

<b>NRC Form 313 I</b> (12-81) 10 CFR 30		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>	
<b>APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL</b>		<b>1. APPLICATION FOR:</b> <i>(Check and/or complete as appropriate)</i>	
<i>See attached instructions for details.</i>  <i>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.</i>		a. NEW LICENSE	
		b. AMENDMENT TO: LICENSE NUMBER	
		c. RENEWAL OF: LICENSE NUMBER X      21-18375-01	
<b>2. APPLICANT'S NAME</b> <i>(Institution, firm, person, etc.)</i>  GAMMA ANALYSIS & DISTRIBUTING CO.  TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (313) 336-6529		<b>3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION</b> DENISE GEORGIOU, PRESIDENT  TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION (313) 336-6529	
<b>4. APPLICANT'S MAILING ADDRESS</b> <i>(Include Zip Code)</i> <i>(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)</i>  1463 Birchcrest Drive Dearborn, MI 48124		<b>5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED</b> <i>(Include Zip Code)</i>  On premises of licensees authorized under 31.11(a) or equivalent authorization.	
(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)			
<b>6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL</b> <i>(See Items 16 and 17 for required training and experience of each individual named below)</i>			
FULL NAME		TITLE	
a. DENISE GEORGIOU		PRESIDENT	
b.			
c.			
<b>7. RADIATION PROTECTION OFFICER</b>  DONALD JEFFREY HOUSE		<i>Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.</i>	
<b>8. LICENSED MATERIAL</b>			
LINE NO.	ELEMENT AND MASS NUMBER  A	CHEMICAL AND/OR PHYSICAL FORM  B	NAME OF MANUFACTURER AND MODEL NUMBER <i>(If Sealed Source)</i>  C
			MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME  D
(1)	IODINE-125	LIQUID	N/A
(2)	IRON-59	LIQUID	N/A
(3)	COBALT-57	LIQUID	N/A
8510030269 850918 REG LIC 30 21-18375-01      PDR			
<b>9. DESCRIBE USE OF LICENSED MATERIAL</b> E			
(1) Prepackaged diagnostic test kits will be used to perform invitro diagnostic (2) tests on the premises of general or specific licensees in the state of (3) Michigan. (4)			

License Fee Information  
on Page 3

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## 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)	N/A		
(2)			
(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)	GAMMA COUNTER	NUCLEUS	600	1	GAMMA	0-10 <sup>6</sup> CPM
(2)	GAMMA COUNTER	GENERAL MEDICAL SYS.	1200	2	GAMMA	0-10 <sup>6</sup> CPM
(3)						
(4)						

## 11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

☒ b. CALIBRATED BY APPLICANT

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

## 12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
<input checked="" type="checkbox"/> (1) FILM BADGE <input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD) <input type="checkbox"/> (3) OTHER (Specify): _____	SIEMENS GAMMASONICS, INC.	<input checked="" type="checkbox"/> MONTHLY <input type="checkbox"/> QUARTERLY <input type="checkbox"/> OTHER (Specify): _____

## N/A 13. FACILITIES AND EQUIPMENT (Check where 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

Radioactive wastes will be disposed of according to the general or specific license of the premises where the tests are performed.

# 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.

RECEIVED BY LFMB	
Date	5/8/84 (Comp 5/9/84)
Log	Mar 9
By	P. D. H.
Orig. To	P. D. H.
Action Compl	Comp

## 18. CERTIFICATE

(This item must be completed by applicant)

Applicant	04749
Check No.	511034
Amount/Fee	511034
Type of Fee	Comp 5/8/84
Date Check Rec'd	5/8/84
Received By	GP

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)	b. CERTIFYING OFFICIAL (Signature)
\$110.00	Denise Georgiou
(1) LICENSE FEE CATEGORY: 3 L	c. NAME (Type or print) Denise Georgiou
(2) LICENSE FEE ENCLOSED: \$110.00	d. TITLE President
	e. DATE April 30, 1984

## Item #11 Calibration of Instruments

RADIONUCLIDE CALIBRATION

ALLOW MINIMUM TEN (10) MINUTES WARM-UP

1. Press POWER switch - power switch will light - LED display will light.
2. Set mode switch to PRESET TIME and PRESET TIME to one (1) minute.
3. Set RADIONUCLIDE switch to calibrate (Cs-137) and place Cs-137 test source in counting well.
4. On the back of the unit is the FINE GAIN control. Unlock and turn the fine gain control fully counter clockwise to where the dial indicates "00".
5. Press RESET switch and then press COUNT switch. After one minute, the instrument will have completed its count and the COUNT LIGHT will go dark.  
Copy the number that appears on the LED display for future plotting on linear graph paper as FINE GAIN ADJUST vs. COUNTS PER MINUTE.
6. Turn FINE GAIN ADJUST clockwise till vernier dial indicates "050".
7. Press RESET switch, then press COUNT switch. After one minute the instrument will have completed its count and the COUNT LIGHT will go dark. Copy down the number that appears on the LED display for future plotting on linear graph paper.  
Continue the above steps in FINE GAIN ADJUST increments of "050".

## Item #11 Calibration of Instruments (Cont.)

8. Plot FINE GAIN ADJUST vs. COUNTS PER MINUTE.
9. Using the graph, determine the FINE GAIN ADJUST settings where the maximum number of counts per minute occur. Log this setting for future reference.
10. Set the FINE GAIN ADJUST at the number and lock. It is preset at the factory at or near "500." This setting may change with time due to long term drifts in the photomultiplier tube and is no cause for alarm unless it approaches one end of the dial (e.g. less than 100 or more than 900.)

NOTE: The windows (differential energy range of the gammas counted) for all radionuclides are referenced to Cesium 137. When the Cesium window is calibrated as above, the windows are calibrated for all radionuclides. See the typical Cesium curve.

THIS COMPLETES THE RADIONUCLIDE CALIBRATION PROCEDURE.

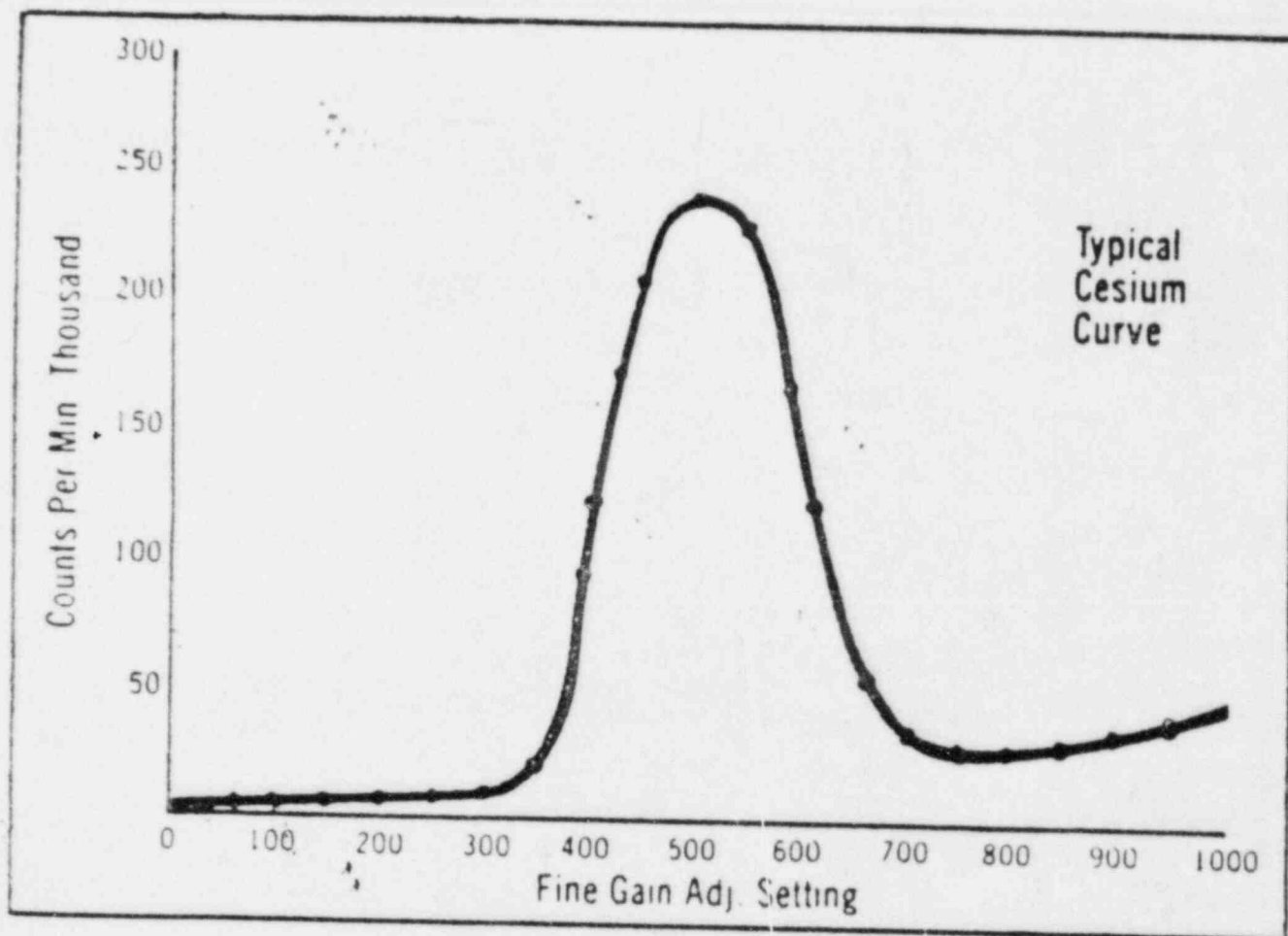
NOTE: These instructions are copied from the operation manual for the Nucleus 600. These or similar procedures will be followed for calibration of all gamma counters.

Gamma counters will be calibrated every six months. Serial numbers and fine gain settings will be recorded. Records will be kept at Gamma Analysis.

#### DAILY CALIBRATION

A cesium source will be counted daily before assay tubes are counted. The result will be recorded and kept with the gamma counter. Any day to day variation greater than 10% will be reported to Denise Georgiou.

Item #11 Calibration of Instruments (Cont.)



TYPICAL Cs-137 PEAK CURVE FROM FINE GAIN ADJUSTMENT.



## Item #15 Radiation Protection Program

Only radioactive material licensed under 10 CFR 31.11(a) will be purchased and tests will be performed only on the premises of general or specific licensees. While on the premises of these licensees, their radiation safety program will be followed.

The manipulation of isotopes will be done on an absorbent pad. A wipe test of the sink and counter area will be done before leaving. Any area that is 200 counts over background should be cleaned with soap and retested. Any area that is 1000 counts over background should be considered contaminated and should be cleaned thoroughly with soap; notify this office for further instructions. Any problems of decontamination or any unusual occurrence, eg., spilled reagents, unacceptable assay results, leaking kits, etc., will be recorded on daily worksheets and Denise Georgiou (313) 336-6529 or the R.P.O. Donald J. House (313) 561-8020 will be contacted immediately. Solid and liquid radioactive waste will be disposed of according to the license of the premises where the assays are performed.

Film badges will be worn at all times while using radioactive reagents. Monthly film badge reports will be maintained. An exposure of greater than 10% of that specified in 10 CFR 20.101 will be investigated and appropriate action taken.

The following records will be kept:

- 1) Inventory of radioactive isotopes
- 2) Copies of licenses of clients
- 3) Instrument calibration and wipe test data
- 4) Use of radioactive material, ie., the kind and number of tests performed and the location where the tests were performed

Item#15 Radiation Protection Program (cont'd)

## GAMMA ANALYSIS AND DISTRIBUTING COMPANY

## Technician's instructions

- 1) Perform all reagent manipulations on absorbent pads.
- 2) Lab coats and film badges are to be worn at all times while using radioactive reagents.
- 3) At each site, a background and standard (Cs-137) count for ½ minute is to be recorded in the calibration log book. If counts differ by more than 10% of the previous count, notify Denise Georgiou (313) 336-6529 or Donald J. House (313) 561-8020.
- 4) All radioactive waste should be disposed at the job site according to that facility's radiation safety program.
- 5) When finished for the day, perform a wipe test of the sink and work area and record the results. Any area that is 200 counts over background should be cleaned and retested. Any area that is 1000 counts over background should be considered contaminated and should be thoroughly cleaned; notify this office for further instructions.
- 6) If there is any unusual occurrence, eg., spilled reagents, unacceptable assay results, leaking kits, etc., please note them on the worksheet and notify Denise Georgiou or the R.P.O., Donald J. House.



Curriculum Vitae

DENISE GEORGIU

Birthdate: Detroit, Michigan, May 8, 1956 U.S. Citizen

Marital Status: Single

Education: Edsel Ford High School - Dearborn, Michigan  
University of Michigan, Ann Arbor 1974-1978 B.S. Biology/Chemistry

Experience: 6/80 - Present: Immuno Assay Corporation - Dearborn Hts., MI  
Assistant Technical Director

6/80 - Present: Gamma Analysis and Distributing Co. Dearborn Hts., MI

Areas of Specialization: RIA Manufacture and quality control; research and development clinical diagnostics.

Professional Associations: 1) American Association of Clinical Chemistry  
2) Midwest Radioassay Society  
3) Clinical Ligand Assay Society  
4) College of American Pathologists Survey Programs  
5) American Association For The Advancement of Science

Item #16 & 17 Training and Experience of Denise Georgiou

1974-1978: In the course of pursuing the Bachelor of Science Degree from the University of Michigan, the applicant was familiarized with basic radiation physics as well as radiation safety. Basic skills with G.M. survey meters, and gamma counters were developed:

1980 to Present: As assistant technical director of Immuno Assay Corporation, the applicant underwent extensive in house training in radiation health physics, radiation safety and measuring equipment use and calibration. Isotopes used are Iodine-125, Iron-59, Cobalt-57, and Cesium-137. In addition, the applicant is responsible for radiation survey procedures including Bioassays. Applicant is responsible for the manufacture of commercial RIA kits utilizing radioactive materials.

1980 to Present: As a field supervisor for Gamma Analysis and Dist. Co., the applicant is responsible for the supervision of a radioassay technical service.

Duties include: 1) establishing quality control procedures  
2) training of personnel in radiation safety  
3) establishment of proper waste disposal procedures  
4) inspection of satellite facilities and personnel especially regarding isotope use, disposal and records

#16 & 17: Training and Experience of Donald J. House

- 1971-1975 As a laboratory assistant at the University of Michigan Flint College, the applicant functioned as the student radiation safety officer and was responsible for the distribution and storage of radioactive materials, H-3, and C-14 in particular. Standard monitoring and decontamination procedures were performed by the applicant. Equipment utilized included G.M. survey meters, Beta and Gamma scintillation counters. The applicant was also responsible for designing laboratory experiments involving the use of radioisotopes for in vivo and in vitro studies.
- 1975-1977 As a Research Associate at Wayne County General Hospital and as Co-Director of Radio Allergic Testing Service, the applicant received training in radioimmunoassay techniques and proper handling, storage, and disposal of radioactive materials. Isotopes utilized were Tritium and Iodine-125 (3.4 mCi maximum activity).
- 1977 The applicant served as Assistant Technical Director of Radioassay Systems, Inc. and was involved in the manufacture of radio-diagnostic kits. Isotopes involved were Iodine-125 (15 mCi max.) and Iron-59 (2 mCi max.). The applicant had full supervision in the absence of the director, of the use of the byproduct material.
- 1978-1980 The applicant served as Assistant Technical Director of Immuno Assay Corporation a manufacturer of commercial RIA reagents. Responsibilities included the design and set up of the manufacturing facility including radiation safety considerations. Applicant was responsible for actual manufacturing processes utilizing byproduct material (15 mCi Iodine-125 and 15 mCi Iron-59) as well as designing and implementing the facilities radiation protection program.
- 1979 Applicant completed post graduate course Radiation Biology at Wayne State University, Professor Chaviss. Course was an in depth theoretical study of Radiation Physics.
- 1980-present Applicant serves as Technical Director and CEO of Immuno Assay Corporation, and serves as its Radiation Protection Officer. Is responsible for the entire radiation protection program including iodination procedures, as well as the manufacturing and marketing aspects of the Company.

Curriculum Vitae

DONALD J. HOUSE

Birthdate: July 31, 1951, Lampoc, California, U.S. Citizen

Education: Grand Blanc High School 9/65-6/69  
University of Michigan Flint College 9/69-5/73  
University of Michigan Ann Arbor 9/73-5/74 B.Sc. Biology 1974  
Wayne State University Detroit 1979

Experience to present:

Laboratory Demonstrator - University of Michigan, Flint, 1972-1973  
Clinical Chemist - Physicians Clinical Laboratory-Ann Arbor 1973-1974  
Research Associate-Wayne County General Hospital-Eloise, MI 1974-1977  
Cancer Research. In vivo and in vitro development of an immunological approach to cancer therapy, esp. leukemia.  
Co-Director - Radio Allergic Testing Service-Southfield, MI 1976-1977  
In vitro diagnosis of allergic diseases by radio immuno assay.  
Founder & Director - Sudden Infant Death Research Institute of Michigan.  
July 1977 to present.  
Consultant in clinical diagnostics to Assarian Nuclear, Inc. Southfield MI, 4/77-8/77.  
Assistant Technical Director - Radioassay Systems, Inc. Southfield, MI, 1977. Manufacturer of in vitro clinical diagnostic kits.  
Assistant Technical Director - Immuno Assay Corporation, Dearborn Hts., MI 1978-1980  
Technical Director and CEO, Immuno Assay Corporation, Dearborn Hts., MI 1980 to present.

Associations:

American Association for Advancement of Science  
American Chemical Society  
Biological Photographic Association  
Midwest Radioassay Society  
Clinical Ligand Assay Society  
New York Academy of Science  
American Association of Clinical Chemistry

## Item #16 &amp; 17 Training and Experience in Radiation Safety

Gamma Analysis services are performed by qualified technicians under the general supervision of Denise Georgiou. Technicians working for Gamma Analysis and Distributing Company will generally be subcontractors. Technicians will be added in the future and those presently employed may move on, therefore, the following is submitted as requirements for Gamma Analysis technicians:

Technicians must fall under one of the following categories:

- 1) Possess a degree from a certified Medical Technologist or Technician school. Have appropriate training and/or certification in the use of RIA reagents and radiation safety procedures.
- 2) Have three years on the job experience and training with RIA reagents and radiation safety procedures.
- 3) Possess a high school diploma and have completed an intensive training course in the use of RIA reagents and radiation safety procedures. Training will be a combination of on the job experience in conjunction with current technologists as well as "textbook" lectures by the R.P.O. Donald J. House and/or Denise Georgiou. An exam must be passed at the completion of the training course.