

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 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. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollections.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

Br. 4

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

03038382

X

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, 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 BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

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 06-32815-01

2 NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

General Electric Company dba GE Healthcare
P.O. Box 36
Tolland, CT 06084

3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Temporary jobsites anywhere in the United States where
US NRC maintains jurisdiction for regulating the use of
licensed material.

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Tracy L. Gale

TELEPHONE NUMBER

(860) 896-1608

2011 OCT 28 AM 10:31

RECEIVED
REGION I

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 LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3N (services) AMOUNT ENCLOSURE \$ 16,800.00

3. 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 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.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

JAMES R. KEITH EHS LEADER, AMERICAS

SIGNATURE

[Signature]

DATE

10/26/11

FOR NRC USE ONLY

FEE OF FEE FEE LOG FEE CATEGORY AMOUNT RECEIVED CHECK NUMBER COMMENTS

APPROVED BY

DATE

576289
NMSS/RGN1 MATERIALS-002

US NRC Radioactive Materials License Application

Form 313, Question #5

#5 – RADIOACTIVE MATERIAL

- a. Element and mass number
 - 1. Gadolinium-153
 - 2. Germanium-68
- b. Chemical and/or physical form
 - 1. Sealed sources (which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations)
 - 2. Sealed sources (which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations)
- c. Maximum amount which will be possessed at any one time
 - 1. Not Applicable (see note below)
 - 2. Not Applicable (see note below)

Note: The licensee does not take possession of radioactive material(s) and/or source(s) while at the client facility.

SSDRs attached.

US NRC Radioactive Materials License Application

Form 313, Question #6

#6 – PURPOSE(S) FOR WHICH LICENSED MATERIALS WILL BE USED

For use incident to installation, relocation, removal from service, repair, source replacement, calibration, testing and radiation surveys of sealed and their devices which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations as a service to customers at customers facilities.

US NRC Radioactive Materials License Application

Form 313, Question #7

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

Tracy L. Gale will be the RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures (resume attached)

Duties and Responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped;
- Radiation exposures are as low as is reasonably achievable (ALARA);
- Development, distribution, implementation, and maintenance of up-to-date operating procedures;
- Installation and use are consistent with the limitations in the license, individual Sealed Source and Device Registration Certificate(s), and the manufacturer's specific recommendations and instructions;
- Evaluations of occupationally exposed individuals are performed to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided;
- When necessary, National Voluntary Laboratory Accreditation Program (NVLAP)-approved personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Unusual occurrences are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Radiation safety program audits are performed and documented at least annually;
- When the licensee identifies violations of NRC requirements or program weaknesses, the licensee develops, implements, and documents corrective actions;
- Appropriate records are maintained;
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner;
- Monitoring and surveys of all areas in which radioactive material is used;
- Training personnel;
- Investigating any incidents and responding to any emergencies;
- Serving as a point of contact for NRC's and licensee's management during routine operations, emergencies, or incidents;
- Maintaining records required that are necessary to support the license and satisfy NRC regulations.

US NRC Radioactive Materials License Application

Form 313, Question #8

#8 – TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

Before beginning work with licensed material, individuals receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual is assigned refresher training on an annual basis (not to exceed 12 months).

The RSO authorizes service by those individuals that have completed the training.

Training Outline is as follows:

Radiation Safety Training Outline

- A. Radiation Principles
 - 1. Basic Radiation Principles
 - a. Radioactivity
 - b. Nuclear Radiation
 - c. Ionizing Radiation
 - 2. The Atom
 - a. Atoms
 - b. Electrons
 - c. Neutrons
 - d. Protons
 - e. Atomic Number
 - f. Atomic Mass Number
 - g. Isotopes
 - 3. Nuclear Fission
 - 4. Ionizing Radiation
 - a. Alpha
 - b. Beta
 - c. Gamma
 - d. Neutron
 - e. Generation of X-Rays
 - f. Emergency Procedures for Radiation Generating Equipment
 - g. Penetrating Capability (alpha, beta, gamma and x-ray)
 - h. Radioactive Decay (Curie and Half-life)
- B. Radiation Protection
 - 1. Written Program and Licenses/Permits
 - a. Radiation Protection Programs
 - b. Licenses/Permits

- c. Training and Instruction (page 2)
- 2. Units of Exposure and Dose
 - a. Units of Measurement – Roentgens (Coulombs/kg), Rads (Grays), Rem (Sievert)
 - b. Measurement Conversion (with examples)
- 3. Biological Effects
 - a. Radiation Dose – External Dose, Internal Dose, Typical Annual Dosage (Background Radiation)
 - b. Effects of Radiation on Human Cells
 - c. Acute vs. Chronic Exposure
 - d. Other Effects of Radiation – Prompt, Delayed, Genetic, Teratogenic
 - e. Radiosensitivity
 - f. Pregnancy – Declaring Pregnancy
- 4. Regulatory Dose Limits
 - a. Government Dose Limits (US and ICRP) – Whole Body, Extremities, Lens, Skin, Internal Organs, Pregnancy Term
- 5. Dose Management
 - a. Control of Radiation Dose (Investigation Level, Constraint Level, Dose Limit)
 - b. ALARA Principles – Time, Distance, Shielding
- 6. Radiation Level Measurement
 - a. Radiation Measurement
 - b. Radiation Level Surveys
 - c. Survey Records
 - d. Radiation Areas
 - e. High Radiation Areas
- 7. Occupational Monitoring
 - a. Dosimetry
 - b. Types of Dosimeters (TLD/OSL, Film, Self-Reading, Electronic)
- 8. Contamination Control

US NRC Radioactive Materials License Application

Form 313, Question #9

#9 – FACILITIES AND EQUIPMENT

Radioactive material licensed by the customer may be used at the licensee's facilities (temporary jobsites) anywhere in the United States where US NRC maintains jurisdiction for regulating the use of licensed material.

US NRC Radioactive Materials License Application

Form 313, Question #10

#10 – RADIATION SAFETY PROGRAM

A review of the content and implementation of the radiation protection program (attached) is conducted by the licensee at least annually.

US NRC Radioactive Materials License Application

Form 313, Question #11

#11 – WASTE MANAGEMENT

Sealed radioactive sources are licensed by the customer. No waste is generated.

US NRC Radioactive Materials License Application

Form 313, Question #13

#13 – CERTIFICATION

EHS Manager, James Keith has signed this renewal application. Tracy L. Gale (RSO) reports to Mr. Keith.

See attached org chart.

Sealed Source Device Registries (SSDRs)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED I N ITS ENTIRETY)

NO.: CA0406S185S

DATE: June 18,2003

PAGE: 1 of 5

SEALED SOURCE TYPE: Medical Line Source

MODEL: A3408, **A3418** and **A3429**

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
(661) 309-1010 (voice)
(661) 257-8303 (fax)

ISOTOPE:

Germanium/Gallium68

MAXIMUMACTIVITY:

5 mCi

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE: (X) Medical Reference Source

CUSTOM SOURCE: _____ YES X NO

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S185S

DATE: June 18, 2003

PAGE: 2 of 5

SEALED SOURCE TYPE: Medical Line Source

DESCRIPTION:

The source consists of a stainless steel tube with minimum outer diameter (OD) of 0.12 inch, 0.060 inch active diameter, maximum 9.06 inch active length, and overall length to range from 5.67 to 12 inches. The stainless steel tube contains a solid suspension (ceramic matrix) or an epoxy matrix of Ge/Ga-68. The stainless steel tube can be sealed by fusion weld or by threaded set screw plugs sealed with thread adhesive. The end is recessed so as to accept the attachment of mounting hardware or handle.

LABELING:

The source is engraved with a symbol for the isotope, the nominal activity, "IPL", and a serial number.

The source storage and shipping container is engraved with the radiation symbol, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION-RADIOACTIVE MATERIAL".

DIAGRAM: (See Attachments)

Attachment 1:	Label supplied on shielded shipping container.
Attachment 2:	Source Drawing Nos. A3408.
Attachment 3	Source Drawing Nos. A3418.
Attachment 4 & 5:	Source Drawing Nos. A3429.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use by trained personnel in a laboratory or clinical environment to provide necessary calibration and correction factors for Positron Emission Tomography (PET) systems. The source may be mounted on a source holder in the scanner or placed directly on the patient couch.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA0406S185S

DATE: June 18, 2003

PAGE: 3 of 5

SEALED SOURCE TYPE: Medical Line Source

PROTOTYPE TESTING:

Capsule	Classification	Recommended Usage
A3408	ISO/99/C32313	Calibration source activity > 1 MBq
A3418	ISO/99/C32313	Calibration source activity > 1 MBq
A3429	ISO/99/C32313	Calibration source activity > 1 MBq

EXTERNAL RADIATION LEVELS:

The specific gamma ray dose constants of $1.653 \text{ E-} 5 \text{ (mSv/hr)/MBq}$ for Ge-68 and $1.789 \text{ E-} 4 \text{ (mSv/hr)/ MBq}$ for Ga-68, from the revised edition of the Health Physics and Radiological Health Handbook, was first converted to the traditional gamma factor (i.e., multiply the specific gamma ray dose constants by 3.7 to convert data in units of (mSv/hr)/MBq to (mrad/hr)/uCi assuming a quality factor of one. Then multiplying by 1000 and then by 10 convert data in units of (mrad/hr)/uCi to the traditional gamma factor in units of $\text{R-cm}^2/(\text{h-mCi})$ [note $1\text{R} = 0.98 \text{ rad}$ in Tissue { $1\text{R} = 0.877 \text{ rad}$ in air} or approximately 1)]. Next, a line source calculation (assuming an active length of 21.74 cm and 16.74 cm {representing the A3408's two active element lengths} and with the activity uniformly distributed) was chosen to approximate exposure values for the A3408 line sources and the 3 standard distances of 5 cm, 30 cm, and 100cm. The exposure rates in mR/hr calculated using the specific gamma ray dose constants of $1.653\text{E-}5 \text{ (mSv/hr)/MBq}$ for Ge-68 and $1.789\text{E-}4 \text{ (mSv/hr)/MBq}$ for Ga-68 with a total activity of 5 mCi at the three standard distances are as follows:

Nuclide	Activity	Distance from source		
		5 cm	30 cm	100 cm
A. Ge-68 (16.74 cm)	5 mCi	75.6	3.28	0.30
B. Ga-68 (16.74 cm)	5 mCi	816.4	35.86	3.30
C. Ge-68 (21.74 cm)	5 mCi	63.4	3.22	0.30
D. Ga-68 (21.74 cm)	5 mCi	694.0	35.28	3.30

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S185S

DATE: June 18, 2003

PAGE: 4 of 5

SEALED SOURCE TYPE: Medical Line Source

Note: Ge-68 attains Secular Equilibrium with its only daughter Ga-68 in 14 hours. The half-life for Ge-68 is 288 days and Ga-68 is 1.1 hr. Therefore, the total exposure rate for A3408's two active length should be approximately the sum of Ge-68 and Ga-68 exposure rates)

QUALITY ASSURANCE AND CONTROL:

Isotope Products Laboratory maintains a quality assurance and control program that has been deemed acceptable for licensing purposes by California Department of Health Services. A copy of the program is on file with the California Department of Health Services.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by the U.S Nuclear Regulatory Commission or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- The A3408, A3418 and A3429 sources are intended to be used by trained personnel in a laboratory or clinical environment to provide necessary calibration and correction factors for positron emission tomography (P.E.T.) systems. They should not be subjected to conditions exceeding their ISO 2919 classification of ISO/99/C32313.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model A3408, A3418 and A3429 sealed source, its ISO classification, and the information and test data cited below, we **continue** to conclude that the source is acceptable for licensing purposes.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA0406S185S

DATE: June 18, 2003

PAGE: 5 of 5

SEALED SOURCE TYPE: Medical Line Source

Furthermore, we **continue** to conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this certificate.

REFERENCES:

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document:

1. Isotope Products Laboratories letter dated November 15, 1995, with attachments thereto.
2. Isotope Products Laboratories letter dated August 20, 1999, with attachments thereto.
3. Isotope Products Laboratories letter dated May 28, 2003, with attachments and the letter dated June 18, 2003.

ISSUING AGENCY: California Department of Health Services

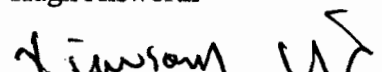
DATE: June 18, 2003

REVIEWED BY:


Hugh Alsworth

DATE: June 18, 2003

CONCURRED BY:



Xiaosong Yin

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA0406D185S

DATE: June 18, 2003

ATTACHMENT: 1

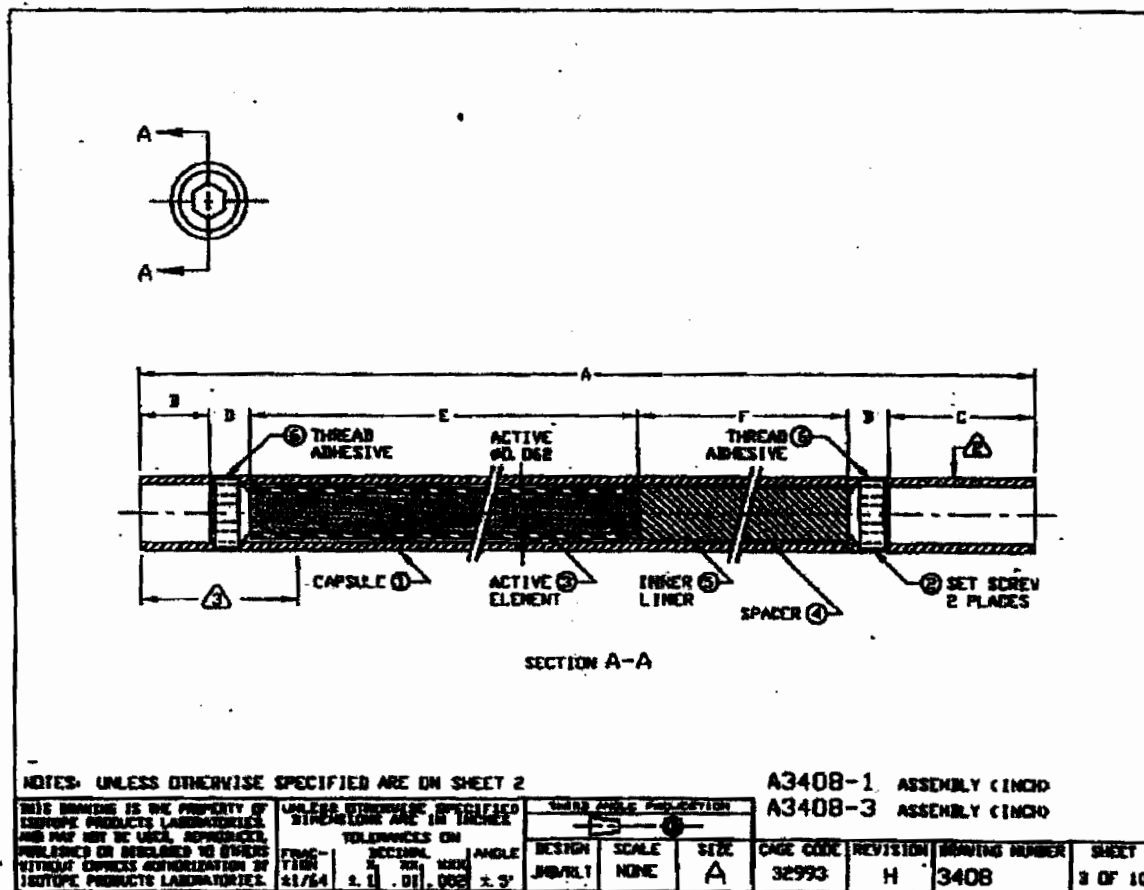
ISOTOPE PRODUCTS LABORATORIES	
BURBANK, CA 818-843-7000	
ISOTOPE:	Dummy
AMOUNT:	x.xx mCi
REF.DATE:	1 Sep 99
S/N:	ZZ-999
CAUTION	
	
RADIOACTIVE MATERIALS	
NOT FOR DRUG USE	

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA0406D185S

DATE: June 18, 2003

ATTACHMENT: 2

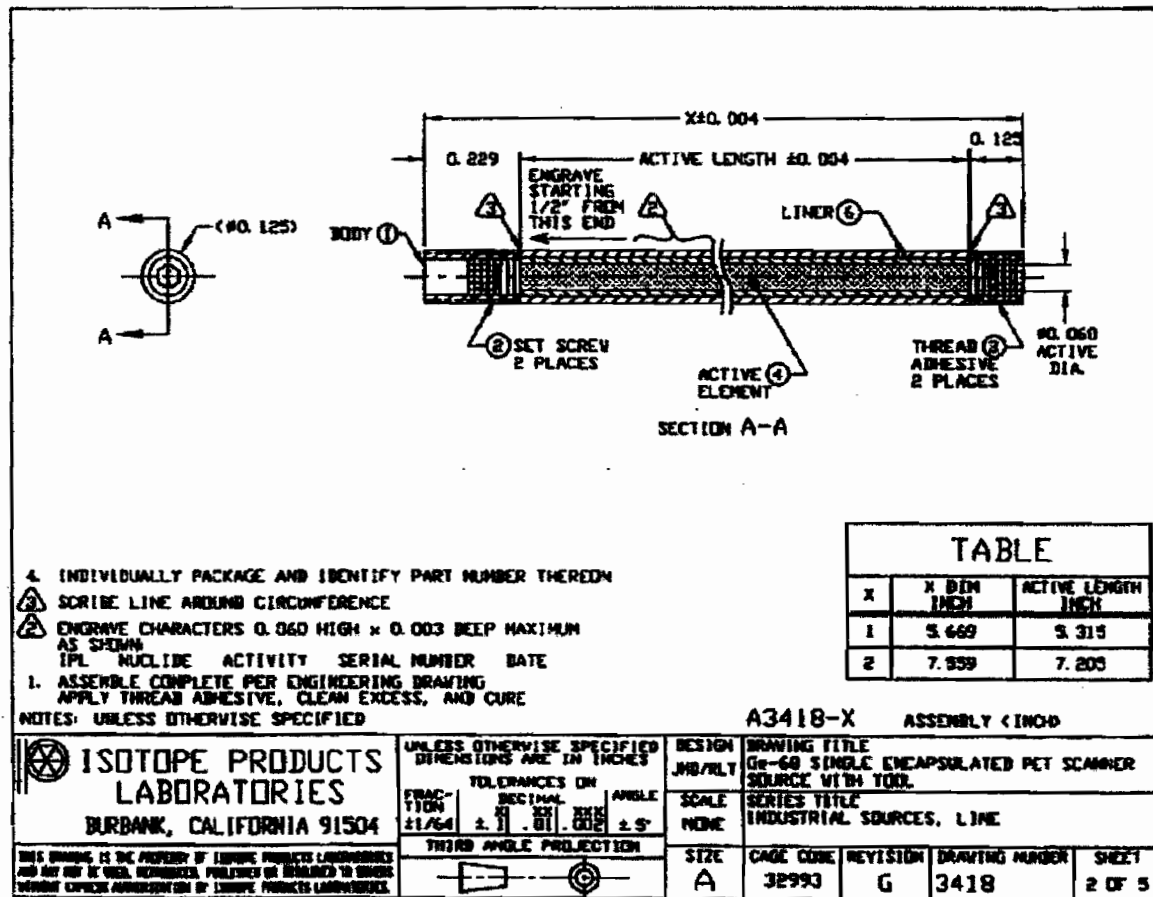


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA0406D185S

DATE: June 18, 2003

ATTACHMENT: 3



ATTACHMENT: 4

0.01368 (±0.0005)

0.00730 (±0.0005)

0.0154 (±0.0020)

0.0087±0.007 (±0.0020±0.0018)

6.30 (±0.01) ± 0.005 (±0.001) ACTIVE AREA

0.0039 (±0.0005)

0.156±0.008 (±0.002) [2.96±0.05]

1.2436289

HANDLE

BASE

SST

ROD ASSEMBLY

TUBE, SST

COLD PLUG, SST

CANE, GLASS

NUCLEONIC, GE-68

SPACER, SST

HOT PLUG, SST

CODE ROD ASSEMBLY PAGE 4 OF 9 FOR MORE DETAILS

0.156±0.008 (±0.002) [2.96±0.05]

1.2436289

7. AVAL. UNIFORMITY: ±5% RW OVER 0.5 cm SEGMENTS AND ±5% RW UNIFORMITY BETWEEN ANY TWO 0.3 cm ADJACENT SEGMENTS.

8. ACTIVITY: 1.40 mCi (51 MBq) ±10%.

9. AVAL CLASSIFICATION: 77632312 MINIMAL.

10. LEAK TEST: LEAK TEST: <1 nCi BETA-GAMMA CONTAMINATION 4 HR.

11. SOAK TEST IN 20°C WATER AND <1 nCi BETA-GAMMA CONTAMINATION PER TOTAL AREA Wipe TEST.

12. CTD INSPECTION POINT

13. EPOXY BASE AND HANDLE IN ORIENTATION AS SHOWN. REMOVE EXCESS EPOXY AND CURE IN GLUING FIXTURE.

14. PREPARE SURFACES FOR GLUING WITH 300 TO 600 GRIT SAND PAPER. REMOVE ALL OIL AND GRIT.

15. ASSEMBLE PER ENGINEERING DRAWING.

NOTES: UNLESS OTHERWISE SPECIFIED

Isotope Products Laboratories

An Eckert & Ziegler Company

WILMINGTON, CALIFORNIA 91355

SPREAD SHEET: SHEET 4 OF 9

TOLERANCES

UNLESS OTHERWISE SPECIFIED

FRAMES 1 AND 2

FRAMES 3 AND 4

FRAMES 5 AND 6

FRAMES 7 AND 8

FRAMES 9 AND 10

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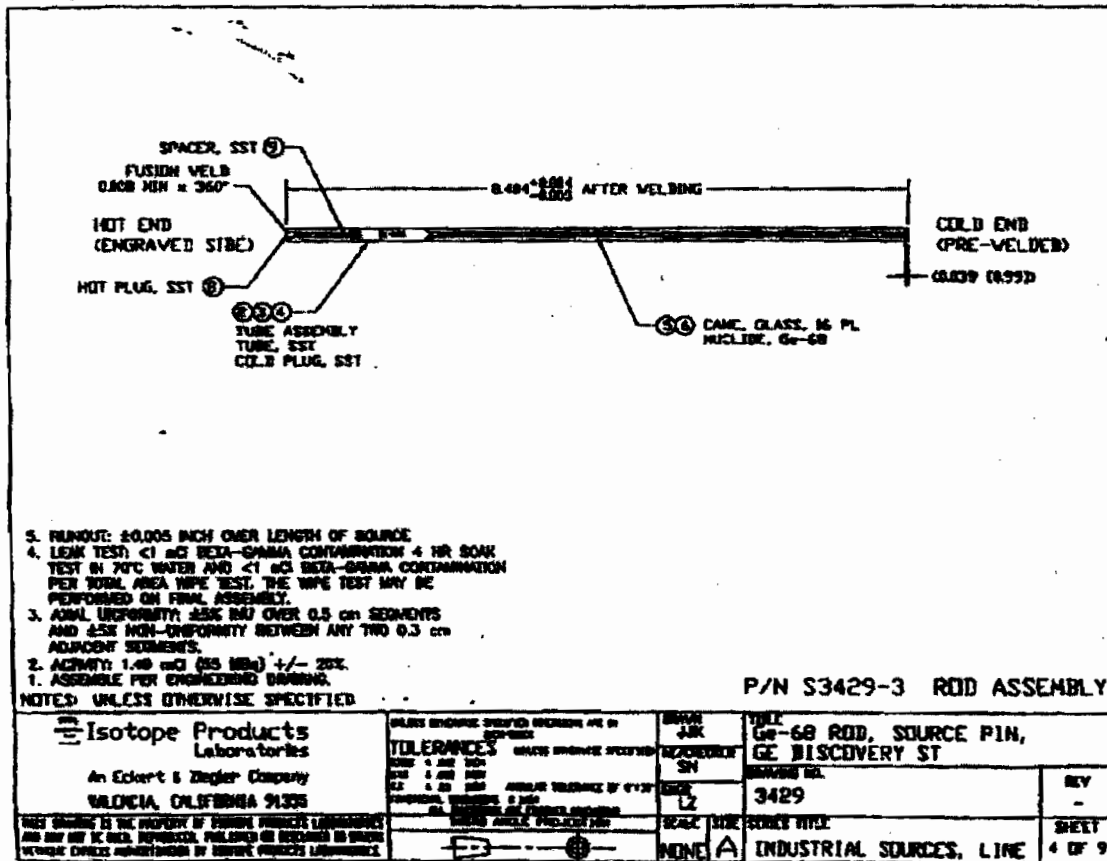
FRAMES 369 AND

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406D185S

DATE: June 18, 2003

ATTACHMENT: 5



Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its entirety)

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Page: 1 of 5

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

MODEL: PET-XXX/YY (Variables indicate length and activity – XXX indicates length in millimeter, YY indicates activity in millicuries)

MANUFACTURER/DISTRIBUTER: Sanders Medical Products
2452A Sutherland Avenue
Knoxville, TN 37919

ISOTOPE: Germanium 68

MAXIMUM ACTIVITY: 20 millicuries

LEAK TEST FREQUENCY: 12 months

PRINCIPAL USE: Instrument calibration and patient transmission determinations

CUSTOM DEVICE: YES _____ NO X

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its entirety)

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Page: 2 of 5

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

DESCRIPTION:

This calibration source consists of a ceramic or epoxy active element with Ge-68 added and doubly encapsulated in stainless steel tubing. The inner tube is sealed using structural epoxy. Using a laser, a stainless steel plug is fusion welded into the ends of the outer tube.

DIAGRAMS:

The source is shown schematically in Attachment 1.

LABELING:

The source is labeled by engraving or etching. Information on the label includes company name, serial number, model number, activity, isotope, and calibration date if space permits. In the case of the smallest size only the serial number will be shown since space does not permit more legible information to be shown. When the source is installed in an instrument's shielded housing, an adhesive-backed identifying label provided by the source manufacturer will be attached to the instrument so that it will be visible to anyone removing the shielded housing. The labels are shown in Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The source is designed for use in controlled medical diagnostic facilities to adjust the response of nuclear medicine diagnostic imaging instruments. The source is either mounted inside source holders which are normally provided with the imaging instruments, or it is placed on the patient couch.

The amount of exposure received during the use of this source should be reviewed by the state licensing the source or other agency having jurisdiction over the possession and use of accelerator produced radioactive material. The useful life of the source is approximately 1.5 years.

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its entirety)

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Page: 3 of 5

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

PROTOTYPE TESTING:

The source was tested by the manufacturer, Sanders Medical Products, Inc., according to American National Standard N542-1977. As a result of that testing, the manufacturer claims an ANSI rating of 77C32312 as specified in the standard for calibration sources with an activity greater than 30 microcuries. The source containment was not breached during testing.

EXTERNAL RADIATION LEVELS:

The radiation profile of the PET source in a range of sizes is detailed in the chart below:

Source Length	Activity	Radiation level at 5 cm	Radiation level at 30 cm	Radiation level at 100 cm
15 cm	10 mCi (370 Bq)	850 mR/hr	65 mR/hr	6 mR/hr
207 cm (coiled)	1 mCi (37 MBq)	90 mR/hr	6 mR/hr	1 mR/hr

QUALITY ASSURANCE AND CONTROL:

The Sanders Medical Products, Inc. "Source Manufacturing Quality Assurance Program" provides for quality checks and tests in the manufacturing process including design, material purchasing, storage, in-process steps, final testing, and certification. Handling instructions are provided for installers and users.

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its entirety)

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Page: 4 of 5

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

This source shall be distributed only to persons who are approved for its use in a specific license issued by this Department, another Agreement State, or other state or agency who maintains jurisdiction over the possession and use of accelerator produced radioactive material.

The source shall be installed, relocated, removed, initially surveyed, leak tested, serviced, and repaired by Sanders Medical Products, Inc. personnel or other persons specifically licensed by this Department, another Agreement State, or other state or agency who maintains jurisdiction over the possession and use of accelerator produced radioactive material. Special attention should be given to hand and extremity monitoring for those performing source installations.

The source shall be leak tested at least annually using techniques capable of detecting 0.005 microcuries of removable contamination. Specifically licensed persons shall perform the test.

This registration sheet and the information contained within the references shall not be changed without the written consent of the State of Tennessee.

SAFETY ANALYSIS SUMMARY:

Based on our review of the manufacturer's information and test data, our conclusion regarding the safety of the Line source is as follows:

Under ordinary conditions of handling, storage, and use, the radioactive material contained in the source will not be released or inadvertently removed from the source. Furthermore, it is unlikely that any person will receive an occupational annual dose exceeding the limits specified in 1200-2-5-.50, 1200-2-5-.55, and 1200-2-5-.56 of the Tennessee "State Regulations for Protection Against Radiation."

It is unlikely under accident conditions (such as fire or explosion) associated with handling, storage, and use of the source that any person would receive an occupational annual dose exceeding the limits specified in 1200-2-5-.50, 1200-2-5-.55, and 1200-2-5-.56 of the Tennessee "State Regulations for Protection Against Radiation."

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source
(Amended in its entirety)

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Page: 5 of 5

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

REFERENCES:

The following supporting documents for the source are hereby incorporated by reference and are made a part of this registry document:

- Application dated May 18, 1995, with attachments
- Letter dated June 5, 1995, with attachment
- Letter dated June 29, 1995, with attachments
- Letter dated June 27, 2000, with attachments
- **Information received September 24, 2001, with attachments**

ISSUING AGENCY:

Tennessee Department of Environment and Conservation
Division of Radiological Health

DATE: 10/16/01 REVIEWED BY: Charles Arnott

DATE: 10/17/01 CONCURRENCE BY: Johnny C. Graves

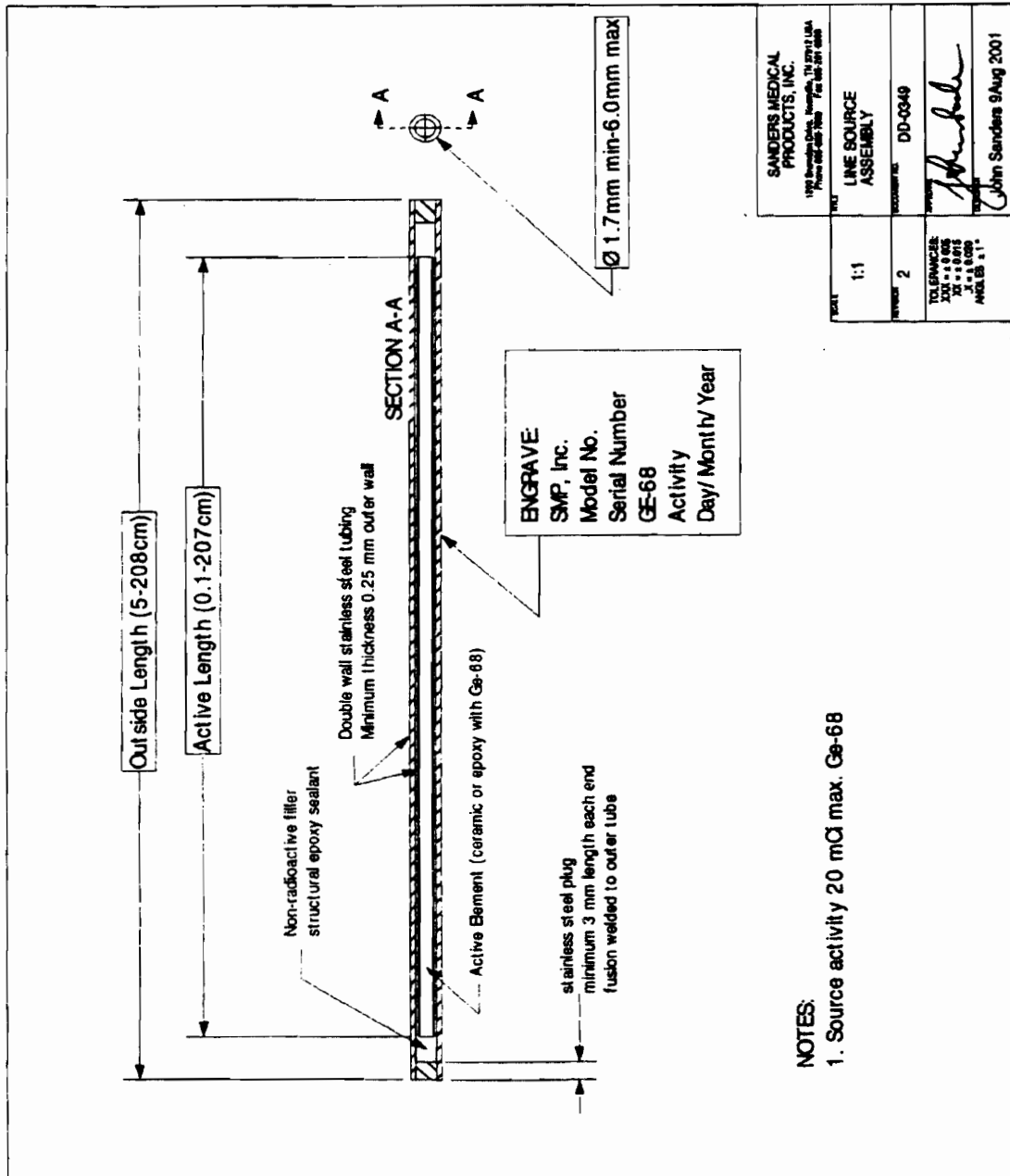
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCE

Amended in its entirety

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Attachment 1



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

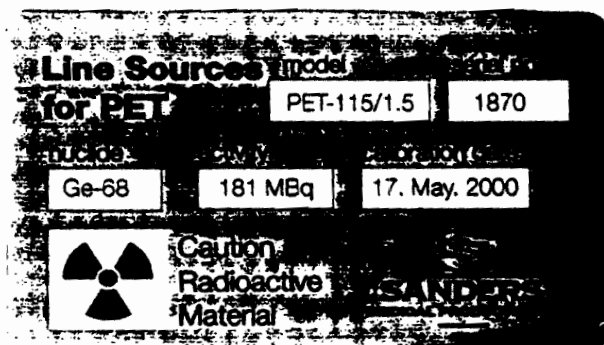
Amended in its entirety

NO.: TN-0241-S-101-S

DATE: October 15, 2001

Attachment 2

Line Source Label



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: **May 29, 2009**

PAGE 1 OF 7

SEALED SOURCE TYPE: Line Source

MODEL:

3407
34aa Series
HEGL-XXXX Series

MANUFACTURER / DISTRIBUTOR:

Eckert & Ziegler Isotope Products
dba Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
and
1800 N. Keystone St.
Burbank, CA 91504
(661) 309-1010 (voice)
(661) 257-8303 (FAX)

MANUFACTURER:

Nuclitec GmbH
Gieselweg 1
38110 Braunschweig
Germany
or
Eckert & Ziegler CESIO
Radiova 1
102 27 Prague 10
Czech Republic

ISOTOPE:

Cerium-139

Cesium-137

Cobalt-57

Cobalt-60

Germanium-68

MAXIMUM ACTIVITY:

1 millicurie (37 MBq)

300 millicuries (11.1 GBq)

20 millicuries (740 MBq)

300 millicuries (11.1 GBq)

20 millicuries (740 MBq)

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(D) Gamma Gauges
(X) Medical Reference Sources
(AB) Medical Diagnosis Sources

CUSTOM SOURCE:

☐ Yes ☒ No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: **May 29, 2009**

PAGE 2 OF 7

SEALED SOURCE TYPE: Line Source

DESCRIPTION:

The source consists of a single, double, or triple encapsulated stainless steel tube with maximum dimensions of 12 inches in length and 0.50 inch diameter. The active diameter is a maximum of 0.486 inches. The stainless steel line sources contain a nickel tube or ceramic or resin matrix of the nuclide. The double and triple-encapsulated source is encapsulated in successive stainless steel capsules of tube and plug construction. The source is sealed by fusion welded plugs on both ends **or by a blind bore with a fusion welded plug on the open end**. A handle or holder may be epoxied **or welded** to one end of the tube source after it is welded and leak tested.

The source activity range shall be +20% and -15% for all models.

Table 1 lists the source model identification scheme used for sources within this series.

Table 1. HEGL Series

Model Number	Overall Length	Maximum Overall Diameter	Handle / Holder
3407	6.850" – 6.889"	0.158"	Required
34aa	1" - 12"	0.500"	Optional
HEGL-0019*	6.850" – 6.889"	0.158"	Required
HEGL-0020*	6.850" – 6.889"	0.158"	Required
HEGL-XXXX	1" - 12"	0.500"	Optional
aa = numeric designation, HEGL-XXXX = High Energy Gamma Line with XXXX numeric designation			

* HEGL-0019 and -0020 are specific configurations of Model 3407.

LABELING:

The source is engraved with **the manufacturer**, nuclide, nominal activity, and serial number. Due to the dimensional limitations inherent to the source, the standard radiation caution symbol may not be included on the source.

The source storage and shipping container is labeled with the radiation symbol, nuclide, activity, serial number, reference date, and the words, "CAUTION-RADIOACTIVE MATERIAL".

In addition, when this source is manufactured for medical use, a label is affixed to the shipping container that states, "CA DPH has approved distribution of this source to persons licensed to use radioactive material identified in Cal Code Regs. title 17, §30170- §30237 & in 10 CFR 35.65, 35.400, 35.500, & 35.600 as appropriate, & to persons who hold an equivalent license issued by the US NRC or an Agreement State. See IFU for additional instructions, as applicable."

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: **May 29, 2009**

PAGE 3 OF 7

SEALED SOURCE TYPE: Line Source

DIAGRAM:

Attachment 1: Models 3407, 34aa Series, and HEGL Series Line Source (Single, Double and Triple Encapsulated)

Attachment 2: HEGL Series Line Source with Optional Handle/Holder

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in gamma gauging, or as a medical reference **or diagnostic** source. For gamma gauging applications, the source is intended to be mounted in a gauging device. The source is also designed and manufactured for use as a component of a medical gamma camera system used in the nuclear medicine department of a hospital or clinic by trained personnel. The line sources should not be subjected to conditions of normal use which require a higher classification than ISO 2919:1999, classification of ISO/99/C32313(7) for the single-encapsulated source or a higher rating than ANSI N542-1977, classification of 77C65444 for the double and triple- encapsulated sources. Other applications of a research and development nature are acceptable provided that the line sources are not subjected to environmental conditions exceeding those listed above. Typical useful life of the line source is dependent on nuclide:

Nuclide	Typical Useful Life (years)
Cerium-139	1
Cesium-137	15
Cobalt-57	2
Cobalt-60	15
Germanium-68	2

PROTOTYPE TESTING:

The prototype sources for Models 3407 and HEGL and 34aa Series single-encapsulated line source design passed the performance tests for a classification of ISO/99/C32313(7) per ISO 2919: 1999. This exceeds the required rating of ISO/99/C22212 for "Calibration source activity > 1 MBq" as defined in ISO 2919: 1999.

The prototype sources for Models 3407 and HEGL and 34aa Series double and triple-encapsulated line source design passed the performance tests for a classification of ANSI 77C65444 per ANSI N542-1977. This exceeds the required ratings of ANSI 77C43232 for "Gamma gauges (medium and high energy)--Source in device" and ANSI 77C22212 for "Calibration source—Activity greater than 30 uCi" as defined in ANSI N542-1977.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
 (AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
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DATE: **May 29, 2009**

PAGE 4 OF 7

SEALED SOURCE TYPE: Line Source

EXTERNAL RADIATION LEVELS:

The external radiation levels from the line sources were calculated using 'Microshield Version 5.05'. Source calculations representing the shortest and longest active lengths for a single-encapsulated source with the activity uniformly distributed were chosen to approximate exposure rates for Models 3407, 34aa Series, and HEGL Series at the 3 standard distances of 5 cm, 30 cm, and 100 cm. The exposure rates in mR/hr are calculated with the respective maximum activities plus tolerance, as listed below.

Cerium-139 Line Sources – Maximum Activity plus tolerance = 1.2 millicuries

Distance from Source	Exposure Rate (mR/hr) from Shortest Line Source 1" length	Exposure Rate (mR/hr) from Longest Line Source 12" length
5 cm	26.64	11.38
30 cm	0.8301	0.7673
100 cm	0.07556	0.07496

Cesium-137 Line Sources – Maximum Activity plus tolerance = 360 millicuries

Distance from Source	Exposure Rate (mR/hr) from Shortest Line Source 1" length	Exposure Rate (mR/hr) from Longest Line Source 12" length
5 cm	39,580	17,190
30 cm	1,233	1,143
100 cm	112.4	111.6

Cobalt-57 Line Sources – Maximum Activity plus tolerance = 24 millicuries

Distance from Source	Exposure Rate (mR/hr) from Shortest Line Source 1" length	Exposure Rate (mR/hr) from Longest Line Source 12" length
5 cm	422.3	176.9
30 cm	13.15	12.15
100 cm	1.195	1.185

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: May 29, 2009

PAGE 5 OF 7

SEALED SOURCE TYPE: Line Source

EXTERNAL RADIATION LEVELS: (continued)

Cobalt-60 Line Sources – Maximum Activity plus tolerance = 360 millicuries

Distance from Source	Exposure Rate (mR/Hr) from Shortest Line Source 1" length	Exposure Rate (mR/hr) from Longest Line Source 12" length
5 cm	159,800	69,430
30 cm	4,982	4,615
100 cm	454.2	450.7

Germanium-68 Line Sources – Maximum Activity plus tolerance = 24 millicuries

Distance from Source	Exposure Rate (mR/hr) from Shortest Line Source 1" length	Exposure Rate (mR/hr) from Longest Line Source 12" length
5 cm	4,490	1,951
30 cm	139.9	129.6
100 cm	12.76	12.66

QUALITY ASSURANCE AND CONTROL:

Program: The Eckert & Ziegler Isotope Products Quality Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B) and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records, source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders.

For medical applications, the manufacturing of the Models 3407 and HEGL and 34aa Series sources and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality **Operations** group at Eckert & Ziegler Isotope Products.

Eckert & Ziegler Isotope Products maintains a quality **system** program, which has been deemed acceptable for licensing purposes by the California Department of Public Health. A copy of the program is on file with the California Department of Public Health.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: **May 29, 2009**

PAGE 6 OF 7

SEALED SOURCE TYPE: Line Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- Models 3407, 34aa Series, and HEGL Series shall not be subjected to conditions exceeding their ANSI N542-1977 classification of 77C65444 for the double and triple-encapsulated sources or ISO 2919: 1999 classification of ISO/99/C32313(7) for the single-encapsulated source.
- The registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Public Health.

SAFETY ANALYSIS SUMMARY:

Based on a review of Models 3407, 34aa Series, and HEGL Series sealed sources, its ANSI / ISO classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes.

Furthermore, we continue to conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents of Models 3407, 34aa Series, and HEGL Series are hereby incorporated by reference and made part of this registry document:

1. Eckert & Ziegler Isotope Products' application dated October 18, 2006, letter dated July 10, 2007, and e-mails dated May 25, 2007, and June 28, 2007, with enclosures thereto.
2. **Eckert & Ziegler Isotope Products' letter dated 26 March 2009, with enclosures thereto.**

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
(Supersedes WA-0406-S-202-S)

DATE: May 29, 2009

PAGE 7 OF 7

SEALED SOURCE TYPE: Line Source

ISSUING AGENCY:

California Department of Public Health
Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

(916) 327-5106 (voice)
(916) 440-7999 (FAX)

DATE: 5-29-09

REVIEWER: Dora Chang-Taylor
Dora Chang-Taylor

DATE: 6-2-09

REVIEWER: Beverly Hill
Beverly Hill

DATE: 6/2/09

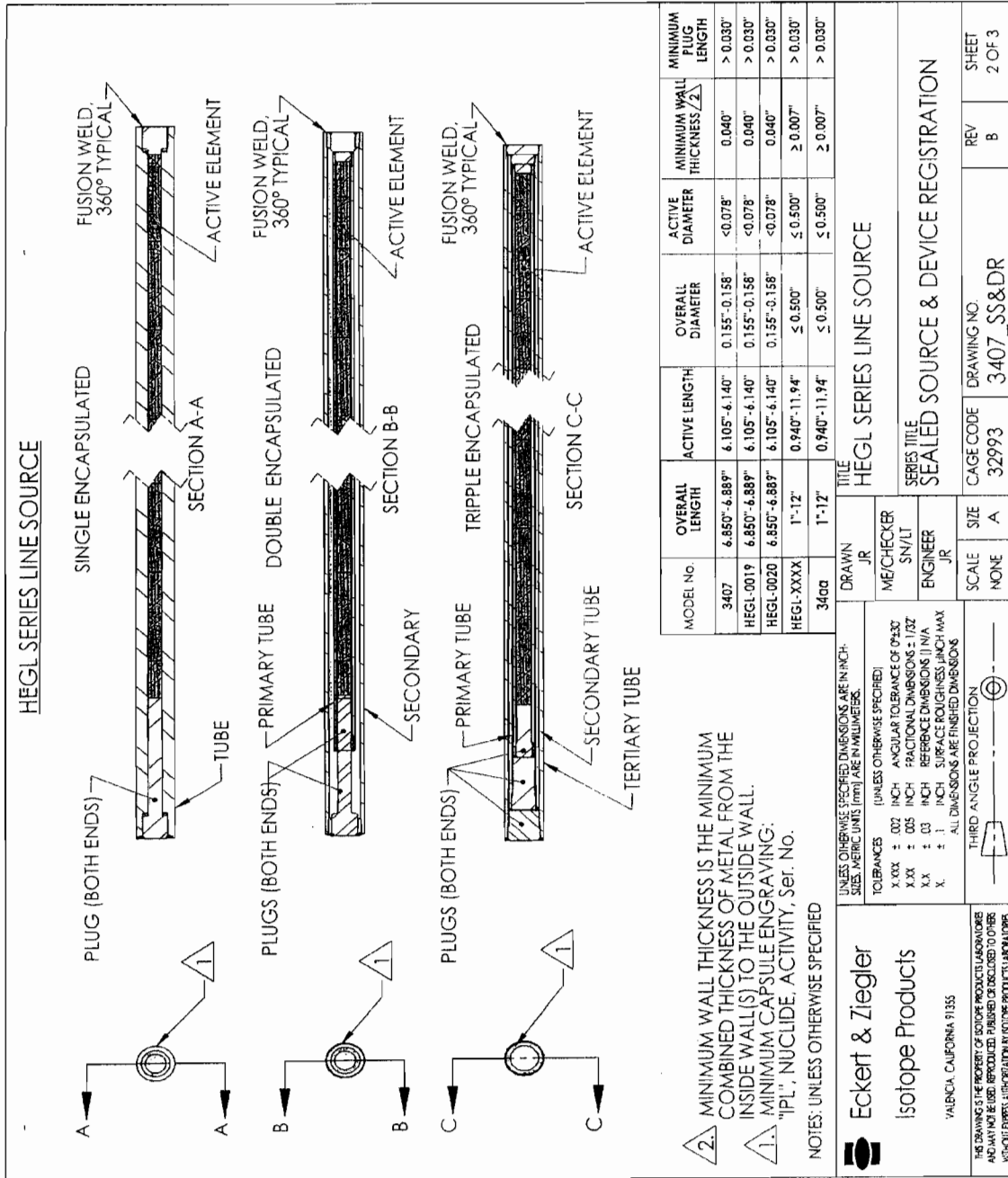
CONCURRENCE: John G. Fassell
John G. Fassell, CHP

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

NO.: CA-0406-S-238-S
 (Supersedes WA-0406-S-202-S)

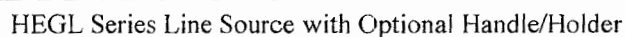
DATE: May 29, 2009

ATTACHMENT I OF 2



Models 3407, 34aa Series, and HEGL Series Line Source (Single, Double, and Triple Encapsulated)

ATTACHMENT 2 OF 2



**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S204S**DATE:** March 26, 2004**PAGE:** 1 of 5**SEALED SOURCE TYPE:** Transmission Line Source**MODEL:**NES8412, NES8422 through NES8426,
NES8429, NES8497**MANUFACTURER / DISTRIBUTOR:**Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
Tel 661 309 1010
Fax 661 257 8303**ISOTOPE:**

Gadolinium-153

MAXIMUM ACTIVITY:

600 millicuries (22.2 GBq) +20%/-10%

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(B) Medical Radiography

CUSTOM SOURCE:☐ Yes ☒ No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)

NO.: CA0406S204S**DATE:** March 26, 2004**PAGE:** 2 of 5**SEALED SOURCE TYPE:** Transmission Line Source**DESCRIPTION:**

The source consists of radioactive Gd-153 uniformly incorporated into an epoxy matrix. The Gd-153/epoxy is contained in a stainless steel or polymer inner tube, then inserted into a stainless steel outer tube. Two stainless steel end plugs are epoxy glued onto the ends of the outer tube to form the encapsulation. For the Model NES8425 each end plug features a 6-32 UNC threaded hole for attachment to a source holder. (Refer to the medical gamma camera system device registration certificate for source holder configuration.)

The model number uniquely designates the active length, active diameter, and maximum activity according to the table:

Model Number	Active Diameter (inches/mm)	Active Length (inches/cm)
NES8412	0.06/1.52	20.00/50.8
NES8422	0.06/1.52	18.18/46.12
NES8423	0.06/1.52	18.18/46.12
NES8424	0.06/1.52	8.78/22.3
NES8425	0.17/4.32	9.25/23.5
NES8426	0.06/1.52	07.75/19.7
NES8429	0.06/1.52	20.00/50.8
NES8497	0.06/1.52	9.61/24.4

LABELING:

Each source is engraved with the radiation symbol, "IPL", nuclide, nominal activity, serial number, model number, and date.

The source storage and shipping container is labeled with the radiation symbol, nuclide, activity, serial number, date of assay, and the words, "CAUTION-RADIOACTIVE MATERIAL".

DIAGRAM:

Attachment 1: Model NES-Series Gd-153 Line Source
Attachment 2: NES8425 Source
Attachment 3: NES8425 End Plug

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S204S

DATE: March 26, 2004

PAGE: 3 of 5

SEALED SOURCE TYPE: Transmission Line Source**CONDITIONS FOR NORMAL USE:**

These sources are designed for use as a component of a medical gamma camera system used in the nuclear medicine department of a hospital or clinic by trained personnel. Therefore, during normal use, the source will be subjected only to controlled conditions suitable for human occupancy. Extremes in environmental or operating conditions are not expected to exceed normal room temperature and humidity fluctuations. The useful life of the source is approximately eighteen months.

PROTOTYPE TESTING:

A prototype of the source design was tested in accordance with the specifications of ANSI N542-1977 and the design achieved an ANSI classification of 77C32314. The ANSI classification is equivalent to the ISO 2919: 1999 standard.

EXTERNAL RADIATION LEVELS:

The external radiation levels from the line sources were calculated using 'Microshield 5.05'. Source calculations (assuming an active length of 7.75 inches for NES8426 and 20.0 inches for NES8412 with the activity evenly distributed) were chosen to approximate exposure rates for the NES8412 and NES8426 line sources at the 3 standard distances of 5 cm, 30 cm, and 100 cm. The exposure rates in mR/hr are calculated with the respective maximum activities plus tolerance, as listed below.

Model No.	Nuclide	Maximum Activity, Including Tolerance (mCi)	Distance from Source (mR/hr)		
			5 cm	30 cm	100 cm
NES8412	Gd-153	720	7146	604.4	65.03
NES8426	Gd-153	720	14,290	699.5	66.15

QUALITY ASSURANCE AND CONTROL:

Program: The IPL Quality Assurance Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B) and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records, source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders.

Activity: Activity levels are held to within +20%/-10% of nominally desired activity.

Isotope Products Laboratories maintains a quality assurance and control program, which has been deemed acceptable for licensing purposes by the California Department of Health Services. A copy of the program is on file with the California Department of Health Services.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S204S**DATE:** March 26, 2004**PAGE:** 4 of 5**SEALED SOURCE TYPE:** Transmission Line Source**LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:**

- The source shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- The source shall not be subjected to conditions that exceed their ANSI N542-1977 classification of 77C32314.
- The information contained within the references shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY

Based on a review of the Models NES8412, NES8422 through NES8426, NES8429 and NES8497 sealed sources, its ANSI classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes.

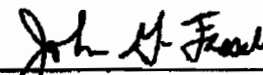
Furthermore, we continue to conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this certificate.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S204S**DATE:** March 26, 2004**PAGE:** 5 of 5**SEALED SOURCE TYPE:** Transmission Line Source**REFERENCES:**

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document:

1. DuPont Merck letters dated December 8, 1995, and August 1, 1996, with enclosures thereto.
2. Dupont Merck facsimiles dated May 8, 1996, April 23, 1996, and November 13, 1996, with enclosures thereto.
3. Dupont Merck letters dated January 22, 1998, and May 26, 1998, with enclosures thereto.
4. DuPont Pharmaceuticals Company letter dated February 3, 1999, with enclosures thereto.
5. Dupont Pharmaceuticals Company letter dated March 31, 1999, with enclosures thereto.
6. IPL letter dated August 22, 2000, with enclosures thereto.
7. Isotope Product Laboratories letter dated February 27, 2004, with attachments thereto.

ISSUING AGENCY: California Department of Health Services**DATE:**3/26/04**REVIEWED BY:**
Hugh Alsworth**DATE:**3/26/04**CONCURRED BY:**
John Fassell

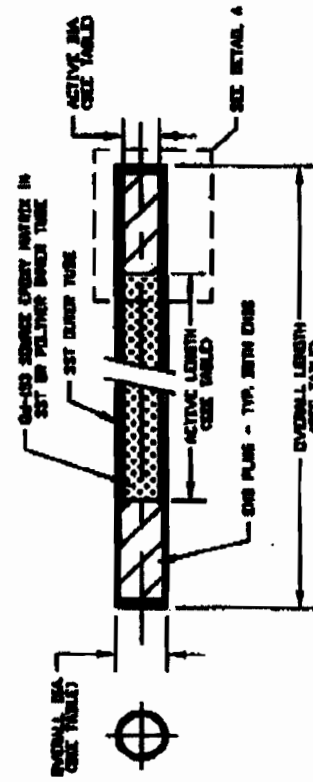
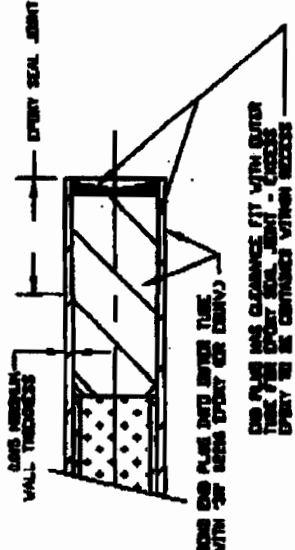

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES **SAFETY EVALUATION OF SEALED SOURCES** **(AMENDED IN ITS ENTIRETY)**

NO.: CA0406S204S

DATE: March 26, 2004

ATTACHMENT: 1

SEALED SOURCE TYPE: Transmission Line Source

 <p>ASSEMBLY DRAWING</p> <p>Labels: NOMINAL DIA. OF TUBE, Gd-153 SOURCE ELEMENT IN SET OF FILTER BINDER TUBE, SET CLAMP TUBE, ACTIVE LENGTH OF TUBE, OVERALL LENGTH OF TUBE, END PLUG - TYP. WITH DMS, SEE DETAIL A.</p>		 <p>DETAIL A TYP. WITH DMS</p> <p>Labels: END PLUG HAS CLEARANCE FIT WITH OUTER TUBE, END PLUG MUST BE SECURED WITH DMS, END PLUG MUST BE SECURED WITH DMS.</p>		 <p>ENGRAVING DETAIL</p> <p>Labels: ENGRAVE ON ONE END OF TUBE, "P.L." - PLATE, "A.C." - ACTIVITY, "D.T." - DATE, "S.N." - SERIAL NUMBER, "M.F." - MODEL NUMBER, "L.A." - LEAK TEST, "L.A.L." - LEAK TEST, "L.A.L." - LEAK TEST.</p>		<p>MODEL NUMBER TABLE</p> <table border="1"> <thead> <tr> <th>MODEL NUMBER</th> <th>ACTIVE LENGTH</th> <th>OVERALL LENGTH</th> <th>END PLUG</th> </tr> </thead> <tbody> <tr><td>000001</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000002</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000003</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000004</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000005</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000006</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000007</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000008</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000009</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000010</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000011</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000012</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000013</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000014</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000015</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000016</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000017</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000018</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000019</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> <tr><td>000020</td><td>0.05 IN.</td><td>0.05 IN.</td><td>0.05 IN.</td></tr> </tbody> </table>		MODEL NUMBER	ACTIVE LENGTH	OVERALL LENGTH	END PLUG	000001	0.05 IN.	0.05 IN.	0.05 IN.	000002	0.05 IN.	0.05 IN.	0.05 IN.	000003	0.05 IN.	0.05 IN.	0.05 IN.	000004	0.05 IN.	0.05 IN.	0.05 IN.	000005	0.05 IN.	0.05 IN.	0.05 IN.	000006	0.05 IN.	0.05 IN.	0.05 IN.	000007	0.05 IN.	0.05 IN.	0.05 IN.	000008	0.05 IN.	0.05 IN.	0.05 IN.	000009	0.05 IN.	0.05 IN.	0.05 IN.	000010	0.05 IN.	0.05 IN.	0.05 IN.	000011	0.05 IN.	0.05 IN.	0.05 IN.	000012	0.05 IN.	0.05 IN.	0.05 IN.	000013	0.05 IN.	0.05 IN.	0.05 IN.	000014	0.05 IN.	0.05 IN.	0.05 IN.	000015	0.05 IN.	0.05 IN.	0.05 IN.	000016	0.05 IN.	0.05 IN.	0.05 IN.	000017	0.05 IN.	0.05 IN.	0.05 IN.	000018	0.05 IN.	0.05 IN.	0.05 IN.	000019	0.05 IN.	0.05 IN.	0.05 IN.	000020	0.05 IN.	0.05 IN.	0.05 IN.	<p>MODEL NES-SERIES Gd-153 LINE SOURCE</p> <p>Label: 3431</p>		<p>REV A</p>		<p>SHEET 2 OF 2</p>	
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<p>NOTES: UNLESS OTHERWISE SPECIFIED</p> <p>1. DRAWING SUPERSEDES SUPPLEMENT 000007 REV C (1995).</p> <p>2. NOMINAL ACTIVITY TO BE SPECIFIED ON PURCHASE ORDER. NOMINAL ACTIVITY TOLERANCE TO BE $\pm 10\%$, $\pm 10\%$ REFERENCED TO LABEL DATE.</p> <p>3. TOTAL Gd-153 CONTENT TO BE LESS THAN 0.002 Gd-153 CONTENT, REFERENCED TO LABEL DATE.</p> <p>4. LEAK TEST PER ANSI N442-1977 PROCEDURE A2.1.1, WIPE TEST. LIMIT TO BE 5 nCi.</p> <p>5. ANSI N442-1977 PERFORMANCE CLASSIFICATION 77C-22314.</p> <p>6. FINAL ASSEMBLY CONSISTS OF A SOURCE CONTAINED IN A 1/8" THICK LEAD STORAGE SHIELD OR A CURTAIN-DESIGNED HOLDER HAVING 1/8" THICK MINIMUM SHIELDING. A LEAK TEST CERTIFICATE AND A RADIATION SAFETY AND INSTRUCTIONS SHEET TO BE SENT WITH EACH SOURCE.</p> <p>7. EACH CONFIGURATION (ACTIVE DIAMETER, ACTIVE LENGTH, AND MAXIMUM ACTIVITY) SHALL BE ASSIGNED A MODEL NUMBER PER THE TABLE.</p>																																																																																																	
<p>Isotope Products Laboratories An Eckert & Ziegler Company VIA FWY 14, CA 11701A 91755</p>																																																																																																	

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCES
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NO.: CA0406S204S

DATE: March 26, 2004

ATTACHMENT: 2

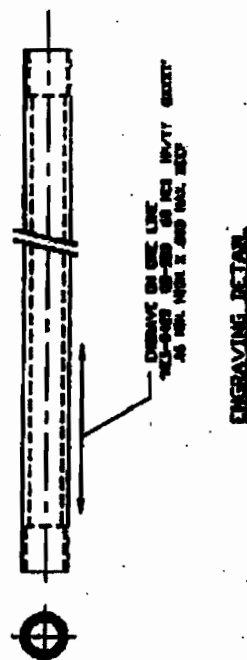
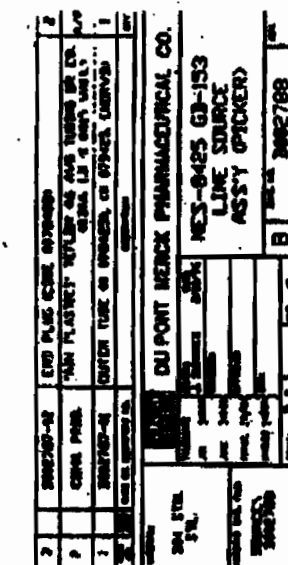
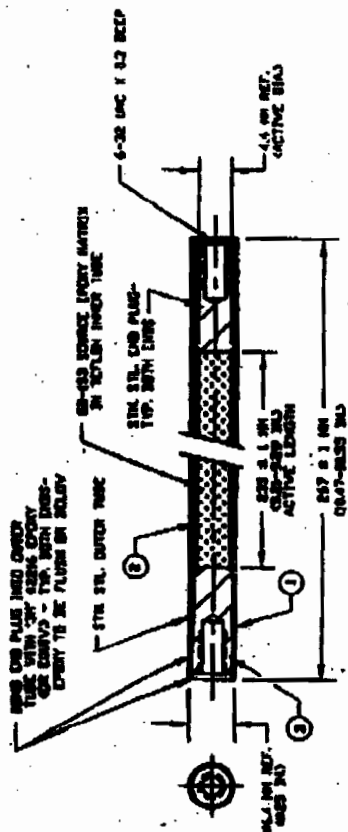
SEALED SOURCE TYPE: Transmission Line Source

NES-8425 Source



NOTES

- [illegible]



ENGRAVING DETAIL

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

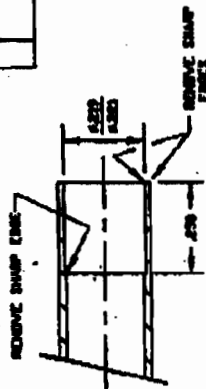
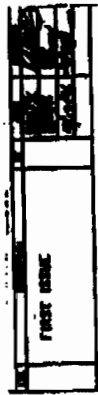
NO.: CA0406S204S

DATE: March 26, 2004

ATTACHMENT: 3

SEALED SOURCE TYPE: Transmission Line Source

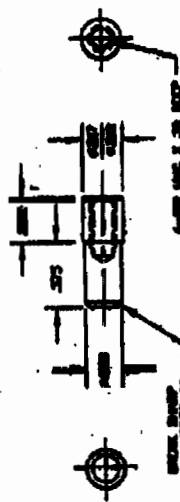
NES-8425 End Plug



END DETAIL
GYP. BOTH ENDS



P/N-84 ENDER TUBE
MATERIAL: 304 STAINLESS STEEL
FINISH: POLISHED
TOLERANCES: ±0.005



P/N-84 END PLUG
MATERIAL: 304 STAINLESS STEEL

DU PONT NUCLEAR PHARMACEUTICAL CO.	
LINE SOURCE COMPONENTS	CPACKER
DATE: 3/26/04	TIME: 10:00 AM
BY: [Signature]	FOR: [Signature]
REVISION: 1	3002787

Tracy L. Gale – RSO
Resume

Tracy L. Gale

[REDACTED] email: [REDACTED] Phone: 860-896-1608

EDUCATION

College: Bloomsburg University
Bloomsburg, Pennsylvania 17815
Major: Health Physics
Cumulative Grade Point Average: 3.22
Degree: Bachelor of Science

WORK EXPERIENCE

October 2005-
Present

GE Healthcare
160 Grant Hill Rd
Tolland, CT 06084

Supervisor: James Keith
262-2524-5164 (office)

Radiation Safety Officer: Responsibilities include maintaining NRC regional and state reciprocity and/or radioactive material licenses for service operations involving 2500 field employees distributed across all 50 states. Preparing applications, renewals and amendments. Developing and implementing radiation safety policies, programs and procedures to ensure protection of employees and the public and to ensure regulatory compliance. Advising senior management on implications and risk mitigation strategies related to new product/service development. Directing the radiation dosimetry program, general and specific radiation training and radiation safety procedures and advising on radiation incidences and emergencies including spills, releases, contamination and exposures. Currently RSO on seven licenses and twenty-nine reciprocity agreements.

November 2004-
October 2005

CTI Molecular Imaging/PETNET Pharmaceuticals, Inc.
14 Walker Way
Albany, NY 12205

Supervisor: Wm. Roger Moroney, CHP
865-218-2595 (office)

Radiation Safety Officer/Regional Health Physicist: Responsibilities include supporting the Corporate Radiological Compliance Department through the implementation of the Radiation Safety Program at the radiopharmacies in the northeast US. In particular, conducting training, maintaining the dosimetry program, overseeing the performance of radiological operations, reviewing effluent monitoring results and cyclotron operations, maintaining the emergency response program and licensing of the facilities. In addition, performing all duties of the RSO for the Albany nuclear pharmacy license issued by NY DOL.

October 2003-

Consultant

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

November 2004

When Imagyn Technologies ceased operations, I continued on a consulting basis, and as their RSO, through the decon/decommissioning process until the radioactive materials license was terminated by the State of Texas. I also consulted for another company whose license was going to be terminated by the state due to various violations. I dealt with the State of Texas concerning this license/business, corrected all violations and worked toward implementing a safety program acceptable to both parties.

**April 2001 –
September 2003**

Imagyn Medical Technologies

3100 Jim Christal Road
Denton, Texas 76207

Supervisor: Julie Powell
[REDACTED] (mobile), [REDACTED] (home)

Radiation Safety Officer: Responsibilities include running/supervising a health physics program and an OSHA program for a radioactive material license allowing up to 1000 Ci of I-125 for a major brachytherapy seed production facility.

**April 1998 –
April 2001**

International Isotopes Inc.

3100 Jim Christal Road
Denton, Texas 76207

Health Physicist: Responsibilities for health physics support for a major radio-chemical and radiopharmaceutical company, including dosimetry, cyclotron and LINAC operations, brachytherapy seed production and process development for the Ho-166 project. Other duties include emergency response, training, developing and implementing procedures, auditing, regulatory compliance, laser safety, bioassay program, environmental monitoring and instrument calibration.

**February 1995 -
April 1998**

Battelle

P.O. Box 30020
Amarillo, Texas 79177

Reference: Mike Ford, CHP
806-477-5727

Health Physics Trainer: Responsibilities included developing computer based training (CBT), classroom training and practical evaluations and conducting training for nuclear weapons workers.

Internal Dosimetry Supervisor: Responsibilities included maintaining an internal dosimetry program to ensure radiation safety and compliance with prescribed health protection procedures in accordance with company policies, DOE and other agency regulations. In addition to current on-going responsibilities, an Internal Dosimetry Technical Basis Manual for tritium, thorium, uranium and plutonium and an Internal Dosimetry Quality Assurance Manual were developed. Internal Operating Procedures used in the program were also developed, reviewed and updated. Audits of subcontracted bioassay laboratories were performed on an annual basis.

**December 1991-
February 1995**

Merck & Co., Inc.
P.O. Box 2000
Rahway, New Jersey 07065

Supervisor: Glenn M. Sturchio, CHP
507-266-5282

Health Physicist: Responsibilities included performing contamination surveys, providing training to both authorized users and maintenance staff entering radioactive material laboratories, measuring the radioiodine thyroid burden of researchers and analyzing all urine bioassay samples for H-3 and C-14 and determining the whole body burden, assisting in responding to radiation emergencies, maintaining inventory of all regulated radiation sources and performing semi-annual leak tests on sealed sources.

**July 1990-
October 1991**

Medi+Physics, Inc.
900 Durham Ave.
South Plainfield, New Jersey 07080

Supervisor: Wayne London
847-398-8400 x5739

Health Physics Technician: Responsibilities included assisting in maintaining facility safety programs to comply with all applicable local, state and federal regulations, assisting in orientation and on-going training in radiological safety and health, performing both environmental and laboratory radiation and contamination surveys, instrument calibration, monthly bioassays and waste disposal.

GEHC Radiation Safety Program

Electronic Signature Information

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Type	Controlled Document
Title	Radiation Protection Program Work Instruction
Originator	214006659_chad_m_vande hei

Name	Reason For Change	File Size (Bytes)
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Implementation plan for Ionizing Radiation Protection Program Work Instruction REV3.doc	Implementation Plan	111616

Route	Signer	Status	Comments	Completion Date
R-4449104	212038434_tracy_l_gale	Approve		31 Jan 2011 17:01:29 GMT
R-4449104	212042553_james_r_keith	Approve		31 Jan 2011 16:57:12 GMT
R-4449104	214006659_chad_m_vande hei	Approve	Approved	27 Jan 2011 17:09:46 GMT

* Printed versions are For Reference Only *

GE Healthcare Americas Service
08 Ionizing Radiation Protection Work Instruction
DOC0438594 Rev 3

GE Healthcare



Ionizing Radiation Protection Program Work Instruction

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1. PURPOSE

The purpose of this work instruction is to define GE Healthcare Service's radiation safety program to meet GE Healthcare Ionizing Radiation Protection Program requirements, NRC regulations, OSHA regulations, and state regulations throughout the United States.

2. SCOPE

The work instruction applies to the GEHC Americas Services Business in the United States.

This program includes licenses, reciprocity agreements, registrations, the GEHC Ionizing Radiation Protection Program, including training, pregnant worker information, and procedures for those Field Engineers (FE) who sell, service, or install radiation-generating equipment. In addition, it covers the safety aspects for those who handle radioactive material or service cyclotrons.

3. REFERENCES

3.1. External References

- Individual state, US territories and District of Columbia: Standards for Protection Against Radiation regulations and x-ray regulations
- NRC Regulations (10 CFR 20)
- OSHA Regulations (29 CFR 1910)

3.2. Internal References

- Global procedures (Fetal Monitoring Program 430.008RS, Radiation Exposure Reporting and Investigation 430.107RS)
- GE Healthcare Ionizing Radiation Protection Program and Guidance
- GEHC Personal Dosimetry Program
- Radiation Safety FAQs
- JSA for Badge Returns
- JSA for service on Cyclotron
- JSA for service Chemistry Boxes
- JSA for service BMD
- JSA for service Fluoroscopy
- JSA for Ionizing Radiation
- JSA for Handling Radioactive Isotopes

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- Personal Radiation Dosimeter form
- "How to Return a Dosimeter" video
- GEHC Field Services Radiation Safety Support Central site
- GE Healthcare EHS Significant Incident, Accident & Event Communication Policy
- Ionizing Radiation Work Plan
- State Notification Procedure
- State Notification Request form
- DOC0604062 US Service Radiation Policy
- DOC0429330 Record Retention Work Instruction
- DOC0684745 Commercial Operations Work Instruction
- DOC0604065 Americas Region Calibration Work Instruction
- Assessment of Anomalous or Unavailable Dose Monitoring Results

4. DEFINITIONS AND ACRONYMS

Below are the definitions of terms used within this document.

Table 4-1: Definitions and Acronyms

Term	Definition
ALARA (As Low As Reasonably Achievable)	Acronym applied to a system of dose optimization that stands for As Low as Reasonably Achievable. This is the cornerstone of the GEHC Ionizing Radiation Protection Program. This hierarchy of optimization of protection is used to limit occupational ionizing radiation dose. It is designed to ensure compliance with statutory limits and external standards and to direct time and resources for risk management of exposed employees. It enables FE's to work with and around ionizing radiation with specific guidelines to minimize exposure and to ensure the regulatory dose limits for occupational workers are not exceeded.
ATS	Audit Tracking System is the application in Gensuite to report events, findings and other observations along with root cause and corrective action, tracked to closure.
BMET	Biomedical Engineering Technician
CAMS	Clinical Assess Management & Service. The CAMS organization is made up field engineers servicing Monitoring Solutions & Diagnostic Cardiology (MSDCAR) and LiFE Support Systems and Maternal Infant Care (LSS/MIC) equipment as well as, the Biomedical Technicians who are located in the hospitals.
Consignment Unit	An X-Ray device that is used at a customer site for an indefinite time period. The consignment unit shall follow the requirements of a new installation.
CT	Computed Tomography: is a medical imaging method employing tomography created by computer processing.
Cyclotron	A circular particle accelerator in which charged subatomic particles generated at a central source are accelerated spirally outward in a plane perpendicular to a fixed

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**Table 4-1: Definitions and Acronyms**

Term	Definition
	magnetic field by an alternating electric field. A cyclotron is capable of generating particle energies between a few million and several tens of millions of electron volts. Cyclotrons are used to produce radioactive materials that are used in diagnostic imaging and other medical isotope applications.
Demo Unit	An X-Ray device that is used at a customer site for a temporary time period. The unit is demonstrated at the site by an applications specialist.
Devices	Equipment installed/serviced by GEHC FE's including MR, PET, Ultrasound, cyclotrons, Nuclear cameras and CT.
Dosimeter	A small portable device (e.g. film badge, OSL, thermoluminescent or pocket dosimeter) for measuring and recording the total accumulated dose of ionizing radiation over a designated period.
Dosimetry Report	A report provided by the dosimetry supplier (an accredited dosimetry company) after receiving an individual's dosimeter at the end of a wear period that documents the dose received.
EHS	Environmental Health and Safety
Electronic Dosimeter	A device that measures the current (i.e., real time) exposure to radiation and provides an immediate result of the dose received that is available to the wearer.
Extremity Dosimeter	Dosimeter worn on the finger(s) that measures the dose to the arms from the elbow to the fingertips.
FDA 2579 Form	Registration form sent to the FDA, customer, and state regulatory agency for x-ray producing devices.
FEMC	Field Engineer Mobile Computing. Tool used by FE's to record service records and order parts.
Field Engineer (Field Service Rep or Service Engineer) (FE)	An employee of GEHC employed to repair, adjust, and calibrated diagnostic imaging equipment made by GEHC. Those individuals that service equipment that emits radiation, contains radioactive sealed sources or cyclotrons.
GEHC	General Electric Healthcare
Gensuite	Computer system used by GE to report and collect EHS data and information. Various applications are used to report events, track corrective actions, collect data, perform data mining, and perform other functions as part of an EHS management system.
Ionizing Radiation	Electromagnetic radiation or particles capable of direct or indirect ionization when interacting with matter. Produced by radioactive materials or equipment that produces ionizing radiation.
Ionizing Radiation Work Plan	Document signed by RSO that outlines the provisions of the GE Healthcare Ionizing Radiation Protection Program following the GEHC standard template. Document includes references to applicable operating and emergency procedures as well as GEHC program requirements pertaining to work performed with radioactive materials and radiation generating machines.
Millirem (mrem)	A unit of measure of radiation dose equivalence.

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**Table 4-1: Definitions and Acronyms**

Term	Definition
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
P & L EHS Leaders	EHS Profit and Loss EHS Leaders – manage their zones compliance by assigning element owners for each of the 21 H & S Framework Elements and the 7 E Framework Elements.
PET (Positron Emission Tomography)	A specific modality of medical diagnostic imaging that uses a medical isotope that emits positrons (e.g. F-18) and a special type of camera to look at organs in the body.
Pin Source	Sealed sources designed in a 'pin' formation. They contain either Gadolinium-53 or Germanium-68 and are used in PET machines.
Pin Source Handling	Handling of Pin sources that include installation, removal, replacement or any procedure in which the sources are manually manipulated.
PSDB and OK	Problem Solution Database Offline Knowledge
Radiation Dose	A general term used to refer to the effect on a material that is exposed to radiation. It is used to refer either to the amount of energy absorbed by a material exposed to radiation or to the potential biological effect in tissue exposed to radiation
Radiation Generating Equipment	Equipment that when turned on emits ionizing radiation
Radiation Safety Officer (RSO)	An individual with training and experience to be competent in radiation protection matters, sufficient for the type and scope of radiological operations for which this role has oversight responsibility.
Radioactive Material	Material that has the property of exhibiting radioactivity or, as a substance, emitting ionizing radiation.
Radioactive Materials License	The written authorization from a state regulatory agency (or federal agency such as the Nuclear Regulatory Commission) that allows the safe handling of radioactive materials or work with radiation generating equipment. This authorization includes specific conditions and other compliance requirements.
Reciprocity	The authorization by a regulatory agency to perform work with radioactive material in one state under the conditions of a radioactive materials license issued by another state.
Registration	State requirement that service providers, installers, and/or sales register with the state as an individual or company.
Regulation	A requirement of any federal, state or other agency with applicable jurisdiction pertaining to an aspect of radiation safety.
Sealed Source	Radioactive material encased in a capsule designed to prevent leakage or escape of the material.
Sievert	The SI unit of dose equivalent; 1 Sv = 100 rem.

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**Table 4-1: Definitions and Acronyms**

Term	Definition
TEDE (Total Effective Dose Equivalent)	Combination of whole body deep dose and internal dose.
Wear Period	The time frame in which a dosimeter is required to be worn
Whole Body Dosimeter	Dosimeter worn (clipped to clothing, <u>not to a lanyard</u>) on the shirt collar at the neck or in any other location between the neck and waist in the location where the highest occupational exposure is likely to occur that measures the dose to the whole body. When a lead apron is also worn, this dosimeter must always be worn on the outside.
X-Ray	Ionizing radiation in electromagnetic form that is produced in the electron orbits of some unstable atoms or can be produced in machine by accelerating electrons into a target within a vacuum tube.

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5. ROLES AND RESPONSIBILITIES

Important: When a title of a position is listed in this procedure, it relates to that position or its equivalence.

Below are the roles and responsibilities discussed within this document.

Table 5-1: Roles and Responsibilities

Role	Responsibility
Customer	The Customer shall design and construct the room environment to meet the requirements in the Pre-Installation Manual. The customer is responsible for registering XR equipment and hiring a qualified Physicist for plan reviews and post installation surveys.
Design Center	Where required, the design center reviews State Acknowledged Shielding Plans and verifies the GE Installation drawings meet the requirements.
Director of Service (DOS)	Manager responsible for planning and organizing the field engineers in their assigned area. Responsible for ensuring that their FE's understand and comply with this program
Field Engineer (FE)	All FE's who work with radioactive materials or radiation generating machines must comply with all aspects of this program to ensure their own safety and the safety of those around them. FE's are also expected to comply with expectations of GEHC's Ionizing Radiation Protection Program as well as Licenses, registrations, Reciprocity Agreements and applicable regulations. FE's are expected to be knowledgeable of all license, reciprocity and registration conditions as well as all applicable regulations. FE's must have on hand, or be able to readily provide copies of, relevant documentation as required.
P & L EHS Leaders	The Field Service EHS Team shall be responsible for complying with the applicable provisions of this program with the aid of an appointed Element Owner (individual who is willing to be a radiation safety advocate for the zone). Both shall agree to ensure compliance of all aspects of this program and to provide the necessary guidance/education to those FE's who work with radioactive materials or radiation generating equipment.
Project Manager of Installation (PMI)	PMI's manage the schedule and resources for installations. Their duties include working with the customer to verify facility registrations, obtaining shielding plans, and submitting notifications of installation.
Quality Assurance	Verifies work instructions are implemented to meet applicable regulations.
RSO	The RSO shall monitor the implementation/adherence of this program through the aid of the Field Service EHS team (Zone Leaders). The RSO will also conduct an annual review (at intervals not to exceed 12 months) of the content and implementation of this program and all associated procedures.
Sales Account Manager	The Sales Account Manager shall be knowledgeable of appropriate regulations.
Services EHS Manager	Responsible for the overall implementation of the Radiation Protection Program (RPP). The following elements of the program will be the responsibility of the person listed below:

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Table 5-1: Roles and Responsibilities

Role	Responsibility
	<ul style="list-style-type: none"> ▪ Written Program: <u>RSO</u> ▪ Licenses/Reciprocity Agreements: <u>RSO</u> ▪ Training Program: <u>EHS Compliance Specialist</u> ▪ Training Assignments: <u>P & L EHS Leaders</u> ▪ Dosimetry Administration/Program: <u>RSO</u> ▪ Compliance with the ALARA Program: <u>RSO/FE</u> ▪ Exposure Reporting and Investigation: <u>RSO</u> ▪ Use and Control of Radioactive Materials: <u>FE</u> ▪ Radiation and Contamination Surveys: <u>FE</u> ▪ Recordkeeping: <u>RSO/Quality designate</u> ▪ Program Assessment: <u>RSO</u> ▪ State Notification Process: <u>RSO</u> ▪ State notification for Overexposures: <u>RSO</u> ▪ State Notification Compliance: <u>RSO/FE</u> ▪ Dosimetry Compliance: <u>RSO/FE</u>
Sourcing	Qualifies and approves suppliers per the purchasing controls procedure.

6. WORK INSTRUCTION

The elements of this program are comprehensive with regards to safety, compliance with state and federal regulations and records retention.

General Program Information:

- Badge Assignment: ~2500 badges are assigned
- Types of Dosimeters: Whole Body (OSL or TLD), Extremity (OSL or TLD), Electronic Dosimeter
- Dosimetry Company: NVLAP accredited dosimeter processor
- Monitoring Period: Monthly (cyclotron and radiopharmacy) or Quarterly (x-ray, CT, PET, NucMed, CAMs (1st look-BMETs))
- Licenses in seven state jurisdictions and NRC: Georgia, Louisiana, Massachusetts, New York, Tennessee, Texas, Wisconsin, NRC
- Reciprocity Agreements (twenty-seven): Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Illinois, Kansas, Kentucky, Maine, Minnesota, Mississippi, Nebraska, North Carolina, North Dakota, New Hampshire, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Utah, Virginia, Rhode Island, Washington.
- Service Provider Registrations (thirty-two): Alabama, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North

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Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Washington, West Virginia.

- **Modalities:** CAMS, CT, Cyclotron, Devices, Interventional, Nuclear Medicine, Radio-Pharmacy, X-ray, Preclinical Imaging equipment
- **License Requirements:** (1) Service equipment containing pin sources (Germanium-68 and Gadolinium-153), (2) Not licensed to possess, transport or ship radioactive materials.
- **Other Radioactive Material:** ~100 sealed sources of exempt quantities of Ba-133 used to calibrate nuclear cameras.

6.1. Licenses/Reciprocity Agreements

Licenses and Reciprocity Agreements are required to allow handling of pin sources that are possessed by customers in accordance with their license. All GEHC licenses and reciprocity agreements are to be renewed on a time frame designated by the individual states or NRC. All reciprocity agreements reference GEHC's Wisconsin License, 133-1108-01.

6.1.1. Tollgate: All reciprocity and licenses renewal dates are entered into Compliance Calendar.

6.1.2. The RSO shall:

- Identify all the states in which a license or reciprocity agreement is required to perform work with pin sources. Confirm and document states that do not require a license, reciprocity agreement, or other authorization to perform work with pin sources.
- Enter license and reciprocity due dates into GEHC Compliance Calendar six weeks prior to the actual due date.
- Initiates check requests when the Compliance Calendar reminder is received.
- Reciprocity - When the check arrives send to the agency with a cover letter explaining the purpose and include the check, copy of the Wisconsin License and GEHC State Notification Form that will be used in lieu of the state's form.

Note: All states in which we have reciprocity agreements have agreed to use the GEHC State Notification Request form for providing the required three days notice prior to service.

- Licenses – Not only are reminders generated through Compliance Calendar, the state will also send a hard copy invoice by mail. Requested checks are included with the invoice and returned via certified/return receipt.
- For each renewed license and reciprocity agreement, document a review of conditions, license application commitments and associated correspondence to identify/update program procedures to maintain compliance.
- Provide approval in writing for individuals that are trained to handle pin sources under license or reciprocity agreement per NRC or individual state license requirements.
- Ensure that the US Field Services Radiation Safety Support Central site is updated with the all documents required to be posted (see Section 6.8)

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- Send P&L EHS Leads a notice when a document has been updated/renewed.

6.1.3. The P & L EHS Leads shall:

- Be able to demonstrate access to all posted information including; licenses and reciprocity agreements, current regulations pertaining to work performed, notice to employees, any notice of violations and any response to the violation by GEHC.
- Be able to explain the provisions of posted documents and provide guidance to FE's who are in need of accessing these documents.
- Forward updated/renewed documents provided by the RSO to all effected FE's and their DOSs.

6.1.4. The DOS shall:

- Ensure that all FE's who handle pin sources are aware of the location and can demonstrate access to all posted information including; licenses and reciprocity agreements, current regulations pertaining to work performed, notice to employees, any notice of violations and any response to the violation by GEHC. Links to these documents must be kept up-to-date at all times on their desktops.

6.1.5. The FE shall:

- Place the document on their computer desktops (or carry hard copies) to all posted information including the Wisconsin Radioactive Materials License (if working under reciprocity), the state regulations in the state in which they work and the state license or reciprocity agreement in the state in which they work, notice to employees, most recent dosimetry report, instrument calibration record, NRC regulations, NRC license and any notice of violations and any response to the violation by GEHC

Note: Regulations, licenses, NOV's and responses to NOV's can be accessed and examined on the US Field Services Support Central site. Dosimetry reports are both mailed and emailed to the FE's. Survey meter calibration records can be obtained through the zone tool coordinator. Regulations, reciprocity agreements and licenses can also be accessed through PSDB (Problem Solution Database and Off-line Knowledge (OK).

6.2. State Notification of Work Under Reciprocity

Each state in which GEHC has a reciprocity agreement requires three days advanced notice (Kansas requires five) prior to handling sources of radiation in the form of pin sources (Gadolinium-153 or Germanium-68). This process also requires a radiation survey to be conducted and documented to ensure proper placement of the source and that dose limits are not exceeded. Timely postings of reciprocity agreements, licenses and regulations pertaining to the work performed are made on the US Field Service Radiation Safety Support Central site, PSDB and OK. GEHC has adopted this practice in all states, regardless of the regulatory requirements, in order to maintain documentation of all service activities of this type.

- 6.2.1. Tollgate:** State Notification Request forms are entered as a workflow in Support Central and are reviewed/approved by the RSO. Monthly reports are provided by Isotopes Products Laboratories for the delivery of new sources, which are compared to the State Notification reports to ensure compliance. Closeout of these forms is required when the service has

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concluded and the FE enters the results of the radiation survey on the form. Periodic audits are performed by generating a workflow report and noting those forms which have not been closed out.

6.2.2. The RSO shall

- Review all State Notification Request forms that have been entered into Gensuite (prior to service) to ensure compliance with the procedure.
- RSO reviews the survey results entered (post service) and if complete, closes out the workflow.
- State Notification Request forms are entered as a workflow in Support Central and are reviewed/approved by the RSO. Monthly reports are provided by Isotopes Products Laboratories, which are compared to the State Notification reports to ensure compliance.
- Enter into Gensuite an ATS finding for each that is not closed.

6.2.3. The P & L EHS Leads shall:

- Forward information regarding a state inspection to the RSO immediately.
- Be knowledgeable of documents required for inspections and where to find them

6.2.4. The DOS shall:

- Ensure that each FE that handles pin sources has taken the appropriate training (see section 6.5)
- Ensure that each FE follows the responsibilities listed in section 6.3.5.
- Ensure that in the event of an inspection, the P & L EHS Lead, and RSO are notified immediately.

6.2.5. The FE shall:

- Initiate a State Notification Request form three days in advance of routine service (i.e., source replacement or initial installation). This is accomplished by calling the State Notification Support Specialists and providing all applicable information.
- Perform service on the day specified on the form or initiate a new form (with three days advanced notice).
- Have a calibrated survey meter appropriate for the surveys to be conducted.
- Conduct a radiation survey around the machine in which the source was installed.
- Close out each State Notification Request form by documenting a radiation survey (or lack of, in the case of a de-install).
- Notify their DOS, P & L EHS Zone Leader and/or RSO if an inspector is scheduled or arrives to perform an audit.
- Ensuring that all the following documents are readily available for the inspection (see Section 6.8)
- Following the State Notification Procedure posted on US Field Service Radiation Safety Support Central site

6.2.6. State Notification Support Specialists

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- Take direct calls from the FE's and begin a Support Central workflow by entering the data on the State Notification Request form and forwarding to the RSO.
- Messages left by FE's are returned within one hour.
- Fax the State Notification Request form to the regulatory agency.

6.3. Assessment and Control of Ionizing Radiation Dose

The use of personal dosimetry is required for all personnel who are likely to receive an occupational total effective dose greater than 1 mSv (100 mrem) in a year or who are allowed to enter a high radiation area (1 mSv/hr (100 mrem/hr) or more at a distance of 30 cm from the source).

NRC and state regulations do not require monitoring if the dose to an occupationally exposed individual is not likely to exceed 10% of the regulatory limit (i.e., 500 mrem/year occupational total effective dose).

Based on previous dosimeter reports, individuals (with the exception of individuals that work on Cyclotron and Radiopharmacy equipment) are not likely to exceed 10% of regulatory limits. Personnel monitoring, however, will continue to be provided to these individuals per GE Healthcare guidance. In order to terminate occupational monitoring, a dosimeter assessment using the standard GEHC process must be completed and the individual must sign a written certification. The certification will confirm that voluntary issuance of a dosimeter is declined, operations and conditions performed will not vary from those considered in the dosimeter assessment, and the individual will notify the RSO prior to the performance of any activities not included in the dosimeter assessment.

The GEHC Ionizing Radiation Protection Program includes requirements to ensure a hierarchy of optimization of protection is used to limit occupational ionizing radiation dose. It is designed to ensure compliance with statutory limits and external standards and to direct time and resources for risk management of exposed individuals. The hierarchy is to be incorporated into the site or organization EHS Goals and Objectives and documented in the Environment Element 7 Work Plan. This is achieved by setting internal ALARA dose reference levels (see Section 8.4) and investigating, documenting, providing corrective action and reporting any dose exceedances.

Dose histories for new employees who will be occupational radiation workers are required to be obtained and the year to date dose added to their new dose history and to ensure that annual dose limits are not exceeded.

Global EHS Procedure 430.107RS (Radiation Exposure Reporting and Investigation) and 403.008RS (Fetal Monitoring Program) is used as a basis for this program.

- 6.3.1. Tollgate: Individuals are advised of their exposure to radiation via dosimetry reports sent directly to each FE at their home address and emailed for each monitoring period and an annual occupational monitoring report (Form 5 equivalent) from the Dosimetry Supplier. The Dosimetry Supplier mails an ALARA Exposure Report to the RSO when the dose exceeds 1 mSv/monitoring period. If a regulatory limit is exceeded, the RSO is immediately notified by the Dosimetry Provider via phone, email/fax, and mail.

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Annual occupational monitoring reports (Form 5 or equivalent) for each monitored FE/BMET are also provided to the RSO each year as electronic records (on a disk or network drive) from the Dosimetry Supplier. Electronic or hardcopy records of annual occupational monitoring reports are maintained indefinitely by GEHC in addition to records available through Landauer.

Doses to those FE's that provide service functions in the cyclotron modality are accessed and reviewed on the Dosimetry Suppliers website on a monthly basis by the RSO.

Each new employee completes a Personnel Radiation Dosimeter form to request a dosimeter. This form requires dose history for the current calendar year.

All dosimeter results greater than the Investigation level as well as any anomalies defined in GEHC guidance are investigated. Investigation reports, root cause and corrective actions are entered into Gensuite and tracked to completion. Internal notification of any doses in excess of the Constraint Level, Company Limit or Regulatory Limit is to be made in accordance with the GEHC EHS Escalation Policy.

6.3.2. The RSO shall:

- Ensure that requests for new dosimeters have included a dose history if applicable when previous monitoring was performed. Contact former employer to obtain these records. If records can not be obtained, obtain a written signed statement from the individual and deduct 1250 mrem/qtr for each qtr in which the records are not available from the total dose the individual is allowed to receive for that year.
- Review doses on a quarterly basis and provide the results to the P&L EHS Leads for entry into Radiation Ops Metrics in Gensuite.
- Ensure that all doses greater than the Investigation Level are investigated, documented, entered into Gensuite Measurements Reporting as both an Event and an associated corrective action as an Automated Tracking System (ATS) finding. All ATS findings are tracked to closure by the P & L EHS Lead.
- Ensure that all missing or lost dosimeters requiring a dose assignment greater than Minimal are entered into Gensuite Measurement Reporting as both an Event and an associated corrective action as an ATS finding. All ATS findings are tracked to closure by the P & L EHS Lead.
- Ensure that all dosimeter results requiring an adjustment are entered into Gensuite Measurement Reporting as both an Event and an associated corrective action as an ATS finding. All ATS findings are tracked to closure by the P & L EHS Lead.
- Make internal reports of any doses in excess of the Constraint Level, Company Limit or Regulatory Limit in accordance with the GEHC EHS Escalation Policy.
- Contact Medical Affairs immediately in cases where reported whole body doses are greater than 5000 mrem (or any other reported dose such as an intake, skin, extremity, or eye in excess of regulatory limits) to determine if other medical response or surveillance is necessary.
- Keep current on all doses, particularly in cyclotron service, to ensure that Constraint Levels are not exceeded.

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- Ensure notification of the regulatory agencies when required by phone and or written letter in accordance with each agency requirements
- Complete/document dosimetry assessments for new groups or current groups to validate the need for whole body or extremity dosimetry.
- Ensure EHS Global and legal review all written documentation that is being provided to regulatory agencies prior to sending.
- Review and/or approve any request for a GE Healthcare Constraint Level exceedance.
- Provide a signed copy, within 90 days of the end of the year, of any annual Occupational Monitoring Report (Form 5 equivalent) for those individuals whom monitoring is required by regulation (those likely to exceed 10% of the regulatory limits, (e.g. 500 whole body or 5000 mrem extremity exposure). These forms will be scanned and emailed to the FEs requesting verification of receipt. Copies of The verification and Form 5 will then be maintained by the RSO.
- Provide dosimeter reports to terminated employees upon written request within 30 days of notification.

6.3.3. The P & L EHS Leads shall:

- Lead all ALARA Investigations with support/direction of the RSO and following the 'Assessment of Anomalous or Unavailable Dose Monitoring Results' guidance document provided by Global EHS, to ensure a complete, thorough and documented review of the circumstances involved in the ALARA exceedance. This should include, as needed, the following: completion of the ALARA Investigation Letter, a review of employee work during the wear date in question, employee interview, review of doses received by co-workers performing similar work functions, equipment specifications (if the badge was left in a room during calibrations/procedures), a review of the FE's work practices and any other circumstances identified by the FE that warrant consideration.
- Ensure closure of the entire investigation process within 30 days.
- Review the FE's/BMET's response to all ALARA Investigation Letters and then enter an Event/Measurement into Gensuite within 24 hours of receipt (see P & L EHS Leads-Measurement and ATS Entry Guidance Instructions).
- Attach an ATS finding to the Event/Measurement (see P & L EHS Leads-Measurement and ATS Entry Guidance Instructions), if the results of the investigation indicate a non-occupational exposure,
- Understand the GEHC Personal Dosimetry Procedure, GEHC Radiation Safety FAQs, the JSA for Badge Returns and the "How to Return a Dosimeter" video.
- Enter ATS findings into Gensuite for those people who did not return their dosimeters by the due date of the 21st of the next monitoring period (for example, 1st qtr 2010 badges must be received by Landauer by the 21st of April 2010). Require disciplinary action per the EHS PDP for those individuals whose dosimeters have been received by Landauer by the 21st of the next monitoring period.
- Provide routine communications to the field on dosimeter responsibility

6.3.4. The DOS shall

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- Ensure that all FE's/BMET's required to wear dosimetry have completed radiation safety training and have ordered/received this dosimetry prior to engaging in work with ionizing radiation. Ensure that any FE changes in modality or work assignments are permitted only after appropriate training and dosimetry is issued as required.
- Ensure that FE follows the requirements listed below.
- Understand that the GEHC Constraint Level can be exceeded only where prior justification has been made by the site or operations manager, documented and agreed with the Radiation Safety Officer and the GE Healthcare Global Nuclear Safety Manager. That justification will include but not be limited to:
 - Identification of the root cause of any elevated precursory dose that led to the total approaching the Constraint Level;
 - A risk/benefit analysis of the situation if the Constraint Level was not to be exceeded;
 - A description of the additional control measures that will be applied to the work of the individual (or group of individuals); and
 - An agreed upper bound to the amount by which the Constraint Level may be exceeded.

6.3.5. The FE/BMET shall:

- Wear the dosimeter when required, worn with label facing outwards, clipped to clothing, not to a lanyard on the shirt collar at the neck or in any other location between the neck and waist in the location where the highest occupational exposure is likely to occur and that measures the dose to the whole body.
- Never leave a dosimeter in a room during procedures, calibrations, etc.
- Wear the dosimeter outside any protective apron or garment.
- When traveling, place the dosimeter with carry-ons. NEVER place with checked luggage.
- Return the dosimeter when the new dosimeter arrives or, at the latest, by the first of the new wear period.
- Return badges with the associated control via ground shipment only.
- Follow the GEHC Personal Monitoring Procedure
- Review/understand the document Radiation Safety FAQs.
- Follow the JSA for badge returns and the "How to Return a Dosimeter" video
- Complete a Personal Radiation Dosimetry Form immediately upon a change of address or a lost dosimeter.
- Notify the P & L EHS Lead or RSO immediately after realizing that a badge may have been exposed while left in a room during scans, calibrations, etc.
- Be responsible for the location of badges at all times: both when wearing the dosimeter as required and when not wearing the dosimeter.
- Respond immediately to ALARA Investigation Letters and actively participate in an investigation when a dose exceeds the GEHC ALARA Investigation Level.
- Understand that the GEHC Constraint Level can be exceeded only where prior justification has been made by the site or operations manager, documented and agreed with the Radiation Safety Officer and the GE Healthcare Global Nuclear Safety Manager. That justification will include but not be limited to:

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- Identification of the root cause of any elevated precursory dose that led to the total approaching the Constraint Level;
 - A risk/benefit analysis of the situation if the Constraint Level was not to be exceeded;
 - A description of the additional control measures that will be applied to the work of the individual (or group of individuals); to manage additional dose for the current year and to prevent a recurrence in subsequent years and
 - An agreed upper bound to the amount by which the Constraint Level may be exceeded.
- Make every attempt to acquire prior dose history if applicable
- Not perform any work with or around radioactive materials or radiation producing machines until the required radiation safety training is completed and dosimetry has been ordered and received.
- Notify your P&L EHS Lead, manager, or RSO immediately if the dosimeter for the new wear period is not received by the first day of that period.
- Not wear their dosimeter for at least 24 hours after a medical, nuclear stress test
- Never expose themselves to the useful x-ray beam for training or service purposes

6.4. Radiation Incident Communications

Field Service Engineers (FEs), Directors of Service (DOS) and P&L EHS Leads are responsible to immediately report to the Radiation Safety Officer (RSO) all incidents and unusual situations involving radioactive materials or radiation generating machines.

6.4.1. RSO Shall

- Make timely and proper notification to GE Healthcare Global EHS in accordance with the GE Healthcare EHS Escalation Policy.
- Engage other internal functions that also require prompt communication of events, in consultation with GE Healthcare Global EHS, such as Legal, Communications, Crisis Management and Medical Affairs, as necessary.

6.4.2. Below are examples of circumstances in which *immediate* internal notification to the RSO is required:

X-Ray Generating Machines

- Accidental Radiation Exposure to X-Rays to yourself or others
- Suspected loss, theft of GE Owned/Controlled Radiation Machines

Radioactive Materials/Cyclotrons

- Radioactive Material Spills
- Personal Contamination
- Suspected Damage to Sealed Radioactive Material Sources
- Suspected exceedances of ALARA Levels

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Please be prepared to provide information to the Radiation Safety Officer who will assist with follow-up investigations and corrective actions.

6.5. Radiation Detection Devices

It is a regulatory requirement in every state that a radiation survey is conducted and documented when pin sources are placed into a machine. This survey must be conducted with either a calibrated meter assigned to the FE or the customer's meter (also calibrated). Meters must be calibrated within intervals not to exceed 12 months. The radiation survey is a part of the State Notification Request form initiated by the FE prior to pin source handling. This survey must be documented with all information required on the State Notification Form and reviewed and approved by the RSO prior to closing out the workflow.

All individuals trained and allowed to enter an unshielded cyclotron's bunker or shielded cyclotron's room with unshielded activated components must wear an electronic dosimeter in addition to their assigned dosimeter.

All FE's trained to perform service on a cyclotron are required to order and maintain an annually calibrated survey meter and an electronic dosimeter in order to keep real-time exposure records to avoid exceeding GEHC ALARA Dose Reference Levels.

- 6.5.1. Tollgate: Each State Notification Request form that is initiated by an FE contains a section in which to document a radiation survey. When this information is completed, the form is reviewed and approved by the RSO. Routine audits are conducted of all State Notification Forms to ensure this closure. Any forms that remain open due to a lack of survey or inadequate survey information is entered into Gensuities as an ATS regulatory finding, requiring both the FE and his manager to investigate and following all corrective actions for closure verification by the RSO.
- 6.5.2. The FE shall follow the Americas Region Calibration Work Instruction, DOC0604065, which is employed to account for all equipment that has a radiation safety functional requirement.

6.6. Training – Radioactive Materials

The GE Healthcare Ionizing Radiation Protection Program includes requirements for initial and annual radiation safety training. State regulations require that each person who works with/around radioactive materials (pin sources, cyclotron components, calibration sources) has been trained according to their requirements that include but are not limited to the topics listed in Section 8.2. For reciprocity agreements, the training must be commensurate with Appendix J, WISREG 1556, Volume 7, July 2003 and for licenses Appendix J of NUREG 1556, Vol 7, Dated 12/99. This training is provided on an annual basis and cannot exceed 12-month intervals.

In addition to initial and annual Radiation Safety Training, a State Notification Training/Survey Meter course is required to be taken annually for pin source handling. (1) State Notification Training includes the regulatory requirements for notification of pin source handling. (2) Surveys are required after pin sources have been installed to ensure that regulatory radiation levels are not exceeded. The training includes the proper use of the survey meter, location in

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which the documentation is made, and allowable regulatory dose rates at 6 inches and 12 inches from the source housing.

In addition to initial and annual Radiation Safety Training, individuals working in cyclotron bunkers and rooms with unshielded cyclotron components must complete additional training related to radiation hazards in a cyclotron environment.

6.6.1. Tollgate: Required radiation training courses are listed in the EHS Training Matrix listed on the EHS Support Central site. These courses are assigned annually and are tracked via Training Tracker to ensure completion

6.6.2. The RSO shall:

- Ensure training components include those specified in the GEHC Ionizing Radiation Protection Program, applicable regulations and in our reciprocity agreements and licenses (see the overview above).
- Ensure training components for cyclotron and radiopharmacy are sufficient to control hazards inherent in those operations.
- Ensure training components for nuclear medicine imaging involving radioactive sources are sufficient to control hazards inherent in those operations.
- Ensure annual review of training content and implementation and update as necessary.
- In states where required, ensure that each FE has a Training Validation Form signed by the RSO.
- Review/ensure that survey results accompany all State Notification Request forms where service has been conducted involving pin source handling.

6.6.3. The P & L EHS Leads shall:

- Ensure that the required radiation training courses are assigned and completed prior to work with radioactive materials and on an annual basis or as otherwise required.
- Provide training reports on request, meeting notification timelines specified by state or NRC.

6.6.4. The DOS shall:

- Ensure that the P & L EHS Lead is aware of each FE and the modality in which he/she works.
- Ensure that appropriate training is provided prior to new assignment or change in modality or work assignments.
- Ensure that each FE has assigned to them the required Radiation Safety courses
- Ensure that any FE who changes to another modality or is trained in additional modalities has had the proper Radiation Safety courses assigned to them and has completed them prior to performing work with or around ionizing radiation.

6.6.5. The FE shall:

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- Complete all required courses, on-time, prior to working with or around ionizing radiation and all assigned annual refresher courses.
- Have ready access to documentation of training and be able to provide copy upon request.

6.7. Training – General X-Ray Devices

- 6.7.1. Tollgate: Required radiation training courses (pertinent to radioactive materials) are listed in the EHS Training Matrix listed on the EHS Support Central site. These courses are assigned annually and are tracked via Training Tracker to ensure completion. Required radiation training courses (pertinent to x-ray) are listed in the Field Training Matrix. These courses are tracked via MyLearning to ensure completion
- 6.7.2. Per State service provider registrations, FE's and/or Sales personnel shall meet the experience and training requirements of the state prior to performing service in that state.
- 6.7.3. Training and experience requirements are defined in each state regulation and application process and summarized in Appendix 8.1
- 6.7.4. Before FE's are permitted to perform service, the DOS shall verify that the individual state training requirements have been met as well as applicable requirements in the GEHC Ionizing Radiation Protection Program.

6.8. Inspections

The regulatory agencies with jurisdiction over GEHC where GEHC has a registration, reciprocity agreement or license will periodically perform inspections. The agency may or may not notify GE Healthcare of an inspection in advance. These inspections may be record based, field based or both. Records typically reviewed by inspectors include, but are not limited to:

- Meter calibration records
- Dosimetry reports
- State specific license or reciprocity agreement
- State specific regulation
- State specific Notice to Employees
- RSO Training authorization-for those working under reciprocity agreements
- Wisconsin License (if working under a reciprocity agreement)
- Any notice of violations and any response to the violation by GEHC in accordance with state or NRC requirements and any additional state approvals received.
- NRC license
- NRC regulations
- Training history (for Radiation Safety)
- State registration

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All personnel who may be involved in an inspection must understand the relevant regulatory requirements, be prepared to demonstrate compliance and make immediate internal notification as required when an inspection takes place.

- 6.8.1. Tollgate: Inspection requirements are included in the State Notification course. All necessary documentation is accessible through the GEHC Radiation Safety SC site, the HHS SC site, DVMT, Training Tracker and Dosimetry Supplier.
- 6.8.2. The Quality Leader shall:
- Ensure that all pertinent regulatory documents required to be posted (ie, x-ray regulations, notices to employees, x-ray registrations, Ionizing Radiation Program, Notices of Violations) are accessible, updated and located on the HHS SC site.
- 6.8.3. The RSO shall:
- Ensure that all pertinent regulatory documents required to be posted (i.e., radioactive material regulations, notices to employees, licenses, registrations, reciprocity agreements, Ionizing Radiation Work Plan, Notice of Violations) are accessible, updated and located on the GEHC Radiation Safety SC site.
 - Ensure that all P & L EHS Leads are aware of the documents necessary for an inspection and their location.
 - Be prepared to readily provide additional information requested by an inspector.
 - Arrange for a backup in the event the RSO is not available to provide support in the event of an inspection.
 - Participate in any discussions with the inspector, particularly close-out, to the extent practicable.
 - Document inspections in Gensuite within 24 hours of notification.
 - Make internal notifications in accordance with the GE Healthcare EHS Escalation Policy.
 - Respond to all findings made in writing by the regulatory agency as a result of the inspection. Any written response requires review by Global EHS and Legal prior to submittal.
 - If applicable, enter corrections to findings into Gensuite ATS and track to closure.
- 6.8.4. The P & L EHS Leads shall:
- Notify the RSO as soon and they become knowledgeable of an inspection in progress or if a prior notice of inspection is received.
 - Ensure that they are knowledgeable about the type and location of documents needed during an inspection.
 - Be able to obtain/provide training reports or other documents to the RSO as requested.
- 6.8.5. The DOS's shall:
- Notify the RSO and P & L EHS Lead as soon and they become knowledgeable of an inspection in progress or if a prior notice of inspection is received.
 - Ensure that they are knowledgeable about the type and location of documents needed during an inspection.

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- Be able to obtain/provide training reports and records of experience to the RSO as requested.

6.8.6. The FE shall:

- Notify the RSO, P & L EHS Lead and DOS immediately once an inspector arrives to perform an inspection.
- Ensure that the customer is present during the inspection
- Ensure that they are aware of the required documents, the location of these documents and how to readily access the documents.
- Ensure that they are knowledgeable of their radiation doses, how they are notified of their dosimeter results, and how to obtain their records.
- Ensure that they know how to obtain their survey meter calibration records.
- Ensure that they are wearing their dosimeter, label facing outwards, clipped to clothing and not to a lanyard.
- Ensure that they are aware that they are working under the Wisconsin Radioactive Materials License when working in other states under a reciprocity agreement.
- Ensure that they have accessibility to all posted information including the following:
 - Meter calibration records
 - Dosimetry reports
 - State specific license or reciprocity agreement
 - State specific regulation
 - State specific Notice to Employees
 - RSO Training authorization-for those working under reciprocity agreements
 - Any notice of violations and any response to the violation by GEHC in accordance with state or NRC requirements and any additional state approvals received.
 - NRC license
 - NRC regulations
 - Training history (for Radiation Safety)
 - State registration
- Ensure that they have and use remote handling devices with which to handle the radioactive pin sources.
- Ensure that they have the RSO signed Training Validation Form.
- Ensure that they can verify the last date they took Radiation Training (and can print a certificate, if requested)

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6.9. Room Shielding Requirements

Per the table in Appendix 8.1, some states require the Installer to verify the customer has a state acknowledged approved X-Ray shielding plan. In Arkansas, this requirement applies only to radiation machine installations in new construction rooms. If an X-Ray generating system had been installed in the room prior, the shielding plan is not required for the State of Arkansas. Federal Facilities are excluded from this requirement, i.e. VA hospitals, military bases, Federal correctional facilities.

- 6.9.1. Tollgate: The GEHC installation drawings shall meet the requirements of the state acknowledged shielding review. Shielding plans shall be entered in eOM prior to equipment shipment.
- 6.9.2. The PMI shall verify the customer has the appropriate approvals by State and document the approval in the Notice to Proceed System and eOM.
- 6.9.3. The Installation Services Design Center shall review the GEHC final drawing to verify that the drawing meets the requirements of the physicist's plan review.
- 6.9.4. For Lunar BMD product, the OTR Project Manager shall verify the install plan matches the state acknowledged shielding plan. The field engineer shall verify the customer's site matches the install plan in Arkansas (new construction only), District of Columbia, North Carolina and South Carolina, and Washington.
- 6.9.5. FE's shall install per the GEHC supplied site drawing.
- 6.9.6. The FE's shall work with customer during the installation to secure the exposure control, if required by state regulations.
- 6.9.7. In South Carolina, the FE's shall verify a shielding plan or post installation survey request has been approved by the state prior to replacing the certified X-ray control or generator.
- 6.9.8. In South Carolina, the Customer shall install door interlocks on the CT gantry room doors. The FE shall connect the interlock wiring at installation.

6.10. Facility and X-Ray Registration

Per the table in Appendix 8.1, some states require the site to be registered prior to the start of an installation or service event. Federal Facilities are excluded from this requirement, i.e. VA hospitals, military bases, Federal correctional facilities.

- 6.10.1. Tollgate: At installation, the Facility Registration Number shall be obtained from the customer and entered in NTP prior to Installation. The FE shall enter the facility registration number on the FDA 2579 form. The FE shall enter "GOVNT" or "First Install" on the FDA 2579 if the registration number is not required for Federal Facilities or the first install in Illinois or Texas.
- 6.10.2. The PMI or designee shall enter the Facility Registration number in NTP and communicate the number to the Field Engineer. If this is the first radiation machine being installed at the site in the State of Illinois or Texas, this requirement does not apply, and the PMI shall enter "1st Install" in NTP.

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- 6.10.3. The Field Engineer shall complete the FDA 2579 DOC0424451 for radiation emitting products (i.e. X-Ray systems, CT systems, PET/CT systems & Nuclear X-Ray systems) within 3 days of the Installation and Calibration completion date. The Field Engineer shall include the Facility Registration number on the 2579 and Service Record where appropriate.

6.11. Pre-Installation State Notices

Texas x-ray service registration requires a notification be provided to the State at least three days prior to the start of an installation. Federal Facilities are excluded from this requirement, i.e. VA hospitals, military bases, Federal correctional facilities.

- 6.11.1. Tollgate: The state shall be notified prior to the install start date and documented in NTP.
- 6.11.2. The PMI or designee shall provide the Texas Department of Health the notification and document the communication in NTP or eOM.

6.12. FE Registrations

The FE Registration process is defined in the State Registration for Radiation Service Work Instruction, DOC0465810.

- 6.12.1. Minnesota requires that the FE Registration number be documented as part of the service event. FE's performing work in the state of Minnesota shall document their registration number on the service dispatch.
- 6.12.2. Alabama, Colorado, Minnesota, and Nebraska require the FE's to be registered prior to performing service. Arkansas, North Carolina, and South Carolina require FE's to be registered at the time of GEHC Registration renewal. The DOS shall notify QA of new FE's working in their state.
- 6.12.3. QA shall register the FE's with the state, notify the FE and DOS of the registration, and maintain documentation of the registrations.

6.13. GEHC Service Registrations

The GEHC Service Registration process is defined in the State Registration for Radiation Service Work Instruction, DOC0465810.

- 6.13.1. QA shall register GEHC Service with the state (refer to Appendix 8.1) and ensure timely renewals and maintain documentation of the registration applications, registration certifications, and related correspondence.
- 6.13.2. Current copies of registration certificates shall be posted on the HHS Support Central.
- 6.13.3. For each renewed registration, document a review of any new conditions and associated correspondence expectations and identify/update procedures to maintain compliance.
- 6.13.4. All documents, including a copy of the GEHC Service Registration and must be maintained inspection ready and provided upon notification.

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6.14. Consignment and Demo Units

NOTE: The customer site is the State registered site for consignment and demo units. GEHC Services does not maintain site registrations.

- 6.14.1. The Commercial Operations team following DOC0684745 manages consignment units. Consignment units shall follow all new equipment order requirements for Equipment Registration, Facility Registration, and Room Shielding requirements
- 6.14.2. Modality marketing manages the demo units. The marketing manager shall register the XR producing demo units in the State of Wisconsin and maintain an up-to-date inventory of units registered. The marketing manager shall notify the state in which the demo unit will be used prior to the unit be shipped to their state per the state's notification requirements.

Modality marketing managers shall register the individual unit to be registered in the state, if required in Appendix 8.1. In addition, if the demo unit remains at the customer location for longer than the notification period or greater than 30 days, the modality marketing manager shall register the unit per the state's requirement.
- 6.14.3. FE's shall support installation calibration requirements for consignment and demo units.
- 6.14.4. GEHC applications personnel shall be present at the customer sites for demo units.

6.15. Room Moves

An equipment room moves is when a customer relocates an existing x-ray producing device from one location to another location, either within the same site or to a new location.

- 6.15.1. The DOS or FE shall complete a request to inform the PMI that support is needed for a room move. The DOS or Field Engineer may perform the activities of the PMI.
- 6.15.2. In the cases where the PMI is supporting the room move, the PMI shall maintain a customer file similar to a new install. The customer file shall be noted as a system ID rather than a new install Global Order Number. The Service team shall do a physical audit of the equipment prior to the de-installation and verify the equipment configuration. This information shall be communicated to the PMI for the customer file and before a preliminary drawing is completed.
- 6.15.3. The Field Engineer shall do a physical audit of the equipment prior to the de-installation and verify the equipment configuration. This information shall be communicated to the PMI for the customer file and before a preliminary drawing is completed.
- 6.15.4. Older equipment may not have an installation manual. In these cases, the applicable installation section in the service manuals shall be used.
- 6.15.5. The installation shall follow the same requirements for a new installation in terms of confirming customer facility registration, shielding plan approval, etc.

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6.16. Equipment Notifications

- 6.16.1. FE's are responsible for submitting the FDA 2579 form within three days of the installation completion or certified component replacement, which satisfies the state requirement for installation notification.
- 6.16.2. The HHS QA Leader shall ensure the process to transmit a copy of the FDA 2579 Form to the State and Customer.
- 6.15.3. The Customer is responsible for obtaining the needed facility and equipment registrations for their facilities and operations.

6.17. Employee Postings and Training

- 6.17.1. The RSO or QA Leader shall post all state notices to employees and current pertinent state regulations (or links) on the Radiation Safety SC site (for radioactive materials) and the HHS Support Central site (for x-ray).
- 6.17.2. Service employees shall complete annual training on state regulations.
- 6.17.3. Service employees shall meet training requirements specific to the state regulations in Appendix 8.2
- 6.17.4. Before FE's are permitted to perform service, the DOS shall verify that EHS Radiation Safety and the individual state training/experience requirements have been met.

6.18. Regulatory Designee After Major Component Change

In Ohio, a Certified Radiation Expert may designate individuals to perform fluoroscopic output measurements after major component changes.

- 6.18.1. The FE shall provide the Radiation Expert qualifications if required.
- 6.18.2. The FE shall document the following and forward to the Radiation Expert:
 - Test results
 - Technique factors
 - FE Name
 - Date Measurements taken

6.19. Records Retention, Program Review and Compliance

- 6.19.1. Records such as listed in Section 8.3 must be retained per state and NRC regulations RSO shall:
 - Be responsible to ensure that all Radiation Safety Program records described in Section 8.3 are retained for the indicated period of time, but may not have physical custody of them.
 - Annually review the program and all written documents related to this program and maintain documented evidence of the review.

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- Conduct annual team meetings with all P&L EHS Leads to review the current program updates.

6.19.2. P & L EHS Leads shall:

- Attend annual meetings by the RSO to review current program updates into their annual E7 program review and assessment
- Perform an E7 Program review and assessment annually

6.19.3. Service and QA shall follow the Quality Record Retention Procedure Document Retention DOC0371392.

6.20. Notices on Nonconformance or Violation

6.20.1. The EHS Site Lead shall enter any NON/NOV issued into Gensuite within 24 hours of receipt. The QA Leader shall enter any NON/NOV into Powersuite or Trackwise for reasons relating to x-ray installation, service, or registrations into Powersuite or Trackwise. Any corrective actions will be entered into ATS by the EHS Site Lead and tracked to completion.

6.20.2. Internal notifications are made in accordance with the GE Healthcare EHS Escalation Policy.

6.19.3 NON/NOVs and any response by GEHC to the NON/NOV issued for reasons other than those relating to x-ray installation or registrations must be posted by the RSO on the Radiation Safety SC site within the state or NRC regulatory timeframe. NON/NOVs issued for reasons relating to x-ray installation or registrations must be posted by the QA Leader on the HHS SC site. Copies are to be issued to and maintained by FE's operating under jurisdiction of the license, registration or regulation cited by the NON/NOV.

6.21. De-Installation Notifications

6.21.1. Where required, the Mechanical Installation team or Field Engineer shall complete a de-install notification for systems being removed from service.

6.22. Inspection Notification (X-Ray Generating Equipment)

6.22.1. Upon notification of a State, FDA, or other external audit, the FE shall notify the DOS or Zone QA Manager of the inspection.

6.22.2. The QA Manager, RSO, or DOS shall obtain the records that may be required for the inspection.

Possible records may include:

- Dosimetry Reports
- Service Records
- Installation Records
- Ionizing Radiation Protection Program
- Registrations
- State and NRC Regulations

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- Training Records
- Notice to Employees
- Other posted information (NONs)

6.22.3. The FE's shall know how to access State Registrations, Notice to Employees, Past Non Conformances, and other Employee notifications on the HHS Support Central Site under State Requirements.

http://supportcentral.ge.com/products/sup_products.asp?prod_id=16442

7. OWNERSHIP, REVISION HISTORY, AND EFFECTIVE DATE

7.1. Document Owner

Radiation Safety Officer, Americas Service

7.2. Authorization

See MyWorkshop for approval signatures.

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7.3. Revision History

Table 7-1: Revision History

Revision Number	Reason for Change or Change Control Number	Document Author
01	Initial release in MyWorkshop.	Tracy Gale
02	Minor spelling and typographical updates. Added South Carolina requirement for CT Gantry room interlocks. Added South Carolina requirement for shielding review for x-ray control or generator replacement. Updated FE Registration requirements. Added notes to section 6.3.3 and 6.3.5.	Tracy Gale
03	Add CO to shielding plan review states. Removed 2579 form processing from the referenced documents. Clarified customer registration number for federal facilities and first installations. Added JSA's for cyclotron, chemistry boxes, BMD, Fluoroscopy, Ionizing Radiation, and Isotopes. Added reference to US Service Radiation Policy. Updated reciprocity states. Add clarify on typical inspection records.	Tracy Gale

7.4. Effective Date

Table 7-2: Effective date

Site	Effective Date	Periodic Review
GEHC Americas Service - US	Per MWS	January 2012

8. APPENDIX

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8.1. State Requirements

State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
Alabama	X	2 days			Fixed 30"		FE Registration	
Alaska					Operator to remain in protected area			
Arizona	X	3 days						
Arkansas	X	2 days		New Construction Only	Operator to remain in protected area	X	FE Registration	Reciprocity
California					Operator to remain in protected area			Reciprocity
Colorado	X	3 day notices not to exceed 180 days. Form R-200 Documentation present at the work site: 1) Registration 2) State authorization 3) State regs 4) Documentation machine meets		Confirm plan completed by the Physicist. Plan not reviewed by the state.	Operator to remain in protected area	X	FE Reg Training per regulations	Reciprocity

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State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
		manufacturer specs 5) For mammo, a copy of the certificate, QC records, personel records, physicist survey.						
Delaware	X	2 days			Fixed	X	FE Training per regs	
District of Columbia	X			X		X		Reciprocity
Florida	X	10 days Registration Fee Notice of removal			Fixed	X		Reciprocity
Georgia		5 days			Operator to remain in protected area	X		License
Hawaii	X	7 days	X		Operator to remain in protected area	X		
Idaho	X	5 days 180 days max			Fixed			
Illinois	X		Yes, Note first		Fixed			Reciprocity

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State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
			install					
Indiana		2 days			Fixed	X		
Iowa	X	3 days			Fixed	X		
Kansas		5 days			Fixed			Reciprocity
Kentucky	X	2 days	X		Fixed			Reciprocity
Louisiana	X	3 days			Fixed 39"	X		License
Maine	X	2 days			Fixed	X		Reciprocity
Maryland	X	3 days			Operator to remain in protected area	X		
Massachusetts	X	10 days			Fixed 40"	X		License
Michigan		2 days			Operator to remain in protected area	X		
Minnesota		3 days			Fixed 39"	X	FE Registration include on SVC record	Reciprocity

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State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
Mississippi	X	3 days			Fixed	X		Reciprocity
Missouri		4 days			Operator to remain in protected area			
Montana		2 days			Operator to remain in protected area			
Nebraska	X	2 days			Fixed	X	FE Registration	Reciprocity
Nevada	X				Fixed	X		Reciprocity
New Hampshire	X	3 days				X		Reciprocity
New Jersey						X		
New Mexico	X	2 days			Fixed	X		Reciprocity
New York	X				Operator to remain in protected area			License
North Carolina	X	5 days		X	Fixed	X	FE Registration	Reciprocity
North Dakota	X	3 days			Fixed	X		Reciprocity

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State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
Ohio	X	>30 days in state, notification				X		Reciprocity
Oklahoma					Operator to remain in protected area			Reciprocity
Oregon	X	2 days <30 days			Fixed 40"	X		Reciprocity
Pennsylvania	X	2 days <60 days			Fixed	X		Reciprocity
Rhode Island	X	2 days <180 days	X		Fixed	X		Reciprocity
South Carolina	X	2 days <180 days	X	X	Fixed 40"	X	FE Registration	Reciprocity
South Dakota		10 days				X		
Tennessee	X	3 days Form RHS 8-4			Fixed	X		License
Texas	X		Yes, Note first install					License
Utah	X	3 days			Fixed 40"	X		Reciprocity

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State	State Service Provider Registration	Consignment Notification	Facility Registration Confirmation	Shielding Review	Fixed Exposure Control	De-Install Notification	FE/Sales Registration and Training	Registration License
Vermont								
Virginia		2 days			Fixed	X		Reciprocity
Washington	X	3 days	X	X	Fixed 40"	X		Reciprocity
West Virginia	X	2 days			Operator to remain in protected area	X		
Wisconsin		2 days			Operator to remain in protected area			License
Wyoming								

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8.2. Training Content for EHS Services Radiation Safety

General Information:

A. Radiation Safety

1. Radiation vs contamination
2. Internal vs external exposure
3. Biological effects of radiation
4. ALARA concept
5. Use of time, distance and shielding to minimize exposure

B. Regulatory requirements (as applicable)

1. RSO
2. Material control and accountability
3. Personnel dosimetry
4. Radiation safety program audits
5. Transfer and disposal
6. Record keeping
7. Surveys
8. Postings
9. Labeling of containers
10. Handling of reporting of incidents or events
11. Licensing and inspection
12. Need for complete and accurate information
13. Employee protection
14. Deliberate misconduct

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8.3. Retention Requirements

- A. The following records must be kept indefinitely or at a minimum, for the duration of the license, registration or reciprocity agreement and can be found in the locations listed.
 - 1. Surveys (for dose assessment) – Workflows on Radiation SC site
 - 2. Annual exposure records (Form 5 or equivalent) histories – Dosimetry Supplier + electronic copy at home office files
 - 3. Any calculation of dose – resulting from emergencies, etc. - Gensuite
 - 4. Radiation safety incidents/correspondence, etc. – Logged in Gensuite
 - 5. RAM License and amendments – Radiation Safety SC site
 - 6. Overexposure investigations - Gensuites
 - 7. Letter, correspondence with NRC or state regulatory agencies – home office files + attachments to events in Gensuite, as applicable
 - 8. Fetal monitoring records – Dosimetry Supplier
 - 9. Current State Radiation Machine Service Provider Registrations – HHS Support Central
- B. The following records must be kept for 5 years or the time between inspections; whichever is greater.
 - 1. Radiation detection equipment calibration records - DVMT
 - 2. Surveys – Workflows on Radiation SC site
 - 3. ALARA records - Gensuites
 - 4. Training records – My Learning or Training Tracker
 - 5. Monthly/Quarterly monitoring period reports - Dosimetry supplier
 - 6. Internal audit program results - Gensuite

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8.4. Ionizing Radiation Dose Management and Reference Levels

Dose Limit

This is a numerical reference point for annual effective or equivalent radiation dose, not to be exceeded for any reason in normal operations ('Normal' in this context means non-accident /incident situations). It is either the limit currently recommended by the International Commission on Radiological Protection (ICRP) or the limit established by the local agency of jurisdiction, whichever is lower. Separate limits are established the same way for dose to the whole body, skin, extremities, lens of the eye, and dose to the abdomen of pregnant employees.

The Dose Limit is reviewed annually and promulgated at the business level as part of the GE Healthcare EHS Goals and Objectives.

Constraint Level

This is a reference level against which results of occupational monitoring can be measured by sites, organizations and at the business level to consider whether reasonable or practical efforts are effective to reduce or maintain doses at a level that is ALARA. In order to help drive continuous improvement, this is the level of annual radiation dose that can be exceeded *only* where prior justification has been made by the site or operations manager, documented and agreed with the Radiation Safety Officer and the GE Healthcare Global Nuclear Safety Manager. That justification will include but not be limited to:

- identification of the root cause of any elevated precursory dose that led to the total approaching the Constraint Level;
- a risk/benefit analysis of the situation if the Constraint Level was not to be exceeded;
- a description of the additional control measures that will be applied to the work of the individual (or group of individuals); and
- an agreed upper bound to the amount by which the Constraint Level may be exceeded.

The Constraint Levels are set at the GE Healthcare EHS business level at a value below the relevant Dose Limit for different sites and organizations. They are based on historical data for the relevant radiological operations. The objective of a Constraint Level is to place a ceiling on values of individual dose that is considered acceptable in the process of optimization of protection. They are reviewed annually and promulgated as part of the GE Healthcare EHS Goals and Objectives.

Constraint Levels for dose to the whole body, skin, extremities, lens of the eye, pregnant employees and to the abdomen of pregnant employees are standard for most operations within GE Healthcare. However, there may be some variation due to the unique challenges associated with certain operations.

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Investigation Levels

GE Healthcare has established a two-tier system of Investigation Levels that are intended to prompt an investigation of the cause of results that exceed the level for a particular exposure period. They are also used to ensure compliance with applicable limits and as a mechanism to help achieve the goal of the Constraint Level.

A Standard Investigation Level for whole body dose is set at the business level for all GE Healthcare operations. The Standard Investigation Level is set at 1 mSv (100 mrem) dose per monitoring period.

A. U.S. and State Regulatory Limits for Adults

- | | | |
|------------------------------------|---|--|
| 1. Total Effective Dose Equivalent | - | 5,000 mrem/year (50 mSv)
(Whole Body - Deep Dose) |
| 2. Shallow Dose | - | 50,000 mrem/year (500 mSv)
(Skin - Extremities) |
| 3. Lens of the Eye | - | 15,000 mrem/year (150 mSv) |

B. Minors (less than 18 years of age) - 10% of above amounts for adults

C. GE Healthcare ALARA Program Levels

Dose Limits:

- | | | |
|--------------------------------------|---|---|
| 1. Total Effective Dose Equivalent | - | 2,000 mrem/year (20 mSv) |
| 2. Shallow Dose (skin/extremities) | - | 50,000 mrem/year (500 mSv) |
| 3. Lens of the Eye | - | 15,000 mrem/year (150 mSv) |
| 4. Dose to Declared Pregnant Worker: | | 50 mrem (0.5 mSv) per month not to exceed 100 mrem (1 mSv) per term |

Constraint Levels (corresponding to ALARA Level II):

- | | | |
|--------------------------------------|---|---|
| 1. Total Effective Dose Equivalent | - | 1000 mrem/year (10 mSv) |
| 2. Shallow Dose (skin/extremities) | - | 10,000 mrem/year (100 mSv) Skin / 25,000 mrem (250 mSv) ext. |
| 3. Lens of the Eye | - | 10,000 mrem/year (100 mSv) |
| 4. Dose to Declared Pregnant Worker: | | 20 mrem (0.2 mSv) per month not to exceed 100 mrem (1 mSv) per term |

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Investigation Levels (corresponding to ALARA Level I): 1 mSv(100 mrem) per corresponding dosimeter wear period (e.g. month or quarter)

Note: A more restrictive investigation level may be utilized by an individual site for internal dose management purposes. Any investigation in this case would not be required to be entered into PowerSuite unless the 100 mrem (1 mSv) level is exceeded per monitoring period.

D. <u>Member of the Public</u>	-	Limit is 100 (1.0 mSv) mrem/year total effective dose equivalent (TEDE).
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8.5. Standard good Practices for FE's (as examples are):

- Wear an apron or stand behind a lead shield of at least 0.25 mm lead equivalent when in the room when the beam is energized.
- Never place a body part in the useful beam.
- Never expose yourself or others for calibration or training purposes.
- Always wear personnel dosimetry and when in the room place personnel dosimetry over the apron at collar level.
- Make all radiographic exposures from a protected position.
- Wear gloves when handling unsealed radioactive materials.
- Use remote handling tools (long tongs, etc,) when handling sources of 100 uCi or greater whenever possible.
- Keep radioactive sources in their shields when not in use.
- Reduce exposure to sources of radiation as much as possible.
- Increase distance from sources of radiation whenever possible.
- Ensure all sources are returned to a secure area after use.
- Make sure that the controlled area is secure from unauthorized access when the beam is energized.
- Make sure others are not in the room when the beam is energized unless protected by 0.25mm lead minimum and they must be there.
- Ensure site loaded cassettes are not in room when making exposures.

GE Healthcare Americas Service
08 Ionizing Radiation Protection Work Instruction
DOC0438594 Rev 3

GE Healthcare



End of Document

GE Healthcare America Service Quality Form

GE Healthcare

08.131_Quality Document change and implementation Form_DOC0523289 Rev 2**Parent Document: 01.000_Management of Documentation WI_DOC0311310****Document changes**

Date:	26 January 2011	Form Initiated by:	Chad Vande Hei
Document Name:	Ionizing Radiation Protection Program Work Instruction		
Doc Number:	DOC0438594	Rev #	3
Document owner:	Tracy Gale		

☒ **Implementation plan**
Section 1
☐ **Obsolescence process**
 (Complete also section 2)

Activity	Required	Plan completion date	Description / Details of activities
Training	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Per MyLearning	Installation PMI, DOS, and FE's
Communication	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	FW 6 – 8 2011	Notification of Field Staff
Notification to training coordinator	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	FW 6, 2011	Review training material, update course ID and assign training course to affected functions.
Implementation changes	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	N/A	N/A
Identification of other Process affected (per internal references)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	N/A	N/A
Other	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	N/A	N/A
Other (Reg. Filing, Labeling, Validation etc)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	N/A	N/A

(N/A the blanks)

Document Obsolete plan

(Documents that will be discontinued and replace by another process/document).

Section 2

Description of the obsolescence	N/A
Reason for the obsolescence	N/A
Requester:	N/A

Approvals:

Process Manager/SME – See MyWorkshop

QA – See MyWorkshop

Organization Chart

US/Can Service



Richard Neff
VP & GM Americas Service

Commercial



Open
GM Northeast



Amy Freeman
GM West



Andy Pate
GM Central



Ted Dunham
GM Mid America



AnnMarie Lubert
GM Southeast



John McCarthy
GM Asset Mgmt
Professional Svcs



Bill Croft
GM Service Sales



Tom Jones
GM Nt'l Accounts



Wendy Harris
GM Education & IT
Professional Svcs



Ernie Stalvey
GM Svc Transform

MaryAnn Camacho
GM Support Ops
& Integration

Functions

National P&Ls



Fran Dirksmeier
GM CAMS & Agility



Bud DeGraff
GM Multi-Vendor



Art Larson
GM Adv Imaging
(MR/CT/MI)



Anthony Ventress
GM U/S



Rich Eng
GM
Lunar/Xray/Int

Extended P&Ls



Michelle Bockman
Service
Director LS



Pete Strimaitis
GM PACS
Service



Heiner Fuchs
GM Surgery
Service



Shawn Campbell
GM Canada Srv

Support



Paul Rades
GPRS Mgr. AM Service



Jim Keith
EHS Manager



Chris Till
Manager
Communications



Nathan Winters
CFO
AM Service



Nate Bailey
Sr. HR Mgr



Heather Bunyard
GM IT
AM Services



Sarah Hamid
Legal Counsel
Services



Ramiro Roman
GM, Service Mktg



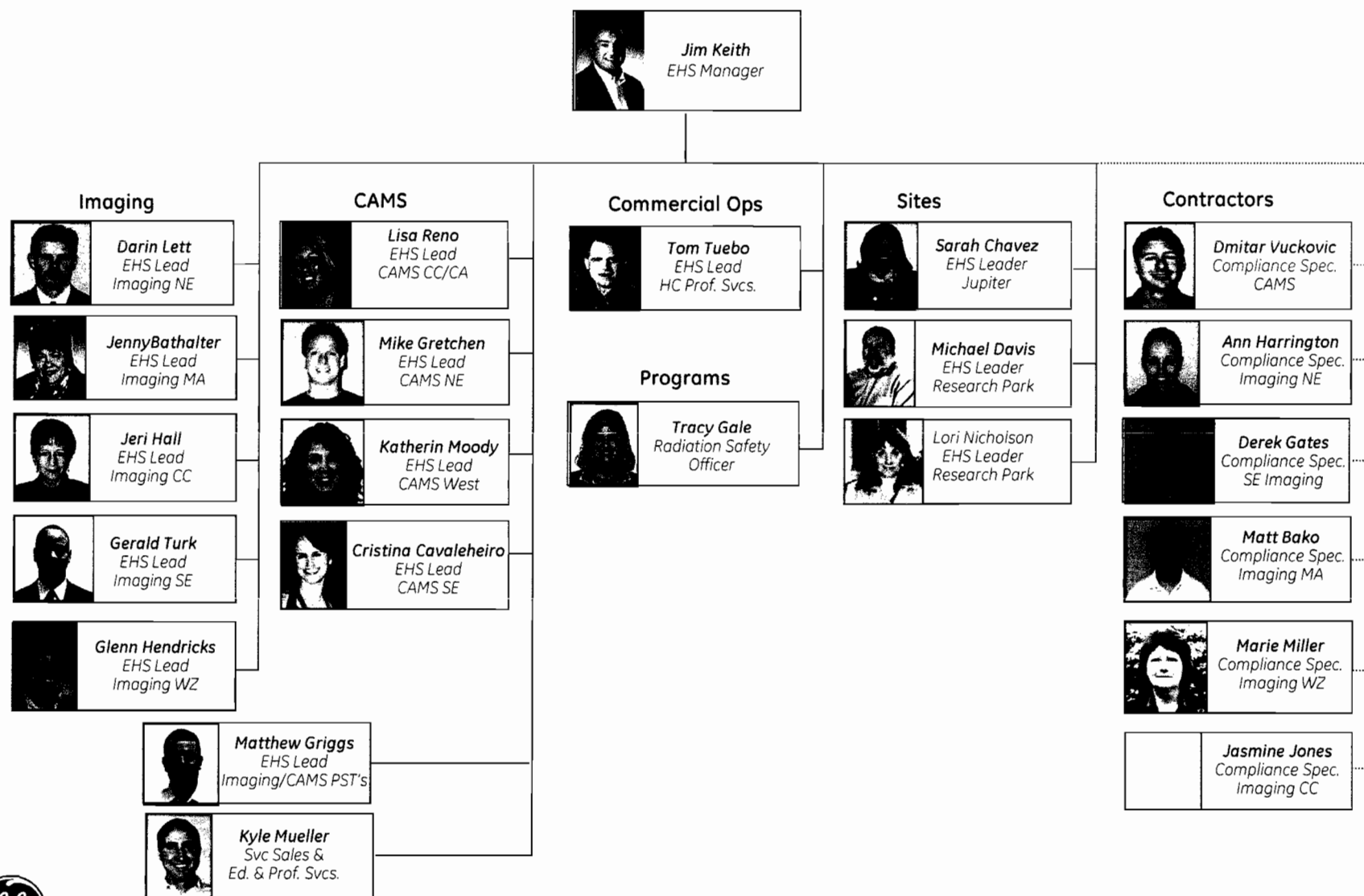
Pam Washburn
Director QA

Open
Administration

Environment, Health & Safety

Sales & Service

US Team



imagination at work

This is to acknowledge the receipt of your letter/application dated

10/26/2011, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Renew (06-32815-01)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576289.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.