ABBOTT

R. L. Fredrickson
Corporate Radiation Protection Officer
Employee Health Department

Abbott Laboratories
14th & Sheridan Road
North Chicago, Illinois 60064

Applicant Oct 2+III
Check No. C099054
Amount/Fee Category $170/SE
Type of Fee REN
Date Check Rec'd. 10/28/85
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October 21, 1985

U. S. Nuclear Regulatory Commission
Region III
Material Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Subject: Renewal of Byproduct Material License 12-00621-09.

Enclosed in duplicate is Abbott Laboratories' application for renewal of Byproduct Material License 12-00621-09 and a check for the amount of the renewal fee, $170.00. This application has been prepared in accordance with Draft Regulatory Guide 10.9, Second Proposed Revision 1, Section 5, Renewal of a License.

Please examine our previous application dated October 16, 1980, to which I shall frequently refer. My responses follow to complete NRC Form 313 (1-84):

5. a.b.c. - Items 8.A,B,C, and D as shown in our previous application on Form NRC-313I(1-79) are unchanged.

6. Item 6 is unchanged from Item 8.E of our previous application.

7. From Item 6.c. of our previous application and from Attachment "F" - Item 16 and Attachment "G" - Item 17, please delete the name of and information about Thomas P. Lypka. The other persons named in these various items, Drs. Carl Bodo and Michael Korczynski, remain as shown; however, they now have five years of experience with the Gammacell 220, Dr. Bodo with direct operational responsibility and Dr. Korczynski as overall area director.

   Dr. Bodo's title is now Radiation Scientist rather than Project manager, Sterilization, as shown in our previous application.

   Please add to Item 7 Dr. Steven G. Meyers, whose training and experience are shown in Attachment "A" of the application.

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CONTROL NO. 80001

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8. Entrance to the Gammacell room is controlled by a magnetic card key lock, and the room is entered only by operators, visitors under escort, or radiation safety personnel. Procedures to be used in safely operating the Gammacell are shown in Attachment "B" of this application, replacing Attachment "E" - Item 15 of our application of October 16, 1980.

9. The facilities and equipment are unchanged from the description in Attachment "D" - Item 13 of our previous application.

10. Several attachments from our previous application relate to the radiation safety program. Please delete those pages of Attachment "E" - Item 15 which include the Charter of the Corporate Radiation Safety Committee (RSC) and the names and qualifications of its members. Although the RSC reviews records of the work under license 12-00621-09, it does not have direct responsibility for these operations as it does for our Type A Broad Scope License 12-00621-03. However, please retain the last four paragraphs of this section, as modified and shown in Attachment "C" of this application. Also add the job description dated June 21, 1984, replacing the one dated May 16, 1978, for the Corporate Radiation Protection Officer.

11. No waste is handled under this license. At time of recharge of the Gammacell unit, the waste material will be retained by Atomic Energy of Canada, Limited.

In addition to changing the items listed above, please remove Attachment "C" - Item 12(3)B of our previous application. By the terms of Amendment No. 01 to license 12-00621-09, the use of Bendix pocket dosimeters was discontinued as, therefore, was the need to calibrate them.

Please contact me at 312-937-5276 if you have any questions about this renewal application.

Sincerely yours,

R. L. Fredrickson

R. L. Fredrickson
RLF/jr

CONTROL NO. 80001

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Abbott Laboratories
North Chicago, Illinois

Attachment "A"

Steven G. Meyers, Ph.D., Section Manager,

Biological Services and Methods Development

College: B. S., 1969, Colorado State University (Microbiology)
Ph.D., 1975, University of Montana (Microbiology)

Training at the University of Montana in radiochemistry. Phosphorus-32 and hydrogen-3 were used in experiments described in his doctoral dissertation.

Supervisory experience and responsibility in the use of the Gammacell 220.

Training at Abbott Laboratories as required by 10 CFR 19.12.

1:

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North Chicago, Illinois

THIS SPECIFICATION IS NOT TO BE USED FOR PRODUCT OR CLINICAL RELEASE

SELECT - QUERY
00001 ALL DOCNO=BOP.N.97K-0097

Attachment "B"

BOP.N.97K-09 DOCUMENT= 1 OF 1
TEXT REVW *84-10-31* EFFC *84-12-07* *BOP.N.97K-0097 * REV # 2
SUBJECT: *OPERATION OF THE GAMMACELL 220, SERIAL NO. 170 *
WRITTEN BY: C. Bodo DATE: 11-27-84 EQUIP. NO.: F-1617
APPROVED BY: J. Grillo DATE: 11-27-84

I. PURPOSE:

The purpose of this document is to describe the procedures for operating the Gammacell 220 to ensure safe operation of the instrument in both the automatic and manual modes of operation.

II. EQUIPMENT AND MATERIALS:

Gammacell 220 Cobalt 60 Irradiation Unit, Equipment No. F-1617, with Timer MB-0719.

Material to be irradiated

III. OPERATION:

Prior to operating the Gammacell 220, the operator should have read and be familiar with the following:

A. United States Nuclear Regulatory Commission Rules and Regulations (Appendix I).

B. Facility License Requirements (Appendix II).

C. Radiation Safety Course attendance at the two hour course on Basic Principles of Radiation, Safety and Monitoring Procedures is required.

D. Radiation Monitoring Equipment

E. Part one (1) of the Operator's Manual for the Gammacell 220 Cobalt 60 irradiation unit.

1. Automatic Operation

a. Raise the drawer by first inserting the key in the key switch and turning it 90 deg clockwise, then press the UP rocker switch.

b. To open the collar doors, press and hold in the button on the top of the door interlock, grasp the right hand door handle, pull back the latch lever, release the button and pull the doors open. See Figure 1 of the Operator's Manual for the Gammacell 220, Edition 7.

c. Slide the sample chamber locking ring to the right, remove the door by lifting it up and outwards (see Figure 4 of the Operator's Manual).

d. Place the sample in the chamber. The access tube in the drawer top accommodates accessory tubes and electrical leads, which should be fitted in accordance with the instructions provided in the Gammacell 220 Accessories Manual.

NOTE: Materials expected to change state during irradiation should be placed in suitable containers.

Liquids expected to expand or boil should be provided with secondary containers for overflow, or vented to one of the access tubes.

The sample chamber and source cage will not withstand repeated spills or corrosive materials.

e. Replace the sample chamber door with a forward and downward motion. Move the locking ring to the left until it snaps into position. If difficulties are experienced, check that the door is correctly positioned in the port.

f. To close the collar doors, press and hold in the button on the top of the door interlock. Grasp the right hand door handle, pull back the latch lever, release the button and push the doors closed.
g. Rotate the selector switch to the minutes position.
h. Depress the blue timer pushbutton and hold it down while setting the required irradiation time in minutes by depressing the white timer pushbuttons as many times as necessary to display the desired number sequence.
i. Push the DOWN switch. The drawer will lower to the irradiating position, activate the timer, and remain there until the preset time interval has elapsed (a) when it will automatically raise.

(a) If it is necessary to change an operation time, DO NOT alter the digit settings while the drawer is down and the timer is operating. Raise the drawer and set the timer as described in AUTOMATIC OPERATION, step h.
i. To remove the sample, repeat steps b and c.

2. Manual Operation
a. For initial set-up, read the preceding steps b to f.
b. Rotate the selector switch to MANUAL.
c. Press the DOWN switch.
d. Begin timing the required irradiation time with a calibrated stopwatch when the drawer reaches its lowest position.
e. Press the UP switch and stop the watch simultaneously when the desired irradiation time has elapsed.

3. Power Failure
In the event of a power failure the timer will stop and it will be necessary to raise the drawer manually.
a. Turn the key switch to the OFF position.
b. Spring out the large round button near the lower right corner of the back cover.
c. Push the crank (Figure 2, Item 14 of the operator's Manual) through the hole until it snaps into the extension on the input shaft of the reducer.
d. Crank in a clockwise direction to raise the drawer.

INDEX OF ATTACHMENTS: NONE

SPECIFICATION NO.(S): N/A
Q.A. GUIDELINE NO.(S): N/A
Q.A. POLICY NO.(S): N/A

97k01

APPROVAL BLOCK

PLANT LEVEL APPROVALS

MQA SUPERVISOR:	N/R	
PRODUCTION MGR:	N/R	
ENGINEERING:	N/R	
QUALITY ASSURANCE MGR:	S. Meyers	11-29-84

REASONS FOR REVISION:
10-31-84 Deletion of non-applicable footnote page 2.i.

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END OF DOCUMENT

NRC Form 313(1-84)
Abbott Laboratories
North Chicago, Illinois

Attachment "C"

Radiation Safety Program

With this attachment is enclosed the current job description for the Corporate Radiation Protection Officer. Please keep in mind that we already have two broad scope Byproduct Material Licenses, 12-00621-02 and 12-00621-03, and there are slight differences in modus operandi from one to another as reflected in the job description. There are six persons in the Health Physics Section of the Employee Health Services Department - the R.P.O., the ADD Health Physicist, three Radiation Monitors, and a Health Services Assistant.

The Gammacell 220 is a standard irradiation unit for which well-established operating procedures are written. We will use the Operator's Manual for the Gammacell 220 Cobalt-60 Irradiation Unit, Edition 7, February 1978, in our work with the Gammacell 220 (Copies of operation section, pages 2-1 to 2-3 are attached).

We presently perform leak tests on a number of sealed sources in our possession, including cesium-137 and nickel-63. We will perform our own leak tests on the Gammacell 220 as described in the Operator's Manual (copies of contamination section, pages 5-2 to 5-3 are attached).

All operators of the Gammacell 220 will be trained in its use and safety precautions to be observed as described in the Operators Manual. Operators will be provided with film badges, and the work area will be equipped with an audio ratemeter and portable Geiger counter survey meter. Independent radiation surveys by Health Physics workers will be made about once each month.

October 21, 1985