FEB 20 1985 License No. 20-02215-01 Docket No. 030-01845 Control No. 03195 Boston University Medical Center ATTN: Victor Evdokimoff, M.S., C.H.P. Radiation Protection Officer 720 Harrison Avenue Boston, Massachusetts 02118 Gentlemen: Please find enclosed an amendment to your MRC Material License. Please 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) 337-5239, so that we can provide appropriate corrections and enswers. Please be advised that you must conduct your program involving licensed radio - tive materials in accordance with the conditions of your MRC license. representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees. The enclosed amendment responds to the first three paragraphs of your letter dated December 3, 1984. With respect to the fourth paragraph of that letter requesting authorization to receive radioactive waste from other persons for disposal by incineration, additional information is needed before we can act. The request will then be referred to headquarters for action. We need more detailed information on the relationship between Boston University Medical Center and the institutions sending the waste, and the financial transactions involved. The importance of this information becomes apparent when one recognizes that a license authorizing commercial incineration of waste involves a fee of \$803.700 (Category 4A, 10 CFR Part 170), official notification of municipal authorities (10 CFR Part 2), and the preparation of an environmental impact statement. Whether any of this will be necessary will be determined by NRC headquarters, based on your response to these questions. Please send your reply in duplicate to my attention, and reference Mail Control Number 03195. Since serious consequences to employees and the public can result from failure to comply with MRC requirements, the MRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees. OFFICIAL RECORD COPY 20-02215-01/LTR - 0001.0.0 02/09/85 PDR

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I Boston University Medical Center

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- Any byproduct material
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 11 of Schedule A. Section
 36.100 of 10 CFR 35
- 8. Any byproduct material listed in Group III of Schedule A. Section 35.100 of 10 CFR 35
- C. Any byproduct material listed in Group 1k of Schedule A. Section 36.100 of 10 CFR 35
- 6. Any expression natural listed to Group W of Schedule A. Section 35.100 of 10 CFR 25
- E. Any byproduct material listed in Group V of Schodule A. Section 35,100 of 10 (fA 35
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A. Any adropharmaceutical listed in Grouns 1 and II of Schedule A. Section 35,100 of 10 CFR 35

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- E. Any form listed in Group 1 111 of Schedule A. Section 35.100 of 10 CFR 35
- C. Any radiopharmaceutical listed in Group 1% of Schedule A. Section 35.100 of 10 CF# 35
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- C. As recessary for uses authorized in Society 9-4
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- [2000 millioweles total for sources authorized in Substantial
- F. 400 billiournes

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- 6. Any byproduct material between Atomic Nos. 3 and 83 inclusive, except es
- below. H. Calcium 45 1. Carbon 14
- J. Chromium 51
- K. Phosphorus 32 L: logine 125
- M. lodine [3] N. Strontium 89
 - O. Hydrogen 3 P. Americium 141
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- b. Not to exceed 500 Model (#C.F2 or #EC. C-324) willicuries per source
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9. Author Jen use

- Any disphostic procedure listed in Grups I and 11 of Schedule A. Section 35 MODE Title 10, Code of Federal Regulations.
- Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A. Section 35, 100 of Title ID. Code of Reduced Regulations.
- Any therapeutic procedure listed in Group IV of Schedule A. Section 15.100 of Title 10. Code of Federal Regulations.
- Any therapeutic procedure listed in Group V of Schedule A. Section 35 100 of little 10, Lode of Federal Recolations.
- Any procedure listed in Group VI of Schedule A. Smitton H. 100 of Title 10, Such Cf. Federal Resulations.
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- through 1. Redical diagrosis, therepy. Research and development as defined to 1. Lea-30.4(g); including medical research with humans, unine; studies
- * For use as this died in a linear accelerator.
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EX A SERVICIO DE LA SERVICIO DEL SERVICIO DE LA SERVICIO DEL A TENENT TO THE MATERIALS LICENSE Dickery Reference non SUPPLEMENTARY SHEET 030-01.45 Amendment No. 39 continued) CONUTTIONS Licersed material shall be used only at 720, 750, and 790 Harrison Avenue, Boston, Massachusetts; 75, 80, 85, and 100 East Newton Street, Boston, Massachusetts; 80 and 82 East Concord Street, Boston, Massachusetts; and 615 Albany Street, Boston, # Massachusetts. The licensee shall comply with the provisions of Title 10. Chapter 1. Lode of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers, Inspections" and Part 20, "Standards for Protection Against Radiation." A. Licensed material shall be used by, or under the supervision of, individuals \$ designated by the Radioisotopes Committee, B. A. Burrows, M.D., Chairman, The use of licensed material in or on humans shall the by a physician as defined in 10 CFR 35.3(69. Physicians designated to use licensed material in or we humans shall meet the ! training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980. The Radiation Protection Officer for the activities authorized by this license is Victor N. Evbokimoff, M.S. .. Chi. licensed naterial in Items 6.A. through BlE. shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and [f] of Title 10. Code of Federal Regulations. Patients containing Indine 131 for the treatment of thyrotid cardinona or patients a co tairing therapeuths quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or less. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-im-storage before disposal in ordinary tress provided: A. Fadloactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives. Frior to disposal as normal wastr, radioactive waste shall be monstored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated. Generator columns shall be secregated so that they have be minitored separately to ensure decay to background levels peror to disposal.

MATERIALS LICENSE

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030-01845

Amendment No. 39

Continued

CONDITIONS

- (6) A. (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than das shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
 - (2) Notwithstanding the periodic leak lest required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta arc/or gamma emitting material or 10 microcuries or less of alpha emitting material.
 - (3) Except for Sipha sources, the periodic leak test required by this condition a does not maply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or fransfer.
 - B. Each sealed source fabricated by the licensee shall be assected and tested for a construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection of best reveals any construction defects or 0.005 microcurie of greater of contamination, the source shall not be used or transferred as a sealed source and it has been repaired, decontaminated and retested.
 - C. Each sealed source containing licensed material, other than Hydroger 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals must to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.
 - D. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee stall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the first with the U.S. huclear Regulatory Commission, Region 1, 631 Park Avenue, King of Prunsia, Fennsylvania 19405, describing the equipment involved, the test results, and the corrective action taken.
- 17. Pursuant to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix 8. Table 11, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix 8, Table 11, 10 CFR 20.

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MATERIALS LICENSE

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COMPLITIONS

- 18. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of little 10. Code of federal Regulations. Part 11. "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
- 19. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
 - B. Detector cells containing scandium tritide fofl shall only be used in conjunction with a properly operating temperature control mechanism which prevents full temperatures from exceeding 325 degrees Centigrade.
- 20. In lieu of using the tonventional radiation caution colors (magenta or purple or yellow background) as provided in Section 20.203(a)(i). If the 10, Code of Federal Fegulations, Fart 20, the likeosee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
- 21. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and mossessed aumber the license. The records of the inventories shall be mulatained for two KPI wears from the date of the inventory for inspection by the Commission, and shall because the quantities and kinds of licensed material, location eV sealed mources and the date of the inventory.
- 22. The licensee shall met use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
- 23. Experim (Le) animals administered licensed materials by their products shall not be used for human consumption.
- 24. Licensed naterial shall not be used in products distributed to the public.
- 25. Written instructions in application dated December 10, 1973, as amended April 11, 1974, and application undated received April 5, 1979, shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of the "Gammacell 40". Any changes in these instructions shall have the prior approval of the U.S. Auclear Regulatory Commission. Region 1, Auclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406.
- 26. The procedures contained in AEGL's instruction manual for the "Gammacell AG" device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed meterial.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Amendment No. 39

(continued)

CONDITIONS

27. Except as specifically provided otherwise by this license, the licenses shall possess a and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated November 25, 1980; latters dated June 22, 1982, April 15, 1983 including ALARA Program May 4, 1984, and December 3, 1984. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.



For the U.S. Nuclear Regulatory Commission

Original Signed by Learence F. Frisings, Ph.D.

FFB 2 0 1985

Date

Auclear Materials Safety and Safequards Branch, Region 1 King of Prussia, Pennsylvania 1940s

MATERIALS LICENSE

Amendment No. 37

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93 – 438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s); and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with application dated November 25, 1980,					
Boston University Medical Center			3. License number 20-02215-01 is amended in its entirety to read as follows:				
2. 720 Harrison Avenue			4. Expiration date		April 30, 1988		
Boston, Massachusetts 0211	8		5. Docket or Reference No.		030-01845		
Byproduct, source, and/or special nuclear material		7. Chemical and form	or physical		 Maximum amount that licensee may possess at any one time under this license 		
Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	Α.	listed in (narmaceutical Groups I and dule A, Section	A.	As necessary for uses authorized in Subitem 9.A.		
Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	В.	Any form 14	Isted in Group edule A, Section	Б.	3 curies of each byproduct material authorized in Subitem 6.8		
Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	С.	Any radioph listed in (Schedule A, 35.100 of 1	, Section	C.	As necessary for uses authorized in Subitem 9.0		
Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D.		narmaceutical Group V of Section	D.	As necessary for uses authorized in Subitem 9.0.		
Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E.	Any sealed	source listed of Schedule	E.	2020 millicuries total for sources authorized in Subitem 6.E.		

THE PERSON OF TH NFIC Form 374A JCLEAR REGULATORY COMMISSION OF 6 2 PAGE PAGES License number 20-02215-01 MATERIALS LICENSE Docket or Reference number SUPPLEMENTARY SHEET 030-01845 CORRECTED COPY Amendment No. 37 (continued) 8. Maximum amount that 6. Byproduct, source, and/or 7. Chemical and/or physical licensee may possess special nuclear material form at any one time under this license F. Xenon 133 F. Gas or gas in solution F. 300 millicuries that is the subject of an active (1.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (f.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Examption for a New Drug" (IND) that has been accepted by FDA 6. 50 millicuries of each G. Any byproduct material G. Any between Atomic Nos. 3 and 83 inclusive, except as below H. Calcium 45 H. 200 millicuries H. Any I. Carbon 14 I. Any I. 300 millicuries J. Chromium-51 J. Any J. 300 millicuries K. Phosphorus 32 K. Any K. 150 millicuries L. Todine 125 L. 300 millicuries L. Anv M. Indine 131 M. 100 millicuries M. Any N. Strontium 89 N. Any N. 100 millicuries 0. 6 curies O. Any 0. Hydrogen 3 P. Sealed source P. 4 millicuries P. Americium 241 Q. Hydrogen 3 0. Sealed source 0. 25 curies R. Nickel 63 R. Sealed source R. 45 millicurtes S. Cesium 137 S. Sealed source S. 10 millicuries T. Uranium (depleted in T. Cadmium plated metal T. 136 kilograms Urantum 235) U. Indine 125 U. Sealed source (Amersham U. Not to exceed 500 milli-Model IMC.P2 or AECL curtes per source C-324) 9. Authorized use A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 Title 10, Code of Federal Regulations. B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title C. 10. Code of Federal Regulations. D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

U. JCLEAR REGULATORY COMMISSION NRC Form 374A License number 20-02215-01

Docket or Reference number MATERIALS LICENSE SUPPLEMENTARY SHEET

030-01845

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Amendment No. 37

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Any procedure listed in Group VI of Schodule A, Section 35.100 of Title 10, Code of E. Federal Regulations.

Blood flow and pulmonary function studies.

6. through S. Medical diagnosis, therapy. Research and development as defined by 10 CFR 30.4(q); including medical research with humans; animal studies.

For use as shielding in a linear accelerator. T.

For use in Lixi Inc. Model LS-80X, LS 82X, LSM 80X or LSM 82X portable fluorescope for research and development as defined by 10 CFR 30.4(q); animal studies. Human use U. is excluded.

CONDITIONS

- Licensed material shall be used only at 720, 750, and 790 Harrison Avenue, Boston, Massachusetts; 75, 80, 85, and 100 East Newton Street, Boston, Massachusetts; 80 and 82 10. East Concord Street, Boston, Massachusetts; and 615 Albany Street, Boston, Massachusetts.
- 无明 () 通 (The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against 11. Radiation."
 - Licensed material in Items 6.A. through 6.E. shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations. 12.
 - Licensed material shall be used by, or under the supervision of, individuals designated by the Radioisotopes Committee, B. A. Burrows, M.D., Chairman. 13.
 - The use of licensed material in or on humans shall be by a physician as defined B. in 10 CFR 35.3(b).
 - Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide C. 10.8 (Revision 1), dated October 1980.
 - The Radiation Protection Officer for the activities authorized by this license D. is Victor N. Evdokimoff, M.S., CHP.
 - (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days A. 14. and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer a sealed source received from another person shall not be put into use until tested.

(2)	Notwithstanding the periodic leak test licensed sealed source is exempt from contains 100 microcuries or less of be 10 microcuries or less of alpha emitti	such leak t	cests w gamma e	nen ti	he so	urce	
(14.A. continu	ed) CONDITIONS						
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(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

- Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.
- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U.S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.
- 15. Sealed sources containing licensed material shall not be opened.

16. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until surveys made with an appropriate radiation detection instrincted that all implants have been removed. The results of these surveys recorded and maintained for inspection by the Commission for five (5) year time the implants are removed.

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ij	(continued) CONDITIONS			

- Patients containing Iodine 131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold 198 shall remain hospitalized until the residual activity is 30 millicuries or lass.
- The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
 - Prior to disposal as normal waste, radioactive waste shall be monitored to B. determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.
 - Generator columns shall be segregated so that they may be monitored separately C. to ensure decay to background levels prior to disposal.
- 18. Pursuint to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispuse of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.
 - The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
- 21. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
 - Detector cells containing scandium tritled foil shall only be used in conjunction B. with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

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CONDITIONS

- 23. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources and the date of the inventory.
- 24. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
- Experimental animals administered licensed materials or their products shall not be used for human consumption.
- 26. Licensed material shall not be used in products distributed to the public.
- 27. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated November 25, 1980, and letters dated June 22, 1982, and April 16, 1983, including ALARA Program. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Original Signed By John E. Glenn, Ph. D.

July 7, 1983

Date

Nuclear Materials and Safeguards Branch Region I King of Prussia, Pennsylvania 19406 Amendment No. 37