NRC Form 313 I (12-81) 10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

1. APPLICATION FOR: *(Check and/or complete as appropriate)*

	a. NEW LICENSE
	b. AMENDMENT TO: LICENSE NUMBER
X	c. RENEWAL OF: LICENSE NUMBER 20-17284-01

2. APPLICANT'S NAME *(Institution, firm, person, etc.)*
Clinical Science Lab., Inc.
TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(617) 339-6106

3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION
Stanley G. Elfbaum, Ph.D.
TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(617) 339-6106

4. APPLICANT'S MAILING ADDRESS *(Include Zip Code)*
(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)
51 Francis Ave.
Mansfield, MA 02048

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED *(Include Zip Code)*
51 Francis Ave.
Mansfield, MA 02048

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

	FULL NAME	TITLE
a.	Stanley G. Elfbaum, Ph.D.	Technical Co-Director
b.	Louis P. Amoruso, Ph.D.	Technical Co-Director
c.		

7. RADIATION PROTECTION OFFICER
Stanley G. Elfbaum, Ph.D.

Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.

8. LICENSED MATERIAL

LINE NO.	A ELEMENT AND MASS NUMBER	B CHEMICAL AND/OR PHYSICAL FORM	C NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)*	D MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME
(1)	Iodine 125	Iodinated proteins and biochemical substances		30
(2)	Hydrogen 3	Tritiated proteins and biochemical substances		1.0
(3)	Iodine 129	sealed source	New England Nuclear (NES-1355)	0.000107
(4)	Iron 59	proteins and other biochemical sources		2

DESCRIBE USE OF LICENSED MATERIAL

E

(5) on additional sheet

(1) Nonvolatile radioactive materials will be purchased mostly in "kit" form to be used in routine clinical laboratory radioassays. Materials will be used for in vitro analysis of physiological specimens only. It will not be used on humans or animals. Iodinations of biochemical substances using Na 125 I will not be performed.

(2)

(3)

(4) 281

8804140281 870909
REG1 LIC30
20-17284-01 DCD

MAR 1987 107028

NRC FORM 313 I

9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	When not in use the sealed sources will be stored in individual		
(2)	lead containers.		
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	Well scintillation spectrometer	NML	#5000	1	Gamma	- - - - - -
(2)	Survey meter (low energy gamma scintillator)	Ludlum	#3 #44-3	1	Gamma	10 Kev- 40 Kev
(3)	Multi crystal gamma counter	Berthold	LB2103 #1376	1	Gamma	16 Kev- 84 Kev
(4)	Multi crystal gamma counter	Berthold	LB2104 #1846	1	Gamma	16 Kev- 84 Kev

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☒ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

Ludlum Survey Meter (#95-34) calibrated every 12 months by Radiation Protection Dept., M.I.T., Vassar St., Cambridge, MA

☒ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

see attached

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
☒ (1) FILM BADGE	ICN Dosimetry Service	☒ MONTHLY
☐ (2) THERMOLUMINESCENCE DOSIMETER (TLD)		☐ QUARTERLY
☒ (3) OTHER (Specify): A. End of day survey meter check on personnel		☐ OTHER (Specify): A. Daily
B. Thyroid check on personnel with survey meter		B. Monthly

13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.

☒ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.

☒ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.

☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

Log April 1
Remitter
Check No. 3174
Amount $120
Fee Category 3P
Type of Fee Renewal
Date Check Rec'd 4/4/87
Date Completed 4/4/87
By: J. Kimberly

18. CERTIFICATE

(This item must be completed by applicant)

107028

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING.—18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)* $120.00	b. CERTIFYING OFFICIAL *(Signature)* Stanley G. Elfbaum, Ph.D
	c. NAME *(Type or print)* STANLEY G. ELFBAUM
(1) LICENSE FEE CATEGORY: BY PRODUCT MATERIAL 3L	d. TITLE TECH. CO-DIRECTOR
(2) LICENSE FEE ENCLOSED: $ 120.00	e. DATE 3/19/87

NRC FORM 313 I (12-81)

GPO 886-424

8. Licensed Material

(5)	AM 241	sealed source	The Nucleus, Inc.	0.000037

11 B.

The survey meter is checked with a standard source on a monthly basis internally and the results are recorded. A battery check and a background determination are performed daily and the results are recorded.

All well scintillation instruments are calibrated with either an Iodine 129 or Americium 241 sealed source on a daily basis. The count rates, settings (if applicable), and percent efficiencies are recorded.

FACILITIES AND EQUIPMENT

Part 13

A. Sketch of laboratory facilities enclosed.

B. Storage Provisions:

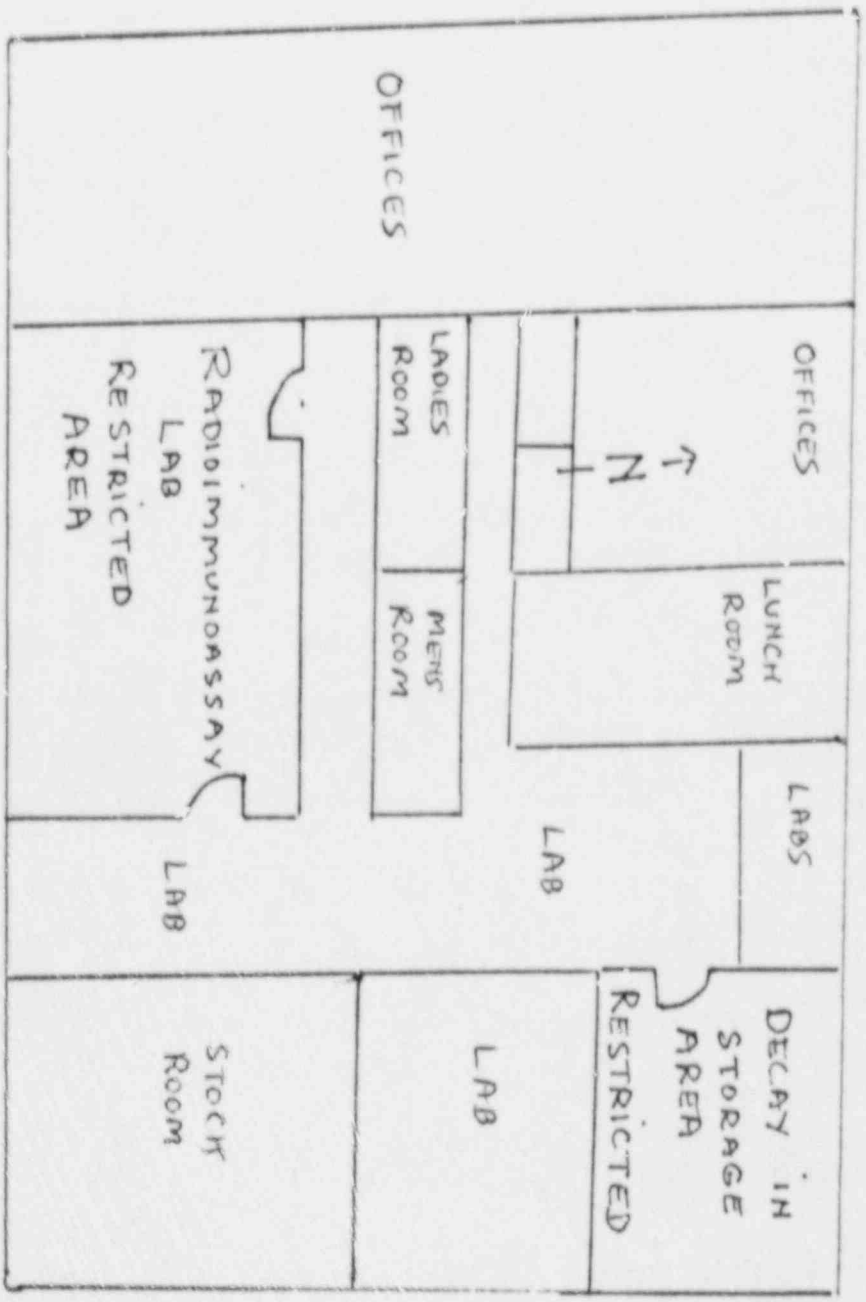
Material will be stored either in a freezer or a refrigerator in a restricted laboratory. This laboratory will be locked outside of regular working hours. During regular working hours this laboratory will be unlocked but restricted to all authorized personnel. (See enclosed diagram)

Shielding:

When by-product material is moved from the above storage areas to the working laboratory areas, it will be placed in the laboratory in fiberglass working trays behind appropriate lead shielding.

C. Handling Equipment:

Apparatus such as lead shielding, automatic pipets with disposable tips, disposable plastic gloves, and non-porous bench top trays containing plastic lined absorbent pads are to be used.



CLINICAL SCIENCE LABORATORY, INC.
91 FRANCIS AVENUE • MANSFIELD, MA 02048
(617) 339-6106

14 B. Waste Disposal

Proposal to dispose of radioactive waste by Decay-In Storage

1. The proposed storage areas is a 21 ft. x 16 ft. room located in the NE corner of the building. This room will be locked when not in use. The building is locked outside of the usual working hours.

2. Within the proposed storage area, metal barrels will be used to store plastic bags containing the solid waste. Liquid waste will be stored in capped glass or plastic jars and these will also be stored in metal barrels. At the present time, it is anticipated that approximately 2-4, 25 gal. barrels of such waste are generated per month (or approximately 800 uCi). There is sufficient space in the proposed storage area to hold more than 100 such barrels. Thus, it is proposed that each filled barrel be stored for a minimum of 18 months or 9 half lives (I 125).

3. Radiation levels in this area will be surveyed weekly with a survey meter and the results recorded. The survey meter has been equipped with a low gamma energy probe suitable for I 125.

4. In order to assure that the levels of radioactivity of the waste has decayed to background levels prior to disposal, it is proposed to do the following:

   a. All waste will be monitored in a low background area.

   b. A low level GM type survey meter suitable for the isotopes in use will be used. All shielding will be removed prior to monitoring.

   c. Records of these surveys will be kept as required under CFR 20.

15. RADIATION PROTECTION PROGRAM

A. The entire program is to be supervised by the Radiation Protection Officer.

B. Film badges or bracelets, monitored on a monthly basis, will be worn at all times by appropriate personnel.

C. Appropriate radiation warning signs will be posted according to Title 10 CFR part 20.

D. Instructions will be given to personnel according to Title 10 CFR part 20.

E. Form AEC-3 (2-72) 10 CFR 20 "Notice to Employees" will be conspicuously posted in the laboratory.

F. All applicable personnel plus each appropriate working area will be monitored at the end of each working day by the use of a Geiger counter.

G. Approximately every month or sooner, swab testing of the appropriate areas will be undertaken.

H. Approximately every month or sooner, detailed surveys of the laboratory areas will be undertaken by the use of a Geiger counter.

I. Records will be kept on personnel, surveys, receipt of by-product materials, disposal of by-product materials, etc. according to Title 10 CFR part 20.

J. Licensed by-product materials will be housed in specially designated freezers or in specially designated refrigerators.

K. Basic rules and regulations will be posted and will be as follows.

1. Only necessary materials will be taken in the laboratories.

2. Monitoring devices will be worn by personnel at all times.

3. Persons with open wounds will not be permitted in the laboratory.

4. Eating, drinking, smoking, and application of cosmetics will be prohibited.

5. Pipetting by mouth is prohibited.

6. Protective clothing and disposable gloves will be made available in the laboratory.

15. Radiation Protection Program (continued)

7. Monitoring of the work areas will be done at the close of each working day.

8. All cases of personnel contamination will be reported immediately.

9. Radioactive wastes will be disposed of in the proper manner.

10. Hands, feet, and clothing will be monitored for contamination before leaving the laboratory.

11. Radioactive wastes will not be removed from the laboratory without prior approval.

12. All accidents or injuries will be reported immediately.

13. All suggestions made by Code of Federal Regulations Title 10, part 20, Standards for Protection Against Radiation will be followed.

L. Waste Disposal

1. Gaseous Waste

Use of gaseous by-products and disposal of by-products by gaseous discharge will be avoided. When discharge of gaseous by-products is unavoidable (i.e. decontamination of glassware from trace amounts) it will be done in a manner and in levels acceptable as published in the AEC regulations.

2. Liquid Waste

Liquid waste will not be disposed of by flushing into the sewer system. Instead, it will be collected in bottles and allowed to decay to background.

3. Solid Waste

All solid waste will be stored in plastic bags in metal barrels. Radioactive iodine solid waste will be stored in metal barrels until the level of radioactivity decreases to that of background. If the quantity of in-house isotopes begins to approximate that of the license limits, radioactive iodine solid waste will be disposed of by Interex Corporation, Natick, MA. Interex Corporation is an authorized licensee of NRC. Tritium waste will be disposed of only by use of Interex Corp. steel drums.

15. Radiation Protection Program (continued)

M. Sealed sources will be checked for leakage by swab testing once a month.

N. Radioactive materials are ordered either verbally by telephone as needed or via a predetermined standing order. Materials thus ordered are delivered by U.P.S. or some other commercial carrier or received at the post office during our daily visits. Upon receipt at the laboratory, packages containing radioactive materials are delivered to a package receiving area. The outsides of the packages are monitored for radioactivity using a survey meter equipped with an appropriate probe. After monitoring the outsides of the packages and recording the results, the boxes are opened and the inner containers are checked for contamination. These results are recorded into our isotope log book. After determining that there is no contamination or leakage, the actual amount of microcuries are then added into our isotope inventory. These records are always available and updated on a daily basis.

O. When a spill occurs, the radiation protection officer or one of the laboratory co-directors, is notified immediately. Any spilled material will be wiped up quickly and thoroughly and the contaminated substances transferred to a suitable receptacle. Disposable gloves and disposable lab coats are available for this purpose. The surfaces involved will be washed thoroughly with an appropriate decontaminant. This will be followed up by survey meter monitoring and/or wipe test evaluation. All information pertaining to spillages will be recorded.

P. On the first day of employment, all personnel, including technologists, clerical, housekeeping, and maintenance personnel receive overall safety instructions. Part of this instruction is devoted to our radioimmunoassay/radioisotope program especially as it pertains to Section 19.12 of 10 CFR Part 19. In addition to the initial instructions, periodic refresher insturctions are provided on at least an annual basis.

Louis P. Amoruso, Ph.D., Asst. Tech. Director

Part	Where Trained	Duration	On the Job	Formal Course
16a	Dept. of Chemistry Boston College Chestnut Hill, MA (1970)	3 months	yes	no
16b,c,d	Boston Medical Lab. 19 Bay State Road Boston, MA (1971-1974) and 15 Lunda Street Waltham, MA (1974-1977)	3 years 3 years	yes	no

17. Experience with Radiation

Isotope	Max. Amount	Where Exper. Gained	Duration	Type of Use
^{125}I	6 millicuries	Boston Med.Lab.(BML)	4 years	in vitro
	12 millicuries	Clinical Science Lab.	10 years	in vitro
^{14}C	2 millicuries	BML	18 months	in vitro
^{3}H	1 millicurie	BML	3 years	in vitro

Stanley G. Elfbaum, Ph.D., Tech. Director

Part	Where Trained	Duration	On the Job	Formal Course
16a	Northwestern U.(NWU) (1965)	6 months	no	yes
	Gillette Co.Res.Inst.(GCRI) (1966-1971)	5 years	yes	no
16b	NWU	6 months	yes	yes
	GCRI	5 years	yes	no
16c	NWU	6 months	yes	yes
	GCRI	5 years	yes	no
16d	NWU	6 months	yes	yes
	GCRI	5 years	yes	no

17. Experience with Radiation

Isotope	Max. Amount	Where Exper.Gained	Duration	Type of Use
^{32}P	25 microcuries	NWU	6 months	in vitro
^{14}C	25 microcuries	GCRI & Boston Med.Lab. (BML)	9 years	in vitro
^{125}I	6 millicuries	BML	6 years	in vitro
	12 millicuries	Clinical Science Lab.	10 years	in vitro
^{131}I	1 millicurie	BML	2 years	in vitro
^{3}H	1 millicurie	BML	6 years	in vitro

03012496
02910
5/87

BETWEEN: C. James Holloway, Chief
License Fee Management Branch
Office of Resource Management

John E. Glenn, Chief
Nuclear Materials Safety & Safeguards Section B
Division of Radiation Safety and Safeguards

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Clinical Science Lab., Inc.

Application Dated: 3-19-87

Control No.: 107028

License No.: 20-17284-01

2. FEE ATTACHED

Amount: $120

Check No.: 3174

3. COMMENTS

Signed SLJ

Date 3-31-87

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3P $120

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal ✓

License _____

Signed S Kimberly

Date 4/6/87

REGION I FORM 213
(MARCH 1987)

New England Nuclear NES-1355

Iodine 129

.000107

The Nucleus Inc.

Am 241 .000037