ATTACHMENT 3 EioSurface Technology, Inc One Kendall Squarc Building 200 Cambridge, MA 02139

(617) 494-8484 FAX (617) 494-6561

BIOSURFACE

22 February 1991

Mr. John White, Supervisor Licensing Materials Section Nuclear Materials Safety & Safeguards Branch U.S. Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406

RE: License Number 20-28072-02

Dear Mr. White:



BioSurface Technology, Inc. (BTI) hereby requests a one time shipment authorization using the Type B packaging materials originally used to transport (import) the licensed material, a Cobalt-60 irradiator, to its current address. By amendment letter of 13 December 1991, BTI requested authorization to change its license address from One Kendall Square, Cambridge to 64 Sidney Street, Cambridge. This request is supplemental to that amendment. The expected time for this move is now predicted to be the end of May 1991. Originally, this move was scheduled for the end of March 1991. (The byproduct materials subject to license number 20-28072-01 are still scheduled for an end of March 1992 move and are the subject of a separate license amendment.)

Discussions with Kristen Smith, Research & Special Programs Administration, US DOT, (202-366-4491) and Charles MacDonald, US NRC, (301-492-3382) have confirmed the Type B packaging materials used in the initial shipment from NORDION (AECL) in Canada to the current address at One Kendall Square, Cambridge are not approved for domestic transport. The US DOT has revalidated Canadian Certificate CDN/2013.B(U) (USA/6125/B(U)) for import/export purposes. BTI knows of the availability of no other Type B packing suitable and available for this shipment. Therefore, it is this packaging that BTI requests authorization to use in a one-time shipment of the irradiator from One Kendall Square to 64 Sidney Street, Cambridge.

In support of the above petition, the following information is provided.

- A. BTI will transport the irradiator at time of low road usage; likely to be in the early morning hours of the day.
- B. Roads projected to be used during the transport are noted in Appendix 1. The route shown traverses a commercial/industrial area having little or no residential use.

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- C. The shipment will be accompanied by an escort knowledgeable in the use of radiation survey instrumentation from NORDION (AECL), the original vendor and shipper.
- D. The escort will be capable of establishing a radiation exclusion area if required.
- E. NORDION (AECL), in addition to providing escort services, will provide all written emergency procedures. A copy of their emergency response form is enclosed as Appendix 2.
- F. BTI will be responsible for rigging, shoring and shipping the irradiator in an exclusive use vehicle. NORDION will be responsible for verifying the Type B packaging integrity.
- G. City and state officials have been advised of expected shipment. When the exact date and time of shipment is determined, these officials will be notified of all particulars. See Appendix 3.

A portion of the Operations Manual including engineering drawings, and the US DOT and Canadian Atomic Energy Control Board certifications for the import/export packaging, are provided in Appendices 4 & 5.

If there is any other information you require in processing this amendment, please contact me at the above address and phone number.

Sincerely,

J.D. Bernardy Director, Regulatory Affairs

JDB:ac Encl: Amendment application (2 copies)



HAZARO INFORMATION - EMERGENCY RESPONSE FORM - For rail and road transportation

Appendax 2

Placard	No	121.0	100	84	010	ACTI	VE.
FIRCHTG	14.25	9 0 8 X P.64	5 K	1.1.6-0	48.2.2.5	1.1.1.1.1.1.1.1	

SHIP TO:	SHIPPEK:
DATE	ORDER NO:
CLASSIFICATION: (7) RADIOACTIVE MATERIAL	CAR NO:
AADIONUCLIDE:	ROUTING
CURIE CONTENT:	
LABEL: ADDOACTIVE I (White) ADDOACTIVE II (Yellow) RADIOACTIVE III (Yellow)	
TRANSPORT INDEX:	ORIGIN: Kanata, Ontario, Canada
MODEL:SERIAL NO:	WEIGHT OR VOLUME:
AEC8 Certificate: CDN/	USA Cartificata: USA/
RADIO, EPLACARD	SHIPPER'S CERTIFICATION
IN CANADA: Placard road vehicles/rail cars when transporting Radioactive I (white) OR Radioactive II (vellow) OR Radioactive III (vellow) labelled packages, IN USA: Placard road vehicles/rail cars when transporting	This is to certify that the above named materials are properly classified, described, packaged, marked and labelled, and are in proper condition for transportation according to the applicable regulations of Transport Canada and the United Scross Department
Radioactive III (veilow) labelled packages only.	of Transportation.
	SHIPPER'S SIGNATURE:
POTENTIA	LHAZAROS

EMERGENCY ACTION

exposure may be a threat to health or life. Effects of radiation may be delayed.

hazard may be external (like x-rays) from contamination on skin or exposure to unshielded material. Prolonged

Keep unmocessary people every. Keep upwind, isolate instand area (at least 50 meters - 164 fd). We ar self-contained prestring apparatus and full protective clothing. Delay cleanup until arrivel of gualified radiation monitoring assistance. Small fires: Dry Chemical or COg FIRE Large fires: Foom or weter

	Fight fire from maximum distance, Move undamaged packages from fire area if without risk. Do NOT move damaged packages.
SPILL OR LEAK	Oo not touch spilled material unleaking or damaged packinges. Small Spills: Take up with sand, earth or other noncombustible speorbent material. Large Spills: Dike for later decontemination and disposal. Do not enter the spill area unless absolutely necessary to save life. Limit entries to shortest possible time. Al ternate persons for entry if possible.
FIRST AID	Cell physiclen. Use standard first aid procedures. Remove contaminated clothing and shower with soap and water. Advise rescue personnal and physicians that person or equipment may be redipectively contaminated.

EMERGENCY . TELEPHONE

IN CANADA:	1. Local Pollos AND 2. Transport Canada (Canutac) (613) 995-6666 (24 hour)		Int. Inc.) - 465 - 3666	
IN U.S.A	1. State Police AND Chemtrec (800) 424-9300 (toll free) OR Coast Guard National Response Centre (900) 424-88	(17) (toi) free)		

BioSurface Technology, Inc. One Kendall Square Building 200 Cambridge, MA 02139

(617) 494-8484 FAX (617) 494-6561 Appendix 3



20 February 1991

Capt. Jospeh Grainger Cambridge Police Department 5 Western Avenue Cambridge, MA 02139

Dear Captain Grainger:

BioSurface Technology, Inc. is in the process of obtaining permission from the Nuclear Regulatory Commission to move a sealed source irradiator in its import/export certified Type B packing from our present address at One Kendall Square, Cambridge to our new facility at 64 Sidney Street, University Park (near Central Square), Cambridge. This irradiator is used in the manufacturing of cultured epidermis (skin).

We expect the make the move near the end of May 1991. The proposed route for an exclusive use truck shipment is marked on the attached map. It lies principally in a commer. I/industrial area. The proposed move will be scheduled at a time of low road usage, likely in the early morning hours. A copy of the Type B(U) packaging certifications for import/export is also attached.

When the exact date and time of transport can be determined, we will again notify your office. Please advise us if there are any special permitting or transport requirements that we must satisfy with your office.

If you have any questions or require any further information, please contact me at the above address and phone number.

Sincerely,

 Bernardy Firector, Regulatory Affairs

JDB:ac encl: 2 copies of letter with attachments

cc: Mr. L. Richard Adams, Department of Labor & Industries Deputy Chief William Cantwell, Cambridge Fire Department BioSurface Technology, Inc. One Kendall Square Building 200 Cambridge, MA 02139

(617) 494-8484 FAX (617) 49--6561

BIOSURFACE TECHNOLOGY

20 February 1991

Deputy Chief William Cantwell Cambridge Fire Department 491 Broadway Cambridge, MA 02138

Dear Deputy Chief Cantwell:

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Sincerely,

J.D. Bernardy Director, Regulator

JDB:ac

encl: 2 copies of letter with attachments

cc: Mr. L. Richard Adams, Department of Labor & Industries Captain Joseph Grainger, Cambridge Police Department BioSurface Technology, Inc. One Kendall Square Building 200 Cambridge, MA 02139

(617) 494-8484 FAX (617) 494-6561

BIOSURFACE TECHNOLOGY

20 February 1991

Mr. L. Richard Adams Radiation Control Program Division of Occupational Hygiene Department of Labor & Industries 1001 Watertown Street West Newton, MA 02165

Dear Mr. Adams:

BioSurface Technology, Inc. is in the process of obtaining permission from the Nuclear Regulatory Commission to move a sealed source irradiator in its import/export certified Type B packing from our present address at One Kendall Square, Cambridge to our new facility at 64 Sidney Street, University Park (near Central Square), Cambridge. This irradiator is used in the manufacturing of cultured epidermis (skin).

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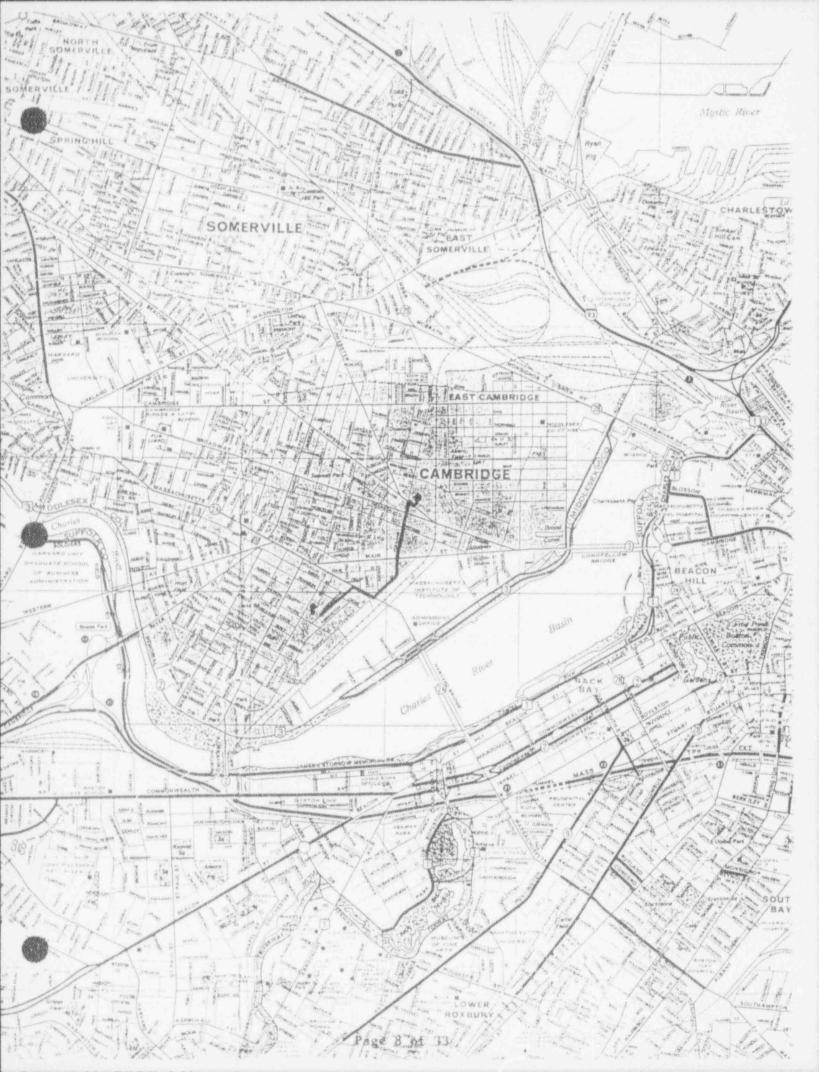
If you have any questions or require any further information, please contact me at the above address and phone number.

Sincerely,

Director, Regulatory Affairs

JDB:ac encl: 2 copies of letter with attachments

cc: Deputy Chief William Cantwell, Cambridge Fire Department Captain Joseph Grainger, Cambridge Police Department



PART 1

DESCRIPTION

1.1 GENERAL

The Gammacell 220 is a Cobalt-60 irradiation facility manufactured by Atomic Energy of Canada Limited for use in an unshielded room. Fig. 1-1 illustrates the external features and Fig. 1-2 the general dimensions of the unit. Part 6 contains the accessories that are available for use with the Gammacell 220.

The unit basically consists of an annular source (see Fig. 1-3) permanently enclosed within a lead shield, a cylindrical drawer, and a drive mechanism to move the drawer up or down along the vertical source centre-line. The drawer has a chamber to carry samples to be irradiated from outside the shield to the source.

Samples up to approximately six inches in diameter and eight inches in height can be accommodated in the chamber. Liquid, gaseous, electrical or mechanical connections can be introduced into the sample chamber through an access tube in the upper portion of the drawer. An electrically powered digital timer automatically signals the drawer to raise at the termination of a sample irradiation. Times may be preset between 1 and 9999 seconds or minutes. Manual operation is also pro-

1.2 ELECTRICAL

The Gammacell 220 operates on a 200V, 3 phase, 50/60 Hz, 15A supply. The supply is connected through a starter to a 1/2-hp drive motor. A step-down transformer connected across one phase of the supply provides the 115V, 3A control circuit.

1.3 WEIGHT

Crated 8,500 lb (3856 kg) Uncrated 8,300 lb (3765 kg)

GC-220

1-1

1.4 <u>HEAD</u> (see Fig. 1-1)

The head (see Fig. 1-1) serves as a cylindrical shield for the source and as a guide for the moving drawer. It consists of a leak-proof shaped steel cylinder which contains approximately six thousand pounds of lead to provide ten-inch thick shielding. A stepped, circular hole running vertically through the centre of the head locates the inner head plug, the source cage assembly and the moving drawer.

1.5 COLLAR (see Fig. 1-4)

Mounted on top of the head is a 6-1/2 inch (16.51 cm) deep lead filled annular steel collar. The collar provides shielding for the transient beam occurring when the relatively unshielded volume of the sample chamber moves through the inner plug. The rear, semi-circular portion of the collar is attached to the head. The front portion opens as two doors, each hinged to the rear portion of collar. Pressure on a lever behind the handle on the right door raises a latch and (permits the overlapping doors to be opened. The doors can be opened only when the drawer is raised, when access is required to the sample chamber.

1.6 INNER HEAD PLUG (s e Fig. 1-2)

The inner head plug is a lead-filled stainless-steel cylinder which fits into the head above the source cage. It forms part of the shielding and also houses the upper drawer guides. The plug must not be removed except for source changing procedures supervised by AECL staff in a hot cell.

1.7 SOURCE CAGE ASSEMBLY (see Fig. 1-3)

The source cage is located in the centre of the head directly beneath the inner head plug. The stainless-steel cage contains forty-eight pencil positions. The source cage contains a minimum of eight double-sealed source pencils, each 8.31 in. (21.11 cm) long, set in an annular formation on an 8.32 in. (21.13 cm) pitch circle diameter (see Fig. 1-3). Each tubular pencil contains seven Cobalt-60 slugs completely sealed in by welded and caps.

 (a_{i}, a_{i})

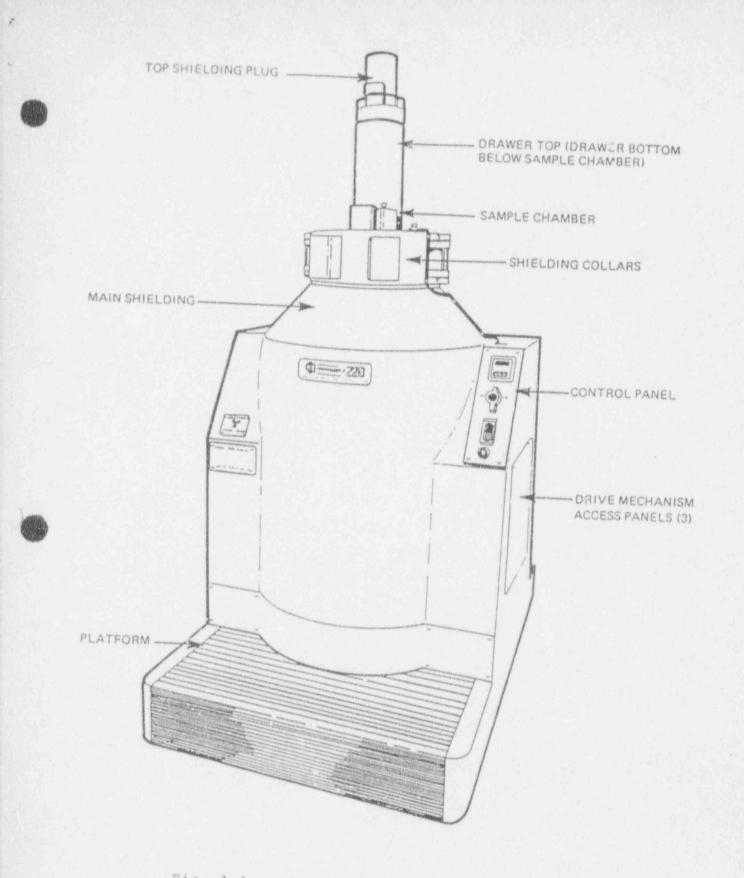


Fig. 1-1. Overall View of Gammacell 220

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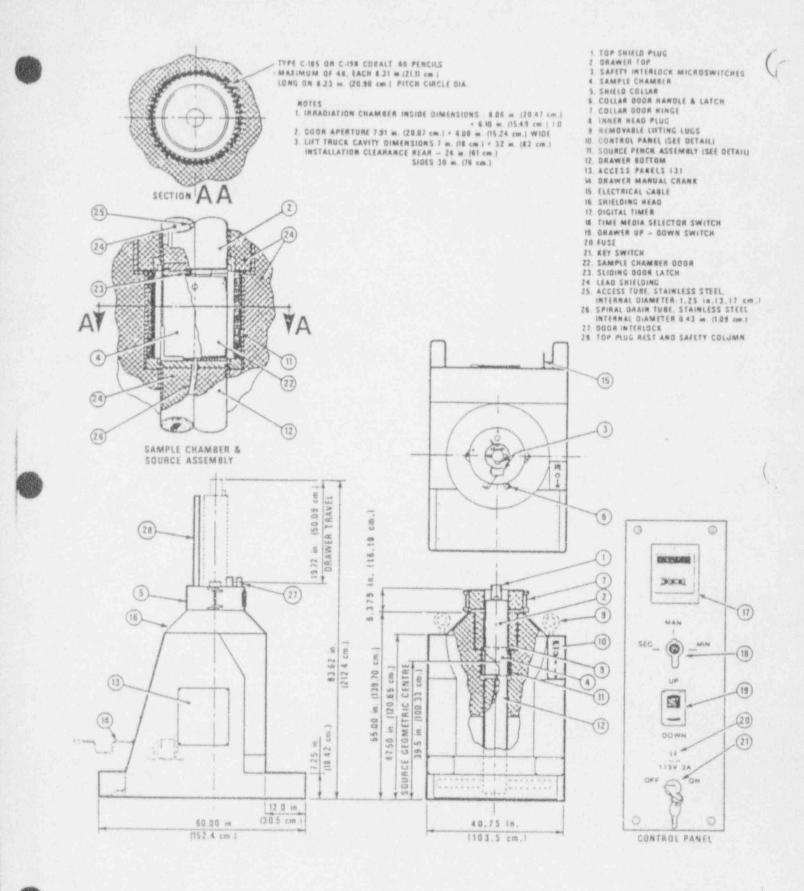


Fig. 1-2. General Dimensions

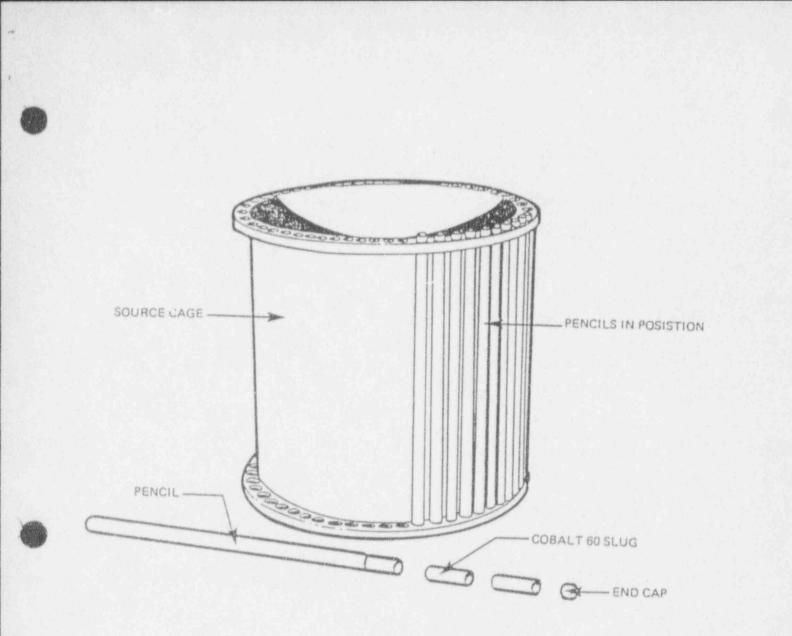
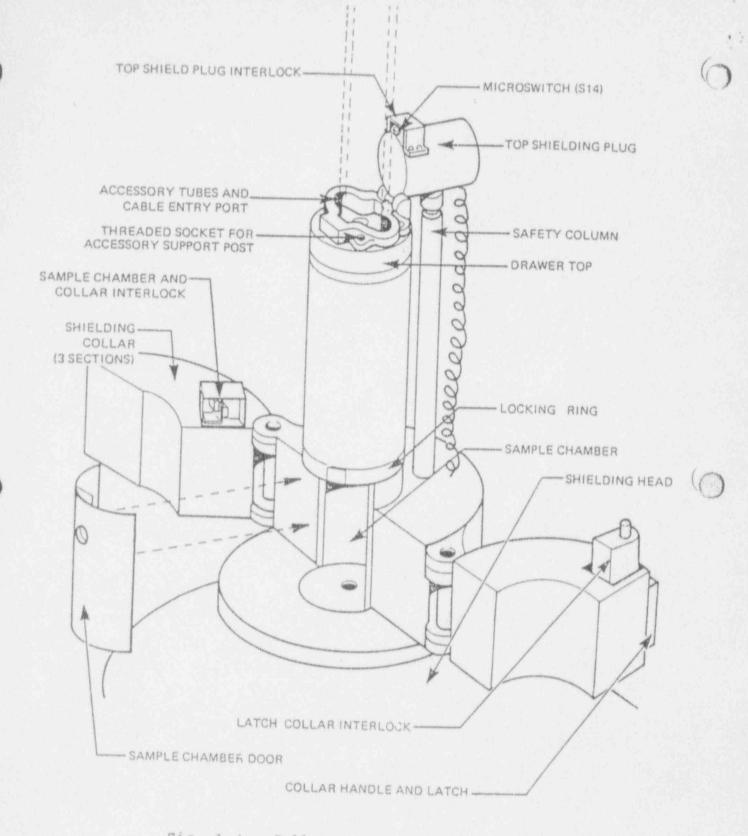


Fig. 1-3. Source Pencils and Cage

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1.8 DRAWER ASSEMBLY (see Fig. 1-2)

The drawer moves vertically through the centre of the head, inner plug and source cage assembly. It is 59.0 in. (149.86 cm) long and 6-1/2 in. (16.51 cm) in diameter, and is constructed from four distinct components; the top shielding plug, the drawer top, the sample chamber and the drawer bottom. The top shielding plug is hinged to the drawer top. The other three components are spigotted together and secured with screws. The drawer is guided in the head and inner head plug by four bronze bearings.

1.9 TOP SHIELDING PLUG (see Fig. 1-5)

The lead-filled closed steel cylindrical plug is 4 in. (10.16 cm) in diameter and 5-1/4 in. (13.34 cm) long. It is hinged to a steel casting on the drawer top and provides a radiation shield over the drawer top access tube. When the drawer is raised, the top plug may be tilted back to permit the introduction of accessories into the sample chamber (see Fig. 1-5). Electrical interlocks prevent the drawer being lowered with the plug in the open position. During a sample irradiation procedure the plug cannot be opened.

1.10 DRAWER TOP (see Fig. 1-4)

The 6-1/2 in. (16.51 cm) diameter, 14-3/8 in. (36.51 cm) long closed stainless-steel cylinder has a 1-1/4 in. (3.17 cm) inside diameter access tube through its centre. The space between the stainless-steel outer casing and the stainless-steel access tube is filled with lead. Welded to the drawer top is a steel casting onto which the top shielding plug is the access tube; it also provides two sockets tapped 1/2 - 20 UNF - 28, 3/4 in. (1.91 cm) deep to accommodate accessory tube insert accessory assembly.

1.11 SAMPLE CHAMBER (see Fig. 1-4)

The chamber is a thin wall closed, non-corrosive metal cylinder with a lift out full width door. The inside dimensions of the chamber are 6.10 in. (15.49 cm) diameter and 8.06 in.

GC-220

(20.47 cm) high. The access port is 7.91 in. (20.07 cm) high and 6.00 in. (15.24 cm) wide. A step on the bottom of the door and a locking ring at the top of the chamber retain the door in place, see Fig. 1-4. An opening is provided in the top and bottom of the chamber for the access and drain tubes. Electrical interlocks prevent drawer movement when the door or door latch is improperly closed.

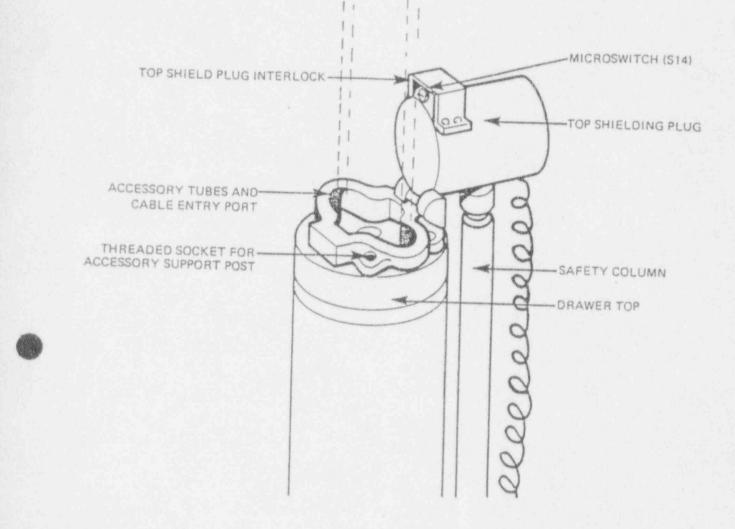
1.12 DRAWER BOTTOM (see Fig. 1-2)

The drawer bottom is formed from a 6.5 in. (16.51 cm) diameter, 30.5 in. (77.47 cm) long stainless-steel tube, leadfilled, and closed at both ends. A spiral stainless-steel drain tube, 7/16 in. (1.11 cm) internal diameter, runs the length of the drawer bottom to facilitate drainage of liquid spills in the sample chamber. The drawer bottom is sufficiently long to provide irradiation shielding beneath the unit when the drawer is up.

A rectangular bracket on the base of the drawer provides a (pin joint connection to the drive mechanism.

1.13 DRIVE MECHANISM (see Fig. 1-6)

The drawer assembly is raised or lowered by a chain and sprocket system. The system motive power is provided by a 1/2 hp, 220V, 3 phase motor; the output speed of which is reduced initially through a V-belt and pulley connection to a worm and gear reducer. Further speed reduction is obtained through a chain and sprocket drive to a shaft. A sprocket at each end of the shaft transmits the shaft rotation to the smaller of double-head sprockets mounted each side of the head base. The head sprockets rotate less than one revolution each complete up or down movement of the drawer. Two roller chains are pinned at one end to each of the larger of the double-head sprockets and at the other end to each end of a full width lift-bar. The lift-bar is pin jointed to a bracket on the bottom of the drawer. With the partial rotation of the head sprockets on upward drawer movement the lift chains wrap around the sprockets and raise the lift-bar.



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Fig. 1-5. Top Shielding Plug

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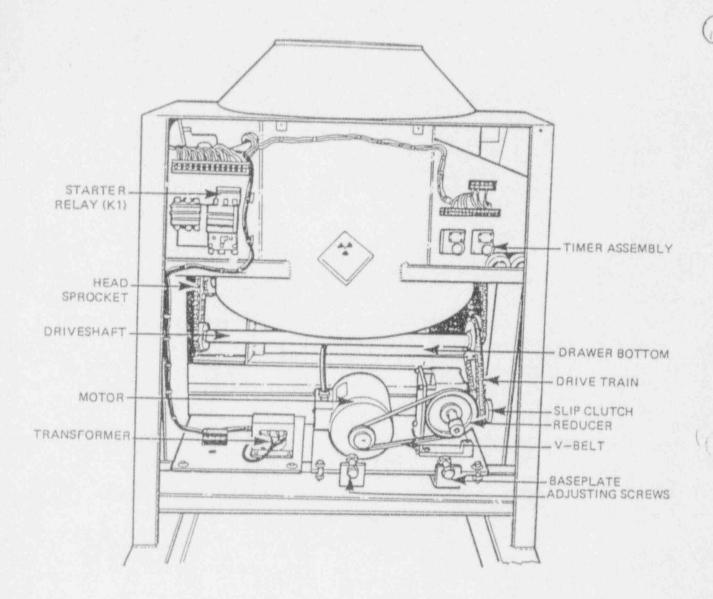


Fig. 1-6. Rear of Unit

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1.14 DRAWER MOVEMENT (see Fig. 1-7)

Drawer movement is electrically governed from the control panel. Microswitches mounted on the head sprockets are cam actuated at the end of drawer travel, disconnecting the electrical supply to the motor (see Fig. 1-7). The drawer travels 19.72 in. (50.02 cm) in approximately seven seconds. Microswitches S10 and S15 provide a back-up to these cam-operated microswitches.

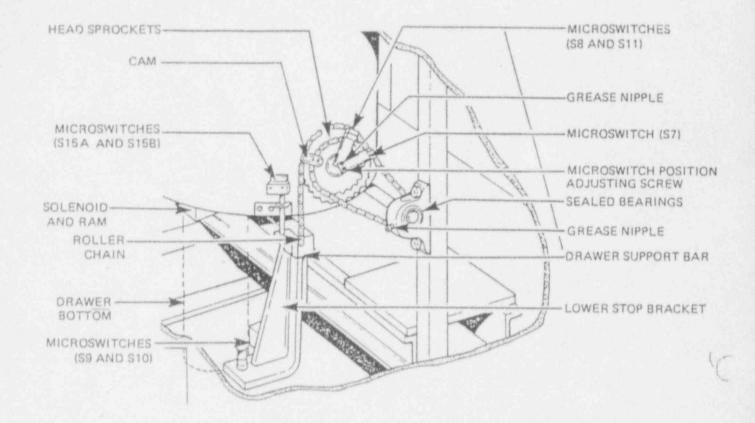
Mechanical stops are provided at the limits of the drawer movement. The upper stop is formed from an adjustable bolt, mounted on the underside of the shield head, which stops against a nylon pad inserted in the top side of the liftbar. The lower stop is formed from a nylon-tipped adjustable bolt, mounted on a fixed bracket (see Fig. 1-7), which stops against the underside of the drawer when it reaches the lowest point of its movement.

A hand crank is provided to enable the drawer to be operated manually in the event of a power supply failure. Hand crank operation is made easier if the V-belt is removed from the drive as the motor is equipped with a brake.

1.15 CONTROL PANEL (see Fig. 1-8)

The unit controls are grouped on one panel situated at the top right of the head, as illustrated in Fig. 1-1. From the top of the panel the controls are:

- (1) Digital timer to provide irradiation time settings between 1 and 9999 seconds or minutes. A reset button returns the timer to its original setting. The time setting is changed by holding in the reset button and pressing the individual digit buttons as required. The timer commences operation when the drawer reaches the irradiation position.
- (2) Selector switch to provide for manual operation or selection of time settings in seconds or minutes.
- (3) Movement switch to select up or down drawer movement.
- (4) Keyswitch to control the electrical supply to the unit control circuit.





GC-220

1-12

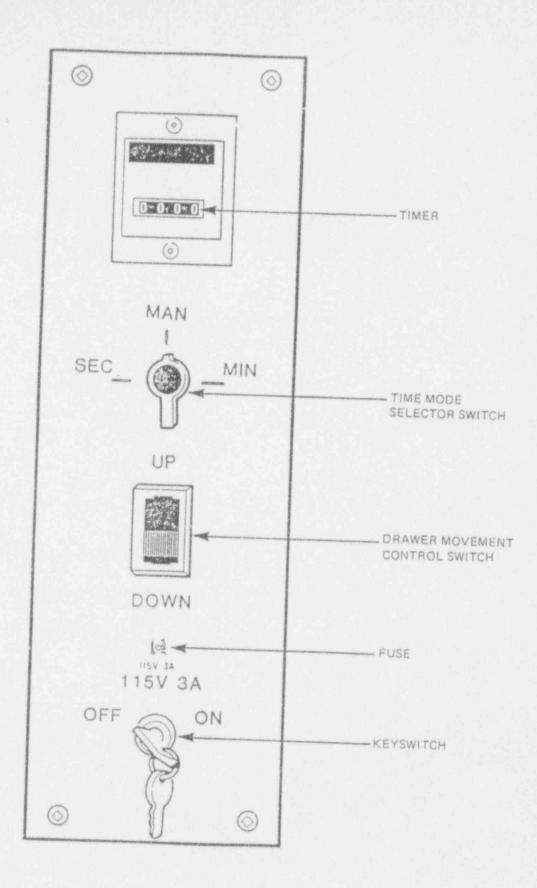


Fig. 1-8. Control Panel

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1.16 SAFETY FEATURES

For the protection of the operator several safety features have been incorporated in the unit.

Three microswitches are mounted on the collar door (Fig. 3-1) to ensure that:

- (a) the sample chamber door is properly located.
- (b) the locking ring is in position.
- (c) both collar doors are closed.

A fourth microswitch is located on the top shielding plug to ensure that the plug is closed. Unless all four microswitches are actuated, the drive motor will not start.

The self-locking feature of the worm gear reducer prevents the drawer moving down under its own weight from rest.

A solenoid-operated bar, mounted on the underside of the head, actuates when the drawer stops in the raised position. The bar locates under the drawer bottom and prevents the drawer moving down in the event of a drive system mechanical failure.

Drawer movement can be arrested by switching off the electrical supply keyswitch.

A solenoid-operated door interlock ensures that the collar doors can only be opened with the drawer in the fully up position.

The top plug rest and safety column ensures that the top plug can only opened with the drawer in the fully up position.

Page 23 of 33

1.	Worm Gear Reducer	13.	Rocker Switch - S2
2.	Reducer Output Chain	14.	
3.	Head Sprocket Chain	15.	
4.	Collar Microswitches - S4, S5, S6	16.	
5.	Roller Chain		Up Coasting Microswitches - S8, S11, S15A
6.	V-Belt	17.	Down Coasting Microswitches - S7
7.	Shaft	18.	
8.	Head Sprocket	19.	Solenoid and Ram - Ll
9.	Shielding Plug Microswitch - Sl4	20.	Drive Motor - Ml
10.	Door Litch	21.	Digital Timer Microswitch - S9
11.	Digital Timer	22.	Bottom Stop Microswitches - S10
12.	Rotary Selector Switch - S3	23.	Door Interlock Microswitch - S158
		24.	Door Interlock

DESCRIPTION

Table 4-1. Component Locations

ITEM

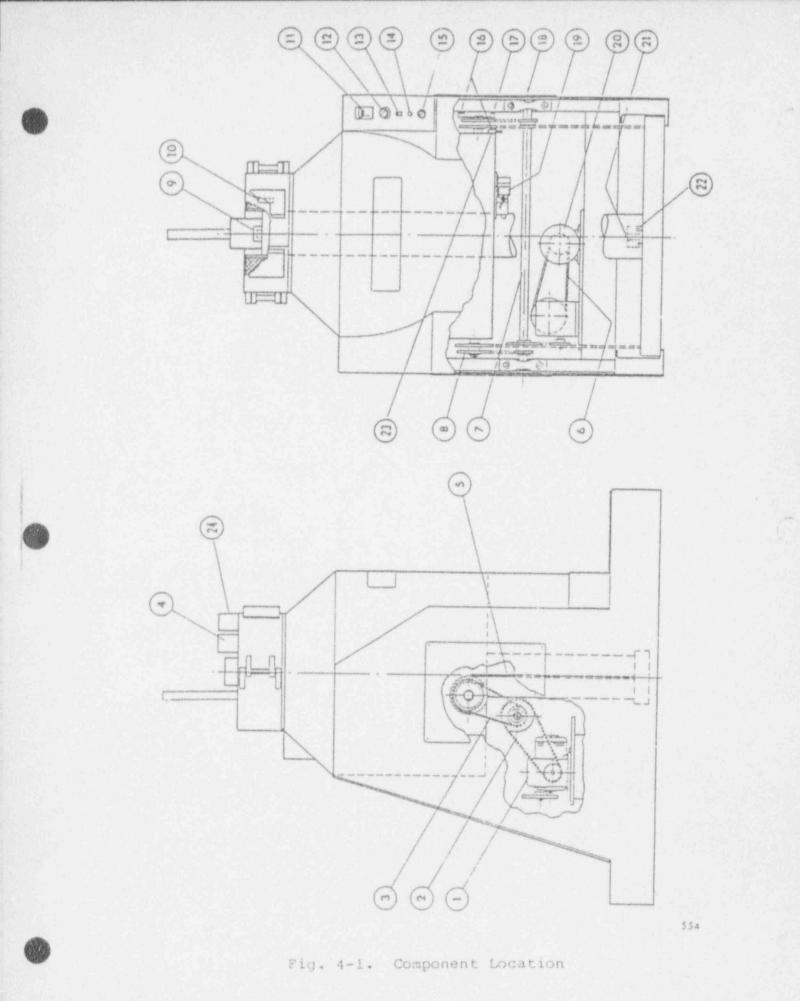
DESCRIPTION

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ITEM

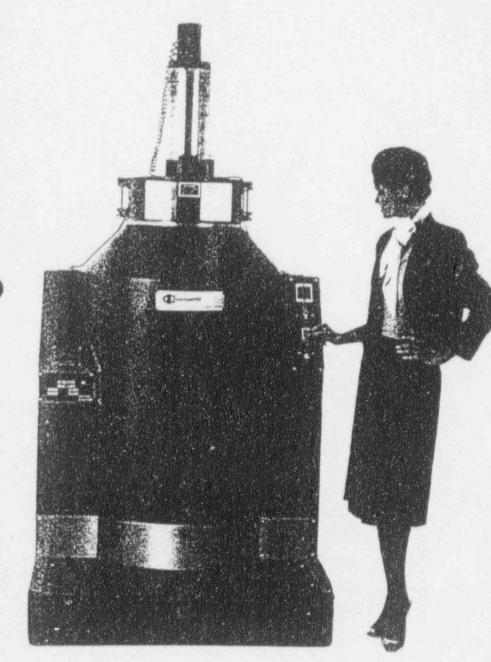
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Gammacell 220 High Dose Rate Research Irradiator



THE GAMMACELL 220 is the most popular of the AECL line of high dose rate research irradiators. Over 200 have been installed in laboratories throughout the world. They are being used in a wide range of studies in the fields of medical product sterilization, biological and genetic effects, food preservation, growth stimulation, chemistry, pollution, radiation effects on materials, sterile male technique for insect control, and the irradiation of semi-conductors.

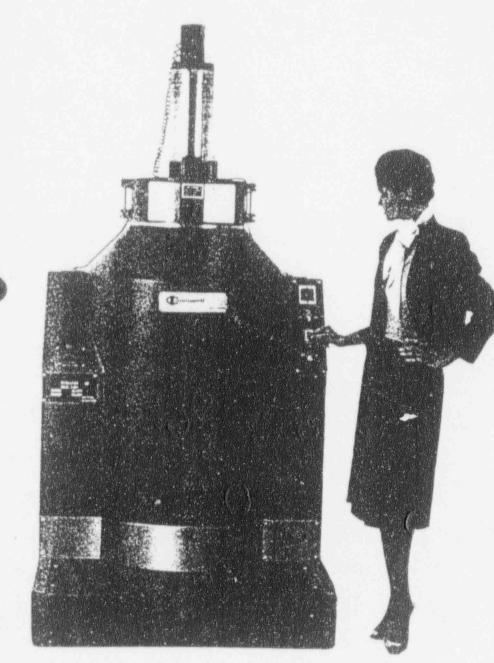
PAGE 1

Features of the Gammacell 220

- Self shielded can be placed right in the laboratory. No further shielding is necessary.
- High dose rate up to 2.0×10^{6} Roentgens/hour when loaded with 24,000 curies of Cobalt 60. Dose rate and loading can be suited to customer requirements.
- Safe source permanently fixed in shielded body. No possible malfunction can expose the operator to the source.
- Simple to operate no special training required.
- Reliable simplicity of design combined with AECL's long experience in irradiator design and construction assure years of trouble-free operation.
- Large radiation chamber --15.2 cm (6.0 in) diameter x 20.6 cm (8.12 in) high. Volume: 3738 cm³ (228 in³). The chamber is located in a vertical drawer which automatically positions the chamber in the centre of the radiation field.



Gammacell 220 High Dose Rate Research Irradiator

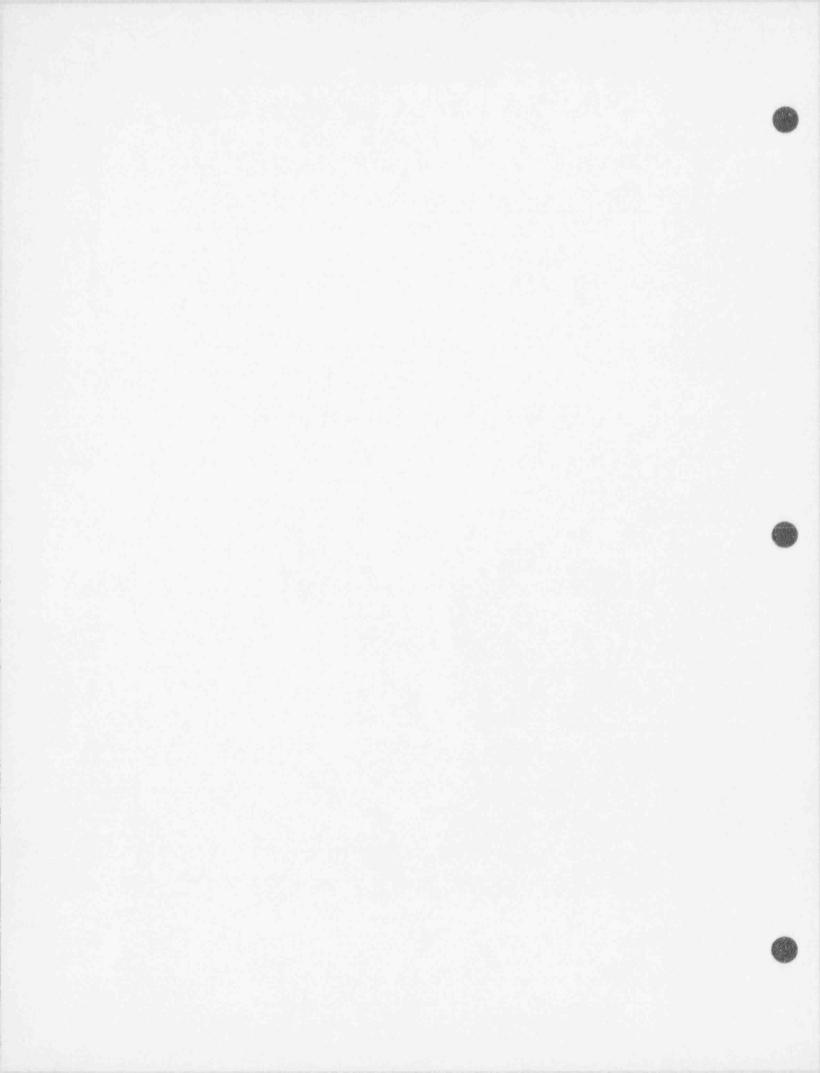


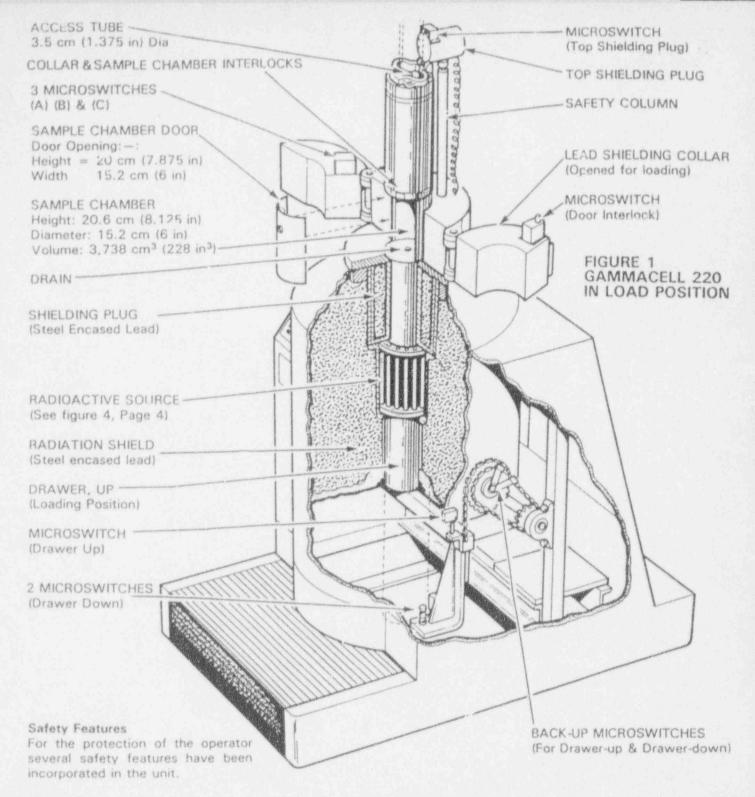
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PAGE 1

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- A) the sample chamber door is properly located.
- S) the locking ring is in position.
- C) both collar doors are closed.

A fourth microswitch is located on the top shielding plug to ensure that the plug is closed. Unless all four microswitches are actuated the drive motor will not start. A solenoid operated ram, mounted on the underside of the head, actuates when the drawer stops in the raised position. In this position the ram prevents the drawer from falling should any part of the drive mechanism fail.

A solenoid operated door interlock ensures the collar doors can only be opened with the drawer in the safe position.

Top plug rest and safety column ensure the top plug can only be opened with the drawer in the full up position.

WEIGHTS & DIMENSIONS

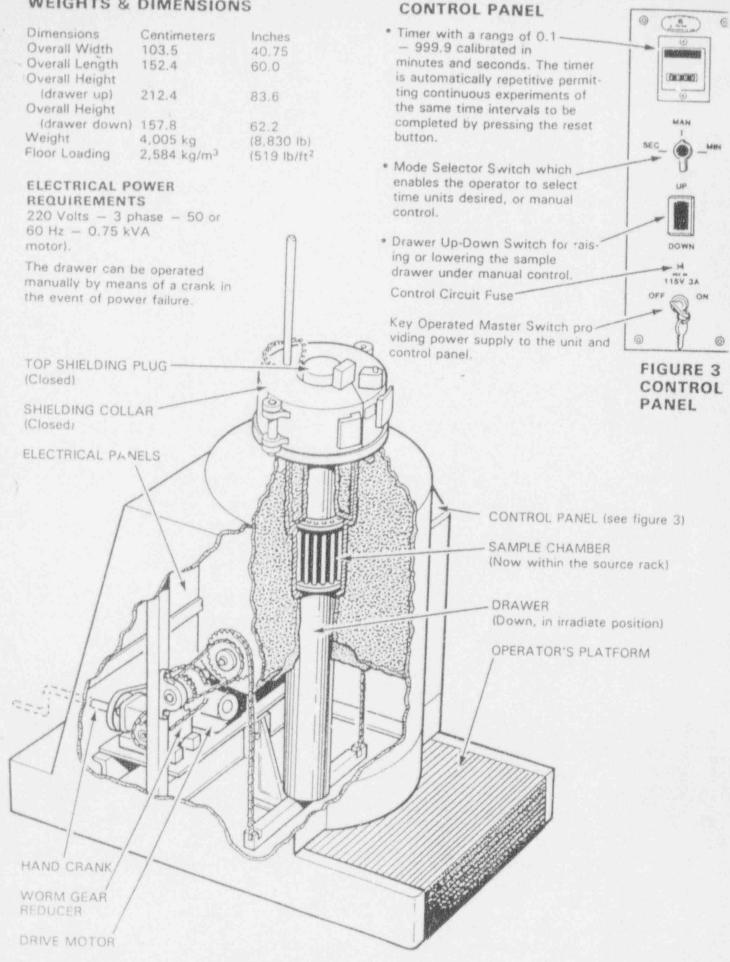


FIGURE 2 GAMMACELL 220 IN IRRADIATE POSITION. Page 27 of 33

A. RADIOACTIVE SOURCE -

The Cobalt 60 source is doubly encapsulated in up to 48 stainless steel source pencils (Model C198). The pencils are equally spaced in an annular source rack which surrounds the irradiation chamber.

The active volume of each pencil is 196.3 mm (7.73 in) long x 6.35 mm (0.25 in) diameter. Cobalt 60 has a half-life of 5.3 years.

B. EXTERNAL RADIATION LEVELS — At 5 cm (2 in) from the surface of the unit the average exposure rate will not exceed 20 mR/h, and the maximum exposure rate will not exceed 100 mR/h.

At 100 cm (39.4 in) from the centre of the source the average exposure rate will not exceed 2 mR/h, and the maximum exposure rate will not exceed 10 mR/h.

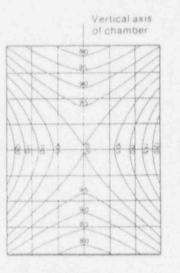
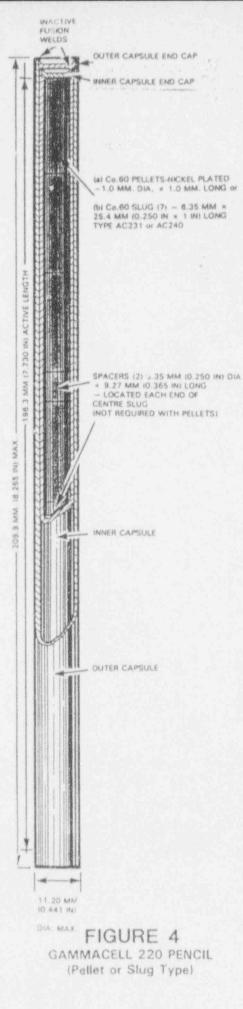


FIGURE 5 Gammacell 220 Sample Chamber Isodose Curves

C. SHIPPING AND HANDLING The Gammacell 220, complete with Cobalt 60 source, is shipped in one package without additional radiation shielding. The package can be handled by a standard forklift, or a platform truck, or an overhead hoisting device. It is licensed for shipment in the U.S.A. by the U.S. Dept. of Transport, and in Canada by the AECB.

The unit has been found acceptable for licensing in the USA by the USNRC, and in Canada by the AECB. When applying for a U.S. Radioactive Materials License, or a



Canadian AECB License, the customer should apply for 10% more. Cobalt 60 than ordered to allow for the $\pm 10\%$ loading tolerance.

The customer should send a copy of the license to AECL-RCC at least 6 weeks prior to the estimated shipping date. Receipt of the licence by AECL-RCC will initiate the loading of the Cobalt-60 into the unit.

Prior to shipment of the unit AECL-RCC's installation branch will contact the customer to make arrangements for a smooth installation by AECL technicians. However, the following points are relevant:

- Local riggers (movers of heavy equipment), with appropriate equipment, must be hired by the customer to move the unit from the customers unloading dock into the room where installation will be done. This move must be supervised by AECL Technicians.
- In order to install the unit there is a requirement for the following minimum wall clearances (when facing the unit):

Rear Wall 36 cm (14 in) Right Wall 36 cm (14 in)

Crated Weight: - 4400 kg (9,700 lb Crated Dimensions: -

Height	170.1 cm	(67 in)
Width	108.4 cm	(42.75 in
Length	156.2 cm	(61.5 in)

D. CERTIFICATION & DOCUMENTATION

A set of isodose curves is supplied with each unit showing the distribution of the dose rate in the sample chamber. See figure 5.

Actual dose rate values are normally within 5% of those indicated by the isodose chart.

The dose rate at the mid-point of the sample chamber is measured by ferrous chemical dosimetry, the accuracy being $\pm 3.5\%$. A Certificate of Measurement which certifies curie content and Central Dose Rate is supplied with each unit.

The Cobalt 60 pencils in the source are individually tested for leakage and contamination. A certificate describing the tests performed is supplied with each unit.

An Operation and Maintenance Manual is shipped with each unit.



U.S. Department of Transportation

Research and Special Programs Administration 400 Seventh St., S.W. Weshington, D.C. 20590

Appendix 5

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/6125/B(U), REVISION 7

ENDORSEMENT OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2013/E(U)

This contifies that the radioactive materials package design described below is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable International Atomic Energy Agency and USA regulations.

- 1. Package Identification Gammacell 220.
- Packaging Description and Authorized Radioactive Contents as described in Canadian Certificate of Competent Authority CDN/2013/B(U), Issue 7.

3. GENERAL CONDITIONS -

- a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation in accordance with the endorsed certificate.
- b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Regulation, Research and Special Programs Administration U.S. Department of Transportation, Washington D.C. 20590.
- c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

"Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (As Amended)" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

²"Title 49, Code of Federal Regulations, Parts 100 - 199, USA."

- 2 -

CERTIFICATE USA/6125/B(U), REVISION 7

- d. This certificate is issued only to authorize transport from point of entry to final destination within the United States and from point of origin in the United States to point of exit.
- 4. The package shall bear the marking USA/6125/B/U) in addition to other required markings and labeling.
- 5. This certificate, unless renewed, expires on October 31, 1991.

Certified by:

Michael E. Wangler

5 1 1

November 25, 1986

Chief, Redioactive Materials Branch Office of Hazardous Materials Transportation

Revision 7 - issued to incorporate revision 7 of CDN/2013/B(U) and to extend the date of expiration.

Certification



Atomic Energy Control Board

Commission de contrôle de l'énergie atomique

- 12 307 ...

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RADIOACTIVE MATERIAL TYPE B(U) PACKAGE DESIGN APPROVAL CERTIFICATE NO. CDN/2013/B(U), (REV. 7)

30-A2-93-0

October 10, 1986

The Atomic Energy Control Board hereby certifies that the package, as described below, has been demonstrated to meet the regulatory requirements prescribed for Type B(U) packages as described in the Canadian Transport Packaging of Radioactive Materials Regulations and in the IAEA Regulations*, subject to the following provisions.

Each shipper under this certificate shall possess the necessary instructions for preparation of the package for shipment prior to the use of the package.

This certificate does not relieve the shipper from any requirement of the government of any country through or into which the package will be transported.

PACKAGE IDENTIFICATION

Atomic Energy of Canada Limited Gammacell 220 Irradiator.

PACKAGING DESCRIPTION

The Atomic Energy of Canada Limited (AECL) Gammacell 220 Irradiator, as shown on AECL Drawing No. A01885, (Revisions S and T), consists of a 760 mm diameter cylindrical steel-encased lead radiation shield which is welded to a support frame and is partially covered with sheet metal covers. A cavity in the radiation shield contains a cylindrical source cage, a drawer and a plug. A steel shipping cover, 57.1 mm thick with a 11.1 mm recess, registers on the plug and retains it in place. The drawer is retained on the top by the shipping cover and on the bottom by a shipping bracket. The radiation shield is wrapped in thermal insulation which is held in place by wire mesh on the iront, the top and the back and by chicken wire on the sides and the bottom. The chicken wire on the sides and bottom is further protected by sheet metal panels. A steel energy absorber (impact limiter) is mounted on top of the radiation shield and the assembly is placed inside a plywood shipping crate. The crate dimensions are 1700 mm high by 1090 mm wide by 1560 mm long and the gross weight of the package is 4400 kg.



CDN/2013/B(U), (REV. 7)

Page 2 of/de 2

Canad'ä

The package shall bear the competent authority identification mark "CDN/2013/B(U)".

AUTHORIZED RADIOACTIVE CONTENTS

This package is authorized to contain not more than 963 TBq (26,000 Ci) of cobalt-60 in the form of metal pellets or slugs. Pellets and unsheathed slugs are doubly encapsulated in C198 stainless steel capsule assemblies. The aluminum-sheathed slugs are encapsulated in C185 stainless steel capsule assemblies. All capsules are mounted in a cylindrical source cage. The decay heat output for this material is not greater than 400 W.

The containment system consists of the capsule assemblies.

SHIPMENT

This package shall be prepared for shipment in accordance with AECL Engineering Spec. DS-0766, (Rev. B) "Preparation for Shipment, Gammacell 220", the Canadian Transport Packaging of Radioactive Materials Regulations and the IAEA Regulations*.

The average surface heat flux of this package with 963 TBq (26,000 Ci) of cobalt-60 is 32 W/m^2 . For heat fluxes exceeding 15 W/m^2 supplementary arrangements must be made with the carrier to ensure adequate heat dissipation.

EXPIRY DATE

This certificate expires 31 October, 1991.

Q.B. Manager Radioisotopes and Transportation

Division

REFERENCE

International Atomic Energy Agency parety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended).

NOTES

1 .	AECL Drawing	Nos. DS-0284, (Rev. H and J) accached.
2.	Revision 0:	February 3, 1976. Original certificate.
3.	Revision 1:	April 24, 1979. Certificate renewed.
No.	Revision 2:	May 27, 1980. Packaging Description and Shipment
		sections revised. Cartificate renewed.
5.	Revision 3:	March 2, 1981. Packaging Description revised.
6.4	REVISION 41	October 30, 1981. Certificate renewed.
6.8	Revision 5:	September 23, 1982. Certificate repead
8,	Revision 6:	November 21, 1983. Certificate reneved.
9.	Revision 7:	Occober 10, 1986. Certificate renewed.

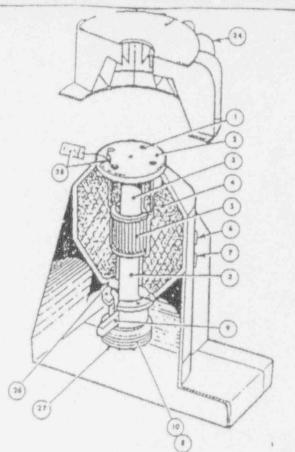
Page 32 of 33

PARTS LIST

- 1, 3/4 In, -10 x 2-1/2 In. LO SOCKET HEAD SCREWS (4)
- 2. SHIPPING COVER STEEL PLATE 1.75 In. (4.4 cm.) THICK
- . LOWER DRAWER

14

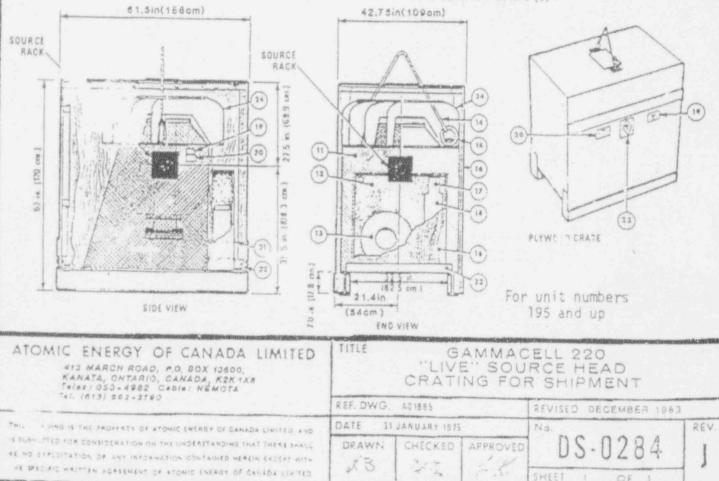
- . LEAD SHIELDING
- STAINLESS STEEL SOURCE RACK 8.8 In. DIA (22.3 cm.) x 8.3 In. (21 cm.) WITH STAINLESS STEEL WELDED CAPSULES CONTAINING COBALT 60
- RADIATION CAUTION PLATE WITH SPECIFIED CONTENT (1) AECL CP SPEC DG0005
- 1. AECL IDENTIFICATION PLATE(1)-AECL-CP SPEC DG0087
- *. DRAWER BOTTOM BRACKET
- *. ELEVATING BAR
- 10. SHIPPING BRACKET ASSEMBLY
- II. KADWOOL 0.5 in. (1.27 cm.) THICK. POLYETHELENE (4 MIL) WIRE MESH 1 in. (2.54 cm.) STANDARD STEEL PACKING STRAPS 0.5 in. (1.27 cm.) WIDE. AECL CP SPEC PO121
- 12. PACKING MATERIAL
- 13 SHIELD COLLAR (END USE ONLY)
- ... HOIST SLING
- 15. SHOULDER EYELET (2)
- 14. 0.6 In. (1.27 cm.) THICK PLYWOOD CRATE
- 17. SHIELDING PLUG (END USE ONLY)
- IN. UPPER DRAWER (END USE ONLY)
- 18. RADIATION CAUTION PLATE (2) AECL CP SPEC DG0098
- 20, AECL IDENTIFICATION PLATE(2) AECL-CP SPEC DG0007
- 21. 1/2 in. -13 x 9 in. LO SQ HO BOLTS (3)
- 22. SHIPPING BRACKET (2) WITH 5/6 lit. 11 x 1-1/4 ln. LQ HEX HO SCREWS (8)
- 23. RADIOACTIVE I or II or III LABEL (2)
- 24 CRUSH SHIELD ASSEMBLY
- 25. WIRE SEAL & TAG 'DO NOT OPEN'
- 24. 3/4-10 * 2.0 in. 10. SOCKET HD. SCREWS (4)
- 27. 3/4-10X3 IN LS SOCKET HD SCREWS(4))



NOTES

I.A.E.A. — TYPE B(u)GROSS WEIGHT 9700 Ib. (4400 kg.) PROJECTED FLOOR LOADING 531 Ib/sq fl. (0.26 kg/sq cm) CAPACITY — 28,000 Cl 60 Co

AECB CERT CDN/2013/B (U) T



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ATTACHMENT 4



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406

MAR 2 2 1991

License No. 20-28072-02 Docket No. 030-30125 Control No. 114039

Biosurface Technology, Incorporated ATTN: J. D. Bernardy Director, Regulatory Affairs University Park 64 Sidney Street One Kendall Square Cambridge, Massachusetts 02139

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

`lease review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.



04080112

Page 1 of 5

Biosurface Technology, Incorporated

We wish you success in operating a safe and effective licensed program.

2

Sincerely,

Francis M. Costelle

Francis M. Costello Nuclear Materials Safety Section C Division of Radiation Safety and Safeguards

Enclosures:

- 1. Amendment No. 02
- 2. Requirements for Materials Licensees

NRC FO (10-89)	DR. M.	ULATORY COMMISSION	
		LS LICENSE	Amendment No. 02
Code o made b nuclear to perso specify.	ant to the Atomic Energy Act of 1954, as amended, the use of Federal Regulations, Chapter I. Parts 30, 31, 32, 33, 34, 35, 3 by the licensee, a license is hereby issued authorizing the license r material designated below; to use such material for the purpose ons buthorized to receive it in accordance with the regulations of t of a Section 183 of the Atomic Energy Act of 1954, as amended, tory Commission now or hereafter in effect and to any condition	rergy Reorganization Act 39, 40 and 70, and in reliance e to receive, acquire, posses (s) and at the place(s) design the applicable Part(s). This li- and is subject to all applicat	e on statements and representations heretofor- is, and transfer byproduct, source, and specia ated below; to deliver or transfer such materia cense shall be deemed to contain the condition
Ur	Licensee iosurface Technology, Inc. niversity Park	December 13, 3. License number	with letters dated 1990 and February 22, 1991, 20-28072-02 is amended in to read as follows:
Ör	4 Sidney Street ne Kendall Square	4. Expiration date	September 30, 1992
C3	ambridge, Massahusetts 02139	5. Docket or Reference No	030-30125
	roduct, source, and/or 7. Chemical and nal nuclear material form	d/or physical	 Maximum amount that licensee may possess at any one time under this license
	C-185, or	66, C-167, C-198)	
Α.	Authorized use For use in an AECL Model Gammacell 220,		radiator for irradiating
Α.	For use in an AECL Model Gammacell 220, samples.	self-shielded irm	radiator for irradiating
A. 10.	For use in an AECE Model Gammacell 220,	self-shielded in TIONS Building 200, One	e Kendall Square.
A. 10.	For use in an AECE Model Gammacell 220, samples. CONDI Licensed material shall be used only at Cambridge, Massachusetts or at Universit Square, Cambridge, Massachusetts.	self-shielded irn TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July	e Kendall Square, 7 Street, One Kendall or individuals who have 14, 1987. The licensee
A. 10.	For use in an AECE Model Gammacell 220, samples. CONDI Licensed material shall be used only at Cambridge, Massachusetts or at Universit Square, Cambridge, Massachusetts. A. Licensed material shall be used by been trained as specified in applic	self-shielded in TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July ividual trained as	e Kendall Square, 7 Street, One Kendall or individuals who have 14, 1987. The licensee
A. 10. 11.	For use in an AECE Model Gammacell 220, samples. CONDI Licensed material shall be used only at Cambridge, Massachusetts or at Universit Square, Cambridge, Massachusetts. A. Licensed material shall be used by been trained as specified in applic shall maintain records of each ind	self-shielded irn TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July ividual trained as aniyi Kehinde.	e Kendall Square, 7 Street, One Kendall or individuals who have 14, 1987. The licensee a user.
A. 10. 11.	 For use in an AECE Model Gammacell 220, samples. CONDI Licensed material shall be used only at Cambridge, Massachusetts or at University Square, Cambridge, Massachusetts. A. Licensed material shall be used by been trained as specified in applic shall maintain records of each ind B. The Radiation Safety Officer is Old Sealed sources or detector cells contain sources removed from source holders or of the sources removed from sources re	self-shielded in TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July ividual trained as aniyi Kehinde. hing licensed mate detector cells by shall be tested for exceed 6 months or a of registration	e Kendall Square, 7 Street, One Kendall or individuals who have 14, 1987. The licensee a user. rial shall not be opened or the licensee. r leakage and/or at such other intervals
A. 10. 11. 12.	 For use in an AECE Model Gammacell 220, samples. CONDIT Licensed material shall be used only at Cambridge, Massachusetts or at Universitisquare, Cambridge, Massachusetts. A. Licensed material shall be used by been trained as specified in applic shall maintain records of each ind B. The Radiation Safety Officer is Old Sealed sources or detector cells contain sources removed from source holders or of A. Sealed sources and detector cells so to each as are specified by the certificate 	self-shielded in TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July ividual trained as aniyi Kehinde. hing licensed mate detector cells by shall be tested for exceed 6 months or e of registration 's.	e Kendall Square, / Street, One Kendall or individuals who have 14, 1987. The licensee a user. rial shall not be opened or the licensee. r leakage and/or at such other intervals referred to in d sources designed to emit
A. 10. 11. 12.	 For use in an AECE Model Gammacell 220, samples. CONDIC Licensed material shall be used only at Cambridge, Massachusetts or at University Square, Cambridge, Massachusetts. A. Licensed material shall be used by been trained as specified in applic shall maintain records of each ind B. The Radiation Safety Officer is Old Sealed sources or detector cells contain sources removed from source holders or of a safe specified by the certificate 10 CFR 32.210, not to exceed 3 year B. Notwithstanding Paragraph A of this alpha particles shall be tested for not to exceed 3 months. 	self-shielded in TIONS Building 200, One ty Park, 64 Sidney Olaniyi Kehinde o cation dated July ividual trained as aniyi Kehinde. hing licensed mate detector cells by shall be tested for exceed 6 months or e of registration 's.	e Kendall Square, / Street, One Kendall or individuals who have 14, 1987. The licensee a user. rial shall not be opened or the licensee. r leakage and/or at such other intervals referred to in d sources designed to emit

NRC F			U.S. NUCLEAR REGULATORY COMMISSION	PAGE 2 OF 3 PAG
(5-84)				License number
			MATERIALS LICENSE	20-28072-02
			SUPPLEMENTARY SHEET	Docket or Reference number
			SOFT CENERITARY SHEET	030-30125
				Amendment No. 02
(13.	con	tinued) CONDITIONS	
	С.	been	he absence of a certificate from a tra made within six months prior to the t received from another person shall no	transfer, a sealed source or detector
	D.	cons	sealed source fabricated by the licen truction defects, leakage, and contami sealed source.	usee shall be inspected and tested for ination prior to any use or transfer
	Ε.	Sea1	ed sources and detector cells need-not	be leak tested if:
		(i)	they contain only, hydrogen 3; or	A
		(ii)	they contain only a gas; or	0
	((111)	the half-life of the isotope is 30 da	ivs or less; or
		(iv)	they contain not more than 100 microc material or not more than 10 microcur	uries of beta and/or gamma emitting ies of alpha emitting material; or
		(v)	they are not designed to emit alpha p being used. However, when they are r transfer to another person, and have leak test interval, they shall be tes sealed source or detector cell shall 10 years without being tested for Tea	emoved from storage for use or not been tested within the required ted before use or transfer. No be stored for a period of more than
	F.	radi kept Comm remo Regu deco regu regu chiel Penns	test shall t. capable of detecting the oactive material on the test sample. in units of microcuries and shall be ission. If the test reveals the preservable contamination, a report shall be latory Commission and the source shall ntaminated, repaired, or disposed of in lations. The report shall be filed with the known with the U.S. Nuclear Regu f, Nuclear Materials Safety Branch, 479 sylvania 19406. The report shall spec- lts, and corrective action taken.	Records of leak test results shall b maintained for inspection by the nce of 0.005 microcurie or more of filed with the U.S. Nuclear be removed from service and n accordance with Commission thin 5 days of the date the leak tes latory Commission, Region I, ATTN: 5 Allendale Road, King of Prussia.
	G.	Johns	licensee is authorized to collect leak son. Alternatively, tests for leakage ormed by persons specifically licensed e to perform such services.	and/or contamination may be
	remo	val of	see shall not perform repairs or alter f shielding or access to the licensed m of sealed sources in the irradiator sha	naterial. Removal, replacement, and

Page 4 of 5

NRC Fo	rm 374A	U.S. NUCLEAR REGULATORY COMMISSI	
(5-84)			License number
		MATERIALS LICENSE	20-28072-02
		SUPPLEMENTARY SHEET	Docket or Reference number
			030-30125
			Amendment No. 02
(Cont	inued)	CONDITIONS	
	conduct f procedure The Nucle represent	rictive than the regulations.	atements, representations, and ng any enclosures, listed below. Ins shall govern unless the statements, e's application and correspondence are
- 1	A. Appl B. Lett C. Lett	ication dated July 14, 1987 er dated August 19, 1987, R RE er dated February 22, 1991	GULAN
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		Page 5 of 5 Kind	g of Prussia, Pennsylvania 19406

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