FIGURE 5 FLOOR PLAN

FLOORPLAN

BETAGEN. INC.
100 Beaver ST
Waltham. MA 02154
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CROSS HATCHED AREAS ARE INSTRUMENT ASSEMBLY AREAS

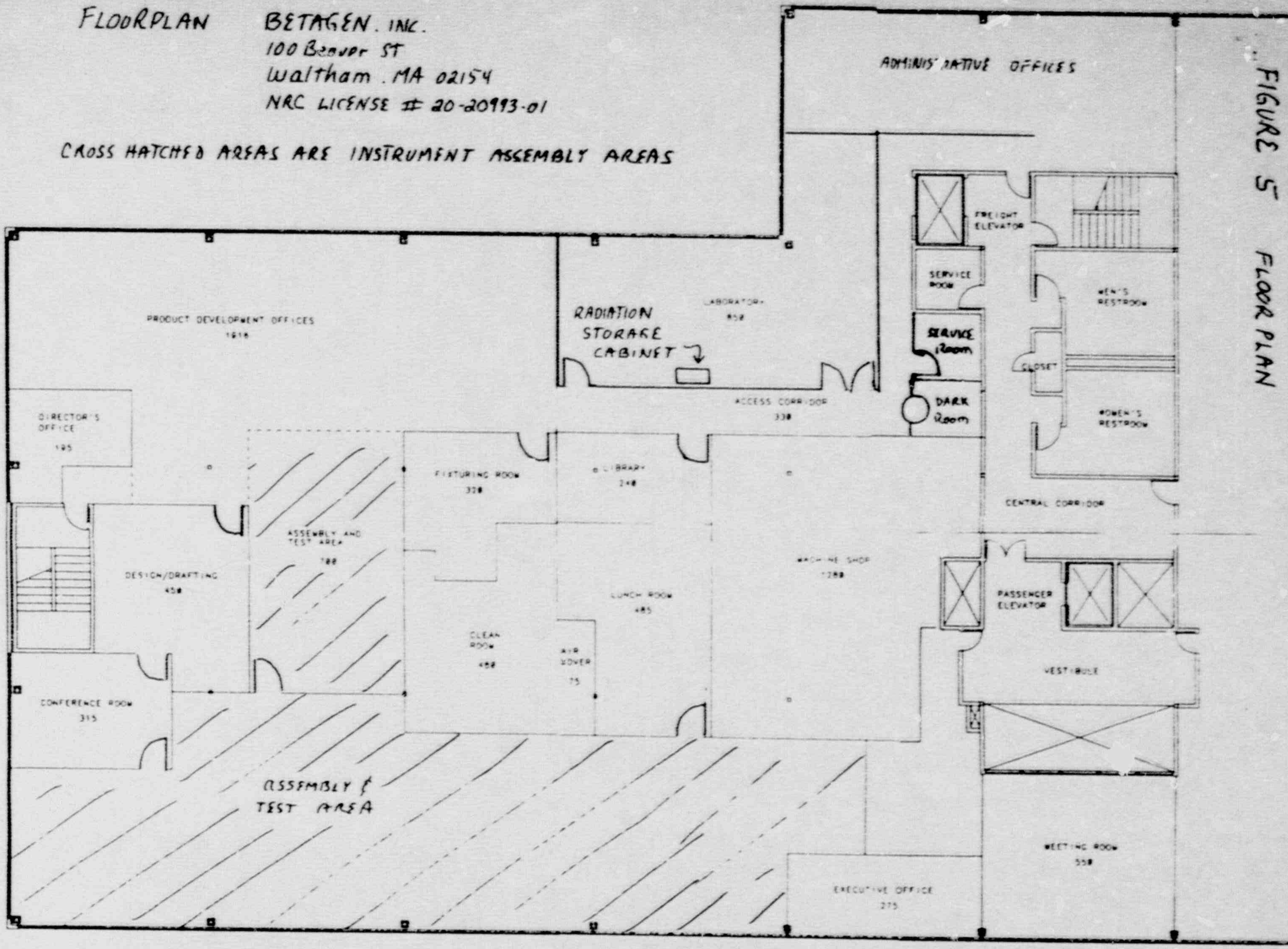

Table 1. Radiation Exposure Levels in milliRems per hour at various distances from: A, 55-Fe source in multi-mount holder, B, 55-Fe source in shutter device with shutter open.

	A				B			
DISTANCE	REPLICATES			AVG.	REPLICATES			AVG.
1 cm	53.6	55.4	56.0	55.0	47.1	52.1	56.2	51.8
10 cm	3.76	3.51	3.81	3.69	3.50	3.42	3.50	3.47
50 cm	0.086	0.071	0.077	0.078	0.083	0.076	0.088	0.082
100 cm	0.023	0.026	0.020	0.023	0.027	0.021	0.018	0.022
BACKGRD.	0.014	0.018	0.018	0.017	0.012	0.021	0.014	0.016

Method of measurement: a 55-Fe "100uCi" NEN-DuPont source in a multi-mount holder was situated on a table (A) or placed in the shutter device which was placed on a table (B) so that the center of the source was aligned with the center of the window of a Geiger-Mueller tube. The tube was moved so that radiation readings could be taken at the stated distances between the surface of the source and the window of the tube. The measurements were taken in March, 1988 using a NEN-DuPont catalog #NES400S 55-Fe source, uncalibrated, 100uCi, October, 1986. The data presented above are corrected to the dose rate from a "fresh" 100uCi 55-Fe source.