

MATERIALS LICENSE

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 I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 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). 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		OFFICIAL RECORD COPY	
1. Sterling Diagnostic Imaging, Inc.		3. License Number	07-30316-01
2. Glasgow Business Community, Bldg. 600 Newark, Delaware 19714-6101		4. Expiration Date	August 31, 2001
		5. Docket or Reference No.	030-34176
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Americium 241	A. Sealed source (Amersham Model AMCQ 6874)	A. 10 millicuries per source and 20 millicuries total	
B. Americium 241	B. Sealed source (Amersham Model AMC 24)	B. 14 millicuries per source and 28 millicuries total	
9. Authorized use			
A. and B. Research and development as defined in 10 CFR 30.4.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at Glasgow Business Community, Bldg. 600, Newark, Delaware.
11. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: (1) the licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and (2) the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 has been notified in writing that activities authorized by the license will be initiated.
- In accordance with the requirements set forth in 10 CFR 30.36(d), 40.42(d), and 70.38(d), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing, of a decision not to complete the facility, acquire equipment, or possess and use authorized material.
12. A. Licensed material shall be used by, or under the supervision of, John C. Musser, Jacob Beutel, David M. Richards, or Joseph R. Romesberg.
- B. The Radiation Safety Officer for this license is John C. Musser.
13. Licensed material shall not be used in or on human beings.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

07-30316-01

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030-34176

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by Stan A. Huber Consultants. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

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Docket or Reference Number

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15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
17. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
18. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated June 3, 1996
 - B. Letter dated June 27, 1996

Date

AUG - 6 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Keith D. Brown, Ph.D

By

Division of Nuclear Materials Safety
Region I

King of Prussia, Pennsylvania 19406

AUG - 6 1996

License No. 07-30316-01
Docket No. 030-34176
Control No. 123328

R. E. Waaser, III
Senior Vice President
Sterling Diagnostic Imaging, Inc.
Glasgow Business Community
Building 600, Mail Stop 603
Newark, Delaware 19714-6101

Dear Mr. Waaser:

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Until your license is terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406 in writing, that activities authorized by the license will be initiated.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user or Radiation Safety Officer, permanently discontinues performance of duties under the license or has a name change; or

OFFICIAL RECORD COPY

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- b. when the mailing address on the license changes (no fee is required if the location of byproduct material remains the same).
- 4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.
- 5. Request and obtain a license amendment before you:
 - a. permit anyone to work as an authorized user under the license;
 - b. change Radiation Safety Officer;
 - c. order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - d. add or change the areas of use, or address or addresses of use identified in the license application or on the license; or
 - e. change ownership of your organization.
- 6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than the Radiation Safety Officer or a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600.

R. E. Waaser, III
Sterling Diagnostic Imaging, Inc.

-3-

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

License No. 07-30316-01
Docket No. 030-34176
Control No. 123328

Enclosures:

1. License No. 07-30316-01
2. 10 CFR Parts 2, 19, 20, 30, 170, and 171
3. NRC Forms 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L0730316.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Brown/kdb <i>[Signature]</i>						
DATE	08/01/96	08/	/96	08/	/96	08/	/96

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STERLING

Diagnostic Imaging, Inc.

030-34176

Q7

June 27, 1996

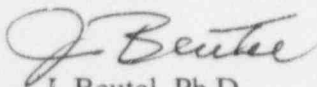
Keith D. Brown, Ph.D.
United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Dear Dr. Brown:

This letter is to provide the following clarifications to Sterling's application for a NRC Materials License:

- Records concerning the results of leak tests and physical inventory records will be retained for a period of three years.
- Establishment of the Radiation Safety Committee mentioned in the application will not be a part of the licence commitment.

Sincerely,

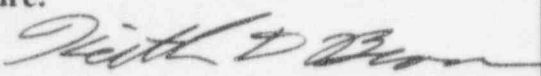


J. Beutel, Ph.D.
Research Fellow

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123328
Glasgow Business Community
JUL - 1 1996 Box 6101
Building 600, Mail Stop 620
Newark, DE 19714-6101

TELEPHONE CONVERSATION RECORD		Date: June 27, 1996	Time: 10:15 a.m.
Mail Control No.: 123328		License:	Docket No.: 030-34176
Person Called: Jack Beutel, Ph.D.		Organization: Sterling Diagnostic Imaging	Telephone Number: (302) 451-9586
Person Calling: Keith D. Brown			
Subject: Amendment Request			
<p>Summary: I asked Dr. Beutel to submit a commitment to maintain a record of physical inventories and of leak tests for at least three years. I also discussed the use of a radiation safety committee by Sterling (mentioned in item 4). He stated that he did not want that to be a license commitment, so I asked him to so state in his letter</p>			
Action Required/Taken: MS15			
Signature: 		Date: June 27, 1996	

JUN 27 1996

R. E. Waaser, III
Senior Vice President
Sterling Diagnostic Imaging, Inc.
Glasgow Building Community
Building 600, Mail Stop 603
Newark, Delaware 19714-6101

Dear Mr. Waaser:

We have reviewed your application dated June 3, 1996 requesting a new license for activities of your company at the above address. We have no further questions about that application.

As you know, the activities and location in question are currently covered by the E. I. du Pont de Nemours and Company, Du Pont Experimental Station license (No. 07-00455-02). It is our policy to not issue two licenses to cover the same activities or location. Therefore, you should request that E. I. du Pont submit an amendment request to have the above address removed from its license as a place of use. Once we receive that request, we will issue the new license and the amendment to the E. I. du Pont license simultaneously. Please be aware that the amendment fees described in 10 CFR Part 170 will apply to the E. I. du Pont amendment request.

If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5048. Thank you for your cooperation.

Sincerely,

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

Docket No. 030-34176
Control No. 123328

DOCUMENT NAME: R:\WPS\DLTR\D0730316.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI				
NAME	Brown/kdb <i>296</i>						
DATE	06/27/96	06/ /96	06/ /96	06/ /96	06/ /96	06/ /96	06/ /96

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STERLING

Diagnostic Imaging, Inc.

LL 30316

030-34176

03610

June 7, 1996

Keith D. Brown, PhD
U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch II
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Brown:

Attached is our application for US NRC Materials License for

Sterling Diagnostic Imaging, Inc.
Glasgow Business Community
Building 600
Route 896, Newark, DE 19714-6101

The issuance of this license has been necessitated by DuPont's divestiture of its Diagnostic Imaging business and the relocation of two sealed Am-241 sources from the DuPont Experimental Station to Glasgow, Building 600. The current operation of these devices is authorized under an extension of the Experimental Station's NRC license, 07-00455-02, granted on May 20, 1996. Since Sterling's agreement with DuPont expires within 6 months, the continued use and operation of these sources, which are critical to our business, depends on the speed with which this application can be processed and a license granted.

Sincerely,

J. Beutel, PhD
Research Fellow
Tel.: (302) 451-9586
FAX: (302) 451-9768

P.S. A Sterling Diagnostic Imaging check (No. 52628991) in the amount of \$530.00 dated June 7, 1996 is attached.

123328

Glasgow Business Community
JUN 12 1996
Box 6101
Building 600, Mail Stop 620
Newark, DE 19714-6101

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(10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19408-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Sterling Diagnostic Imaging, Inc.
Glasgow Business Community, Bldg. 600
Newark, Delaware 19714-6101

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Sterling Diagnostic Imaging, Inc.
Glasgow Business Community, Bldg. 600
Newark, Delaware 19714-6101

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Jacob Beutel

TELEPHONE NUMBER

302-451-9586

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 3P AMOUNT ENCLOSED \$ 530.00
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 82 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.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

R.E. Waaser III, Sr. Vice President

SIGNATURE

R.E. Waaser III

DATE

6-3-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

123328

Attachment 1

5. RADIOACTIVE MATERIAL

A. Americium 241	A. Sealed Source (Amersham Model AMCQ 6874)	A. Not to exceed 10 millicuries and 20 millicuries total
B. Americium 241	B. Sealed Source (Amersham Model AMC 24)	B. Not to exceed 14 millicuries and 28 millicuries total

The maximum total amount of each of the two sources listed above has been doubled to take account of the possibility that, in the event of a minor leak in any one of these sources, this site may temporarily hold two sources of the same kind while waiting to dispose of one of them.

Attachment 2

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

- A. For determining the scintillation spectra of phosphors used in x-ray intensifying screens for medical radiography. This source is designed to emit monochromatic x-rays through secondary x-ray emission from a series of metal discs mounted on a selector "wheel" irradiated by the Americium source and forming an integral part of the sealed source assembly. The secondary monochromatic x-rays, collimated through a 0.1 - 0.5 mm lead aperture and ranging in energy from 17 to 54 keV irradiate $\sim 1 \text{ cm}^2$ of a thin phosphor coating sample mounted directly in front of a photomultiplier tube. The visible or ultraviolet light photons emitted by the phosphor and detected by the photomultiplier tube are counted to determine the probability distribution function associated with the conversion of x-ray quanta absorbed by the phosphor to visible light photons.
- B. For determining the coating weight (in g/cm^2) of phosphor in x-ray intensifying screens for medical radiography. This source is used in combination with a Canberra Model 1702 x-ray scintillation detector to measure the fraction of 60 keV x-rays emitted by the source which is absorbed by the intensifying screen; the coating weight is then calculated from the absorbed fraction.

Attachment 3

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

John C. Mussar, Technical Specialist, Sterling Diagnostic Imaging, Inc.

Mr. Mussar is currently the radiation safety officer for all x-ray generators at Sterling's Building 600 site in the Glasgow Business Community. He has had this responsibility for four years, including the time prior to April 1, 1996, when DuPont sold its diagnostic imaging business and Sterling Diagnostic Imaging, Inc. came into existence. His prior experience includes maintaining standards for licensing and quality control as president of the Austin X-ray Laboratory in Elmwood Park, IL, managing x-ray equipment and radiography standards for Dr. I. T. Barnett of Chicago, IL and being the Chief Nuclear Technologist for the Skokie Valley Hospital in Skokie, IL, where he was in charge of preparing all radiopharmaceuticals, keeping federal and state records and performing weekly quality control operations.

Mr Mussar's has a an Associate degree in Applied Science/Radiologic Technology from the Oakton Community College in Des Plaines, IL, and a BA degree in Applied Health Management from the National Lewis University in Evanston, IL.

Attachment 4

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

All users of radioisotopes must attend a 90 minute training/orientation program covering the safe use of radioisotopes. The subjects covered include:

- procurement of radioisotopes
- handling precautions for radioisotopes
- storage
- waste disposal procedures
- spill cleanup and notification procedures
- signs and labeling
- bioassay requirements
- radiation monitoring (badges)
- wipe test of laboratories
- applicable exposure limits
- employee rights and responsibilities under 10 CFR, Parts 19 and 20
- locations where radioactive material is used and stored
- individual's obligations to report unsafe conditions to the RSO
- workers' right to be informed of occupational radiation exposure
- locations of pertinent regulations and licenses

All groups using radioisotopes shall receive periodic documented training on radiation safety rules and practices at least every two years. Refresher training may be provided more frequently based on program or regulatory changes.

All employees who do not handle radioactive material but who may be exposed to it shall receive initial documented training appropriate to their assignment and exposure potential. Refresher training will be provided at least every two years.

Access to laboratories by janitorial, clerical or other ancillary personnel will be permitted only on an as needed basis and only in the presence of personnel authorized and trained to use the radioactive material. All of this ancillary personnel are familiarized with the posted radioisotope symbol and are instructed not to touch anything which they have no reason to, especially containers and equipment displaying the radioisotope symbol. These instructions are given to them in their orientations when they are hired and at periodic refresher training at least every two years.

The qualifications of the professionals using or working in the vicinity of radioisotopes, as well as their technical competence, are approved by research management in assigning research projects and laboratory facilities.

Principal investigators are required to submit background information (Item F) to ensure they have sufficient training and experience to meet their responsibility for the radioisotopes in their care. The Radiation Safety Committee reviews the form and may, at its discretion, require additional training or guidance by another experienced user.

An assessment of the comprehension and abilities of radiation and ancillary workers will be conducted during the annual management audit of laboratory areas. The audit team will conduct random interviews with radiation workers and support staff. Any issues raised regarding the awareness and knowledge of radiation and ancillary personnel will be addressed in refresher courses for these employees.

In addition to refresher training for the aforementioned groups of employees our electronic mail system serves as an effective tool for rapid dissemination of information. Since all employees have access to the e-mail system, this system will be used to inform them of incidents, to reinforce some aspects of the radiation safety program and disseminate information regarding changes in regulatory or safety program changes.

Training records will include a course outline, the duration of the course, instructor's name, date and a list of participants. The training will be provided by the Radiation Safety Officer or other qualified personnel. Reputable instructors, knowledgeable in their areas of expertise may be used if appropriate as determined by the Radiation Safety Officer.

Attachment 5

9. FACILITIES AND EQUIPMENT

- A. This source is stored in a small box made of 1/16 inch thick lead, which is in turn held within a large locked wood box lined with 1/16 inch thick lead. During use the source, equipped with a 3 mm thick lead collimator (a disc containing a 0.1 to 0.5 mm hole) is mounted in the front opening of a photomultiplier tube housing held on an optical rail within the lead lined wood box; furthermore, the area at the front of the photomultiplier tube where the source is located is covered with a 1/16 inch thick lead shield. The lead box is closed and locked at all times except when replacing phosphor coated samples or when selecting a different secondary monochromatic x-ray source, in both instances for the purpose of performing a measurement.
- B. This source is mounted in a 2 inch diameter cylindrical Delrin block. This block is stored in a small box made of 1/16 inch thick lead which is held within the same lead lined wood box as source A. During use the Delrin block, held in an annular brass holder, is placed on an optical rail within the wood box so that the emitted radiation travels in a direction parallel to the optical rail and is incident on a coated intensifying screen sample placed about 15 inches from the source; a 4 inch diameter lead collimator with a 1 mm aperture is placed immediately in front of the source and the collimator-source assembly is covered with a 1/16 inch thick lead shield. The lead lined wood box is closed and locked at all times except when replacing phosphor coated samples for the purpose of performing a measurement.

The lead lined wood box used to hold both of the above mentioned sources is located in a laboratory whose doors are locked when no one is present and whose access is, at all times, restricted to trained personnel only.

Attachment 6

10. RADIATION SAFETY PROGRAM

- 10.1 The licensed material may be used only at the licensee's facility located at the Glasgow Business Community, Building 600, Newark DE.
- 10.2 The licensed material shall be used by or under the supervision of Jacob Beutel, John C. Mussar, David M. Richards and Joseph R. Romesberg.
- 10.3 The Radiation Safety Officer is John C. Mussar.
- 10.4 A. The sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.
- B. In the absence of a certificate of transfer indicating that a leak test has been performed within six months prior to transfer, a sealed source received from another person or site shall not be put into use until tested.
- C. Sealed sources need not be leak tested if they are in storage and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested prior to use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. The test shall be capable of detecting the presence of 0.005 microcuries of radioactive material on the test sample. If the test reveals more than 0.005 microcuries of removable contamination, a report shall be filed with the US Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired or disposed of in accordance with NRC regulations. The report shall be filed with the US Nuclear Regulatory Commission, Region I, Attn.: Chief Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, PA 19406, within five days of receipt of the result of the leak test. The report shall specify the identity of the source, the test result and the corrective action taken.
- E. The licensee is authorized to collect leak test samples for analysis by Stan A. Huber Consultants, 200 Cedar Road, New Lenox, IL 60451-1751. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the NRC or an Agreement State to perform such services.
- 10.5 Sealed sources shall not be opened by the licensee.

- 10.6 The licensee shall conduct a physical inventory every six months to account for all sealed sources received and possessed under the license.
- 10.7 The licensee shall not acquire licensed material unless the material has been registered with the US Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulation of an Agreement State.
- 10.8 Installation, initial radiation surveys, relocation, removal from service, or any similar activity involving the licensed material shall be performed only by persons specifically licensed by the US NRC or by an Agreement State to perform such services. The licensee may maintain, repair or replace components not directly associated with a sealed source or its related shielding or which will not result in increased radiation levels in accessible areas.
- 10.9 Prior to initial use and after installation, relocation, alignment or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above and below the instrument containing the source. This survey shall be performed by persons authorized to perform such services by the US NRC or an Agreement State.
- 10.10 The licensee shall operate each device containing licensed material within the manufacturer's specified temperature and environmental limits such that the shielding and the source holder are not compromised.

Attachment 7

11. WASTE MANAGEMENT

11.1 LAND DISPOSAL OF RADIOISOTOPES

Disposal of radioisotopes is through a broker in compliance with 10 CFR 20.2006. The Radiation Safety Officer or his designate will be responsible for transferring material to containers. The person handling the waste will, as a minimum, wear disposable gloves and a disposable laboratory coat. The transfer of material will be performed in a manner which ensures that no skin contact occurs. A personal monitoring device will be worn if needed and an appropriate survey meter will be present.

Radioisotopes will be packaged in compliance with NRC, DOT and the broker's instructions. We will use the current procedure supplied by the broker.

Currently, our NRC licensed broker will be Scientific Ecology Group, Oak Ridge, TN. Alternatively, we will only use brokers that are authorized by the NRC.

11.2 INTERIM STORAGE

Radioactive waste generated on site will be held for storage at the original location (Glasgow Business Community, Building 600). The host license conditions will apply to the waste being stored there. After storage the waste may be returned to the original location (vendor) or it may be handled according to the host license conditions, including arrangements for off-site land disposal.

RECEIVED

123328

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

TYPE OF ACTION

- ☒ NEW LICENSE
☐ RENEWAL OF LICENSE
☐ AMENDMENT TO LICENSE

REQUESTED DATE

6-3-96

LICENSE NUMBER

NEW

CONTROL NUMBER

123328

STERLING DIAGNOSTICS IMAGING, INC.
ATTN: J. BEUTEL, PH.D.
RESEARCH FELLOW
GLASGOW BUSINESS COMMUNITY
BUILDING 600, ROUTE 896
NEWARK, DE 19716-6101

*EFFECTIVE DATE FOR NEW FEES WAS 6/11/96. YOUR REQUEST WAS
RECEIVED 6/12/96, THEREFORE, THE NEW FEE IS APPROPRIATE.

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3P	\$ 550.00	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	550.00
PAYMENT RECEIVED	\$	530.00
AMOUNT DUE	\$	20.00

☒ Your request was received without the prescribed application fee.

☒ We received your Check No. 52628991 in the amount of \$ 530.00. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- ☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

- ☐ Enclosed is Check No. _____ which was returned to us by the bank for:
- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- ☐ License No. _____, Amendment No. _____, issued on _____, was issued without the required fee being collected. The fee required is noted in Section I of this form.
- ☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST

BRENDA BROWN

LFDCB

BB/BA

7/1/96

LFDCB

Distribution

MAF Correspondence

LFDCB Chief

Invoice File w/encl

LFDCB Analyst

LFDCB R/F

DATE

06/09/96 (LF-3-2.7)
DAF R/F 7-1-96

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

```
: PROGRAM CODE: 03610  
: STATUS CODE: 3  
: FEE CATEGORY: -----  
: EXP. DATE: 0 -----  
: FEE COMMENTS: -----  
: DECOM FIN ASSUR REQD: -----
```

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: STERLING DIAGNOSTIC IMAGING, INC.
RECEIVED DATE: 960612
DOCKET NO: 3034176
CONTROL NO.: 123328
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED

AMOUNT: \$ 530.00
CHECK NO.: 52628991

3. COMMENTS

SIGNED
DATE

M. A. Perkins
6/17/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED / 27 /)

1. FEE CATEGORY AND AMOUNT:

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER

SIGNED
DATE

Log June 17
Remitted E. J. DUPONT DENEMOURS + Co.
Check No 526 28991 / 52703256
Amount 8530 + 820
Pay Category 3P
Type APP
Date Check Rec'd 7/1/96
Date Completed 8/14/96
By CB

87 for 8/5/96