

SIEMENS

Healthcare

Radioactive Materials License Amendment
Request

Pr. 3

Tuesday, May 12, 2015

Betsy Ullrich
Senior Health Physicist
US NRG Region I Office
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19464
(610) 337-5040

03038762

Subj: **Amendment to NRC Radioactive Materials License 32-35165-01**

Dear Ms. Ullrich:

Siemens Medical Solutions USA, Inc. wishes to submit the following changes to our organization and radioactive materials program with the attached supporting documents.

1. Siemens Medical Solutions USA, Inc. Management Representative is now Peter Soltani. This change is reflected in our Radiation Safety Program Organizational Chart and included as Attachment (1).
2. Changes to our Dosimetry SOP E032 Dosimetry Monitoring Procedures is submitted as Attachment (2).
3. The attached SOP, CX RC-US Authorized User Radiation Protection Program will replace the CX RC-US Working with Radioactive Calibration Sources and Radiation Generating Machines SOP. This updated procedure is included as Attachment (3).

If you have any questions or concerns about this request please feel free to contact me at (919) 208-3026 or email: matthew.daut@siemens.com. Thank you very much for your time and consideration.

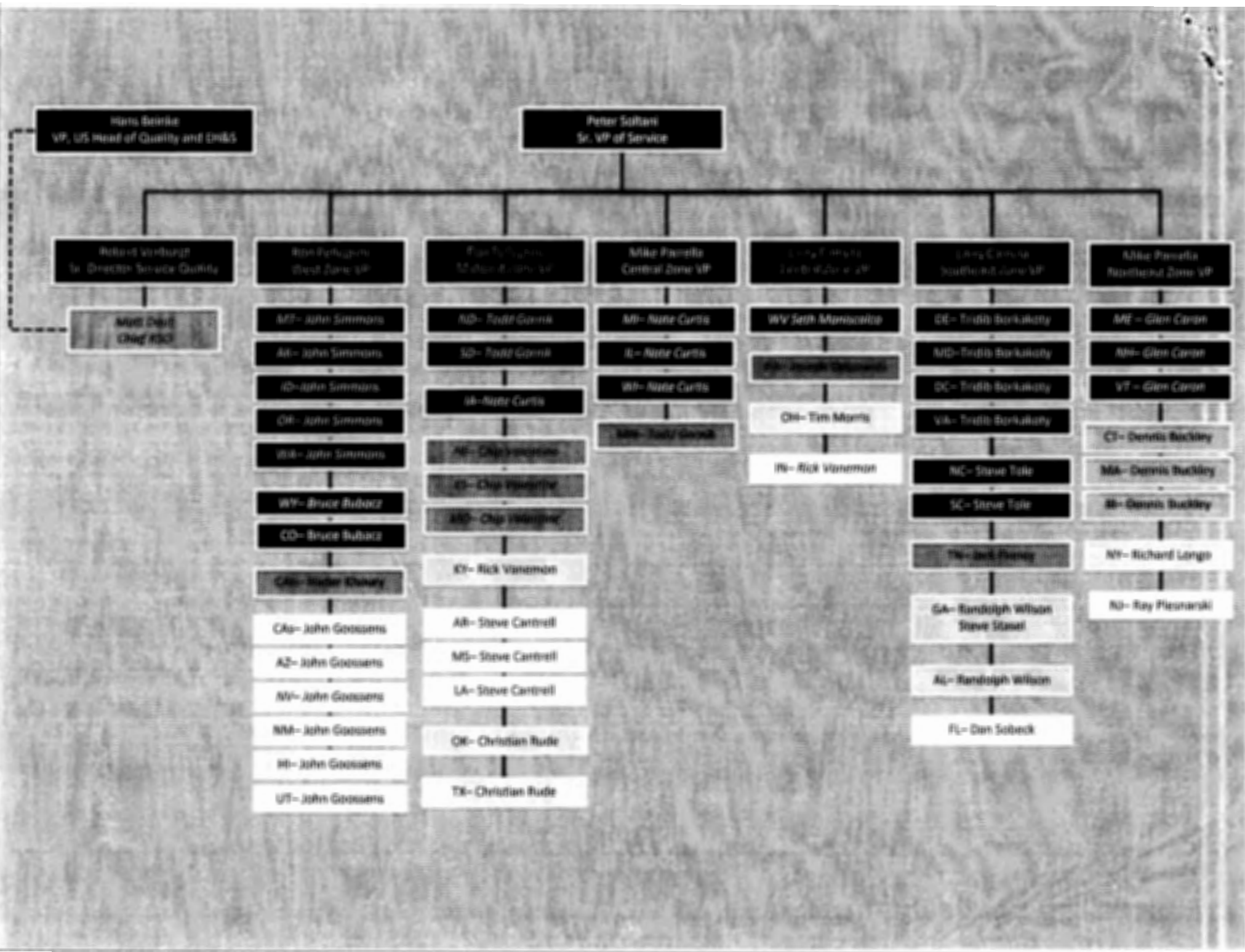
With Best Regards,



Matthew Daut
Chief Radiation Safety Officer
Siemens Medical Solutions, USA, Inc.,
221 Gregson Drive
Cary, NC 27511
(919) 319-2952

REC'D 051315 PM 1025

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DELAGATION OF AUTHORITY

Monday, March 30, 2015

Memo To: Matthew Daut
From: Peter Solani, Sr. Vice President for Service

Subject: Delegation of Authority to the Radiation Safety Officer

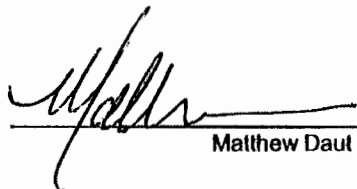
You Matthew Daut, have been appointed Radiation Safety Officer for the Siemens Medical Solutions USA, Inc radioactive material program. You are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the regulations and compliance with the terms and conditions of the license and commitments contained therein.

You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where it is justified by radiation safety concerns. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the State Radiation Safety

Signature and Title of Management:


Peter Soltani, Sr. Vice President of Service:

I understand and accept this Responsibility:


Matthew Daut

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SIGNATURE AUTHORIZATION FORM

Monday, March 30, 2015


Memo To: Matthew Daut, Chief Radiation Safety Officer
From: Peter Soltani, Senior Vice President of Service

Subject: Delegation of Signature Authority for Radioactive Material Licenses

I hereby delegate authority to you for making commitments and signing amendment requests with regard to radioactive material licenses on behalf of senior management for *Siemens Medical Solutions 221 Gregson Drive, Cary, NC 27511*. This authority extends to the maintenance and operation of all state and federal radioactive material licenses.


As a member of management, I recognize the radioactive materials license is a legal document that includes the application and all approved amendments. Furthermore, only management can obligate the institution and management is held accountable for the commitments in the license. In addition, I acknowledge that only a member of management has authority to provide necessary resources to achieve regulatory compliance. Necessary resources include finance, personnel, and physical plant.

Delegation of Signature Authority:



Peter Soltani
Senior Vice President of Service

I hereby accept the above delegated authority:



Matthew Daut
Chief Radiation Safety Officer

	CX RC- US Personnel Dose Monitoring SOP	E032-3
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Restricted

Table of Contents

Change History	2
Document Support	3
Purpose.....	3
Scope.....	3
Reference	3
Definitions/	4
Acronyms	4
Prerequisites	5
Responsibilities	6
Process Description	7
Dosimeter Requirements	7
Records and Attachments.....	11

Uncontrolled Document when printed. Verify current revision prior to use.	Signature on file.	Page 1 of 12
	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Matthew Daut Process Owner	
	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Robert Verburgt Director of Quality / Date	

CX RC-US Personnel Dose Monitoring SOP	E032-3
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Change History

Revision Level	Effective Date	Page	Description of Change
1	10/28/10	All	Initial release to document management system. Training was completed via Learn at Siemens Course # 00257114, prior to this document being made effective.
2	3/24/14	All	Updated dosimetry contact information and acronyms due to organizational title/role changes and updated responsibilities to include an organizational change. Added information concerning lost/damaged badges, exposure investigations and off-boarding. A read and understand task will be deployed via Learn@Siemens.
3	03/06/15	All	Revised procedure to adopt Siemens 1 mSv annual exposure goal and revision of ring dosimetry policy. Consolidated ALARA Levels included dose notification. Training Required

2041-6

Document Support

Purpose

- To provide a procedure for monitoring personnel occupational dose
- To comply with 10 CFR 20.1502(a)
- To identify the "**Badge Vendor**" currently as Dade Moeller and Associates, contact information:

Dade Moeller and Associates
 438 N. Frederick Ave
 Gaithersburg, MD 20877
 Phone # 1-301-990-6006 x25 (direct)
 dosimetry@moellerinc.com

Dade Moeller will supply Instadose Badges from Mirion Technologies, and TLD and Rings from Global Dosimetry.

Scope

The scope includes details for dosimeter use (types of dosimeters, ordering dosimeters, exchange or read frequency, placement of dosimeters, storage of dosimeters and receipt of new dosimeters from the Badge Vendor and reading or return of used dosimeters to the Badge Vendor as required) for CX RC- US identified personnel.

This document also lists other documents for the dosimetry program.

The Training and Development Center in Cary, NC has additional requirements and procedures.

Reference

The reference section lists any other documents supporting, having impact, or are necessary for the execution of the document.

Document Number	Document Title
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose
Nuclear Regulatory Commission Regulatory Guide 8.13	Instruction Concerning Prenatal Radiation Exposure
ARTD -002.731.02	Radiation Protection for X-Ray Systems
EHSD 7.9	Radiation Protection Procedure
E052	CX RC-US (IM/CP) Lost or Missing Badge Report
E053	CX RC-US (IM/CP) Erroneous Dose Results - Personal Dose Equivalent Estimate
E054	CX RC-US (IM/CP) Level 1 ALARA Investigation Form

E055	CX RC-US (IM/CP) Level 2 ALARA Investigation Form
E056	CX RC-US (IM/CP) Declaration of Pregnancy
E057	CX RC-US (IM/CP) Occupational Exposure to Embryo/Fetus
E065	CX RC-US (IM/CP) Prior Occupational Dose Request for New Employees
E131	Environmental Health and Safety Guide
E163	CX RC-US (IM/CP) Level 3 ALARA Investigation Form
E164	CX RC-US(IM/CP) Level 4 ALARA Investigation Form
E198	CX RC-US (IM/CP) Dose in Excess of Limits

**Definitions/
Acronyms**

This section contains definitions and acronyms for this document.

Word/Acronym	Definition
ALARA	As Low as Reasonably Achievable
Ancillary Worker	Individual employed by Siemens who is trained in radiation safety and often works in or around areas that use radioactive material or radiation generating machines. This group includes (but is not limited to) CSEs, PSEs, and PM Techs.
CAS	Clinical Applications Specialist
Chirper	Personal dose monitor with active alarm/notification assigned by Tool and Test
CRSO	Chief Radiation Safety Officer, overall responsible for Radiation Protection Plan
CSE	Customer Solutions Engineer
CSS	Clinical Sales Specialists
CX RC- US	The sales, service, and logistic implementation organization for Siemens Healthcare's portfolio of medical imaging, laboratory diagnostics, medical information technology, medical therapy, consulting, and services in the United States.
DPW	Declared Pregnant Worker
DRSO	District Radiation Safety Officer, RSM responsible for RAD Protection in the general area, over LRSOs

IM/CP	Imaging and Clinical Products
ISE	Installation Solutions Engineer
LRSO	Local Radiation Safety Officer, CSE responsible for Radiation Protection in states or sites assigned
MI	Molecular Imaging
OCS	Oncology Care Systems
PEH	Prior Exposure History
PET	Positron Emissions Tomography
PM (Tech)	Project Manager – Technical
PSE	Product Sales Engineers
Radiation Worker	Individual employed by Siemens who is trained in radiation safety and has the potential to work with radiation generating machines or handle radioactive material. This group includes (but is not limited to) Authorized Users, CASSs, CSEs, ISEs, TDC/TIs and TSEs
RAM	Radioactive Material
REM	Radiation Exposure Monitoring
RGM	Radiation Generating Machine
RSM	Regional Service Manager
TDC/TI	Training & Development Center, Technical Instructors
TLD	Thermoluminescent Dosimetry
TSE	Technical Solutions Engineer
WBD	Whole Body Dosimeter

Prerequisites Radiation Exposure Monitoring (REM) Badges are a requirement for all who work in customer locations on radiation generating equipment or work with radiation sources, or have the potential to work in areas where radiation may be present enough to potentially result in an occupational exposure as listed in 10 CFR 20.1502.

Badges are assigned by job classification until such a time as the individual or group of individuals in a specific job classification has been found to not fall under the potential listed in 10 CFR 20.1502. Badge types are assigned by type of work done, either with x-ray machines, radioactive material or Radiation Therapy systems.

Responsibilities The responsibility of wearing assigned dosimetry is not only a requirement by regulation, it is a safety function and company policy that must be adhered to for the protection of the employee, the company and the customer on whose site the person is working.

Function Name	Responsibility
Chief Radiation Safety Officer	<ul style="list-style-type: none"> Responsible for the Office of Radiation Safety and Protection and all of its functions including dosimeter ALARA Investigations. Responsible for implementing an active Radiation Exposure Monitoring Program for Siemens Medical Solutions USA, Inc. (CX RC-US)
Regional Service Manger	<ul style="list-style-type: none"> Responsible for direct supervision of CSE and their compliance to the dosimetry Implementing performance measures to aid and support dosimetry compliance Timely reporting of radiation exposure Return of REM badges Assure conformance to radiation work prohibition for lost badges or exposures in excess of limits
District Radiation Safety Officer	<ul style="list-style-type: none"> Responsible for overseeing the Radiation Safety Program for the area assigned to them. Assists CRSO with audits/inspections and dosimetry as required Assists CRSO in x-ray service provider renewals and RAM applications. Serves as a point of contact for Radiation safety questions and concerns
Local Radiation Safety Officer	<ul style="list-style-type: none"> Responsible for the radiation safety program in the local area or state including dosimeter compliance where required. Assists CRSO and/or DRSO with duties as required.
Ancillary Worker	<ul style="list-style-type: none"> Responsible for wearing a REM badge when working and responsible for its timely submission. <p>Note: If the Ancillary Worker does not have a badge, work in areas where radiation generating equipment or radiation sources are in use cannot be performed.</p>

<p>Radiation Worker</p>	<ul style="list-style-type: none"> • Responsible for wearing a REM badge(s) when working. • Responsible for not losing or damaging dosimetry. • Timely submission of the REM badge(s) when required. • Timely completion of lost/damaged dosimetry report. • Timely completion of exposure investigations • Turn in of dosimetry for off-boarding to the CRSO or Dosimetry provider. <p>Note: If the Radiation Worker does not have a badge or badges as described by work type, work with or in areas where radiation generating equipment or radiation sources are in use cannot be performed.</p>
<p>VP Service</p>	<ul style="list-style-type: none"> • Responsible for providing support and resourcing an active Radiation Exposure Monitoring Program for CX RC-US

Process Description

Dosimeter Requirements

Dosimetry Assignment

1. All CX RC- US Ancillary Workers and Radiation Workers who are required to enter potential radiation or radiological use areas must wear a whole body (ex: Instadose or TLD) dosimeter if they are expected to receive an annual whole body dose of 1 mSv or more. The determination of who is required to wear badges will be kept by the CRSO.
2. All Authorized Users must wear a WBD and a ring badge on the hand they are handling radioactive material with for monitoring of their extremity dose.
3. All CSEs who work on Therapy equipment must have a TLD capable of neutron detection, as well as a Chirper when in the radiation treatment room.
4. Employees that declare pregnancy in accordance with United States Nuclear Regulatory Commission Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure", will follow the declared pregnancy policy CX RC-US 0733
5. Any changes to current personnel (name, address, delivery information) can be made by the employee by contacting the Badge Vendor. Any new badge requests or changes in badging type must be made by contacting the CRSO.

Type of Monitoring

- Whole Body Instadose Badge
- Whole Body TLD with Fast Neutron (Therapy CSE and TSE only)
- Extremity (Ring) (Therapy, MI-SPECT and MI-PET Personnel only)
- Chirper (Therapy CSE personnel only)
- Fetal Dosimetry for Pregnant Workers as requested in 0733

Training

- Each individual receiving dosimetry will receive annual Radiation Safety training on radiation controls including the principle of ALARA.

Prior Exposure History

1. Prior Exposure History (PEH) must be obtained for each new employee from the individual's prior employer(s), if monitoring was provided.
2. All new employees must complete E065 CX RC-US (IM/CP) Prior Exposure History Request and indicate that they did not receive exposure to radiation in previous work, or indicate all previous employers that provided monitoring. Form E065 will be used to document this information
3. When completed, fax or e-mail the Prior Exposure Requests to the CRSO. The CRSO will contact the individual's previous employers for completion of the PEH using the Prior Exposure Request.
4. The CRSO will keep a copy of each employee's PEH on file.
5. The CRSO will enter the employee's PEH into the Badge Vendor's permanent exposure history for the individual.

Exchange Frequency/Reading

1. Whole body dosimeters must be exchanged or read quarterly (type dependent).
2. Ring badges must be exchanged quarterly.
3. Fetal monitoring badges will be exchanged on a ***monthly*** basis.
4. Wear Periods (quarters): January 1 – March 31, April 1 – June 30, July 1 – September 30, October 1 – December 31
5. The badge vendor will automatically send new badges with return envelopes within the last 2 weeks of the quarter. All badges must be mailed back to the vendor prior to the 14th day of the new quarter.
6. Instadose badges are not returned to the dosimetry vendor quarterly like whole body TLD or ring badges are. They should be read at a minimum quarterly during the prescribed read period (generally the 15th of the closing quarter's month to 15th of the new quarter's month). Instadose badges are returned to the RSO office or the

dosimetry vendor at the following times:

- When the badge is damaged or stops working,
- When requested to be sent back for QA of the badge,
- When the badge is no longer needed for radiation work, or
- When you are restricted from radiation work.

Initializing, Reading and Saving reports instructions for Instadose

1. Instadose badges are initialized and read via a USB connection on your computer.

Note: DO NOT CONNECT THE DEVICE UNTIL PROMPTED TO DO SO.

2. Upon receipt, you are instructed to take the [Learn@Siemens](#) course catalog number # 00257114. The Power Point will explain step by step process for each of the three required steps.
3. For touchpad users, an extension cable may be required to connect device, contact the CRSO for this device.
4. When possible, the Instadose should be double captured secondary clips are available, contact the CRSO for additional clips.
5. These devices are attracted by MRI systems, but are not a danger according to testing done by the MR factory in Germany. The device is not harmed by the magnetic field.

Lost or Damaged Dosimetry

1. Lost badges must be reported immediately to the CRSO
2. Employees must complete the E052 CX RC-US (IM/CP) Lost or Missing badge report and timely submit to the CRSO. The worker may consider using the online Lost Dosimeter Report.
3. For lost or damaged dosimetry, the employee may not perform duties that would expose them to radiation until they receive a new badge.
4. An estimated dose will be calculated and applied to the employee's permanent dose record by the CRSO

Exposure Control Levels:

Siemens Medical Solutions USA, Inc. makes every attempt to keep radiation worker exposure as low as practical and sets an annual exposure goal for each person working under this instruction of 1 mSv (100 mrem).

To assist managers and personnel to help achieve this goal, an Exposure Notification will be sent to the individual, their supervisor, the Local RSO and CRSO if someone exceeds 0.2 mSv (20 mRem) during a quarterly read.

This document is to provide the individual and supervisor with the information needed to manage exposure.

1. Investigations of ALARA triggers will be timely and documented on the following forms using the documented levels on those forms:

E054 CX RC-US (IM/CP) ALARA Level 1 ALARA Investigation Form

- A message is sent to the worker to alert them regarding the dose and request further information. A dose estimate that more appropriately reflects the worker's dose may be made. This is the most common ALARA level to be exceeded. The reason is primarily related to exposure of the dosimeter in checked luggage at an airport.

E055 CX RC-US (IM/CP) ALARA Level 2 ALARA Investigation Form

- It is unusual that any Siemens workers would receive such a dose; however, it does happen that a dosimeter may respond with a dose in this category. A message is sent to the worker to alert them regarding the dose and request further information. A dose estimate that more appropriately reflects the worker's dose may be made.
- Until notified by the CRSO, the worker cannot be exposed to any further ionizing radiation. At this exposure level, the CRSO may have to notify a regulatory agency.
- This level may be indicative of a faulty dosimeter or a real situation of exposure that may or may not be associated with work on radiation producing devices or radioactive sources. The district or local Siemens RSO or CRSO will contact the worker to determine if there must be an action to change the way the worker is handling sources or exposed to radiation.

2. Investigations where occupational dose limits are exceeded will be conducted immediately. All radiation work will be suspended for the employee while the investigation is being conducted. Notifications to the authority having jurisdiction will be made by the CRSO based on legal requirements.

E198 CX RC-US (IM/CP) Dose in Excess of Limits

- NOTIFICATION WILL BE MADE TO THE REGULATORY AUTHORITIES FOR THE STATE IN WHICH THE EXPOSURE OCCURRED OR NORTH CAROLINA IN THE CASE OF RECIPROCITY, OR THE NUCLEAR REGULATORY COMMISSION IN THE CASE OF A NON-AGREEMENT STATE, US TERRITORY, OR FEDERAL FACILITY by the CRSO.

Off-Boarding

1. Employees leaving the company will return their Instadose dosimeter to

the CRSO and their rings and TLD to the dosimetry provider.

2. For Instadose a final reading will be obtained and an annual Form 5 will be sent to the employee's last known address.

For TLD Badges and TLD ring badges, the Form 5 will be generated by the dosimetry provider after the TLD badges have been processed. This may be as long as 120 days past the time that the badges are turned in for processing.

Records and Attachments

Records

The records section lists the specific records that are created from the instructions detailed in this document. This section also lists any special disposal requirements for the records.


Record Identification	Record Location	Record Owner	Retention Period
Radiation Exposure Monitoring (REM) Employee Dosimeter Record	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Prior Exposure History (PEH)	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Radiation Safety Awareness Training	Learn@Siemens	LMS	Length of employment plus 30 years
ALARA Level 1 Investigation Report	File cabinet/Electronic	CRSO	Length of employment plus 30 years
ALARA Level 2 Investigation Report	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Dose in Excess of Limits	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Declaration of Pregnancy Form	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Erroneous Badge Reading and Dose Estimate	File cabinet/Electronic	CRSO	Length of employment plus 30 years

CX RC-US Personnel Dose Monitoring SOP	E032-3
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Fetal Dose Record	File cabinet/Electronic	CRSO	Length of employment plus 30 years
Lost or Missing Badge Report	File cabinet/Electronic	CRSO	Length of employment plus 30 years

Attachments Any supporting information for the process should be attached in this section.

- Attachment 1** E052 CX RC-US (IM/CP) Lost or Missing Badge Report
- Attachment 2** E053 CX RC-US (IM/CP) Erroneous Dose Results/ Personal Dose Equivalent Estimate
- Attachment 3** E054 CX RC-US (IM/CP) Level 1 ALARA Investigation Form
- Attachment 4** E055 CX RC-US (IM/CP) Level 2 ALARA Investigation Form
- Attachment 5** E065 CX RC-US (IM/CP) Prior Occupational Dose Request for New Employees
- Attachment 6** E 198 CX RC-US (IM/CP) Dose in Excess of Limits
- Attachment 7** CX RC-US (IM/CP) ALARA Notification Form

	<p align="center">CX RC-US Authorized User Radiation Protection Program</p>	<p align="center">2608-1</p>
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Table of Contents

Document Support.....	3
Purpose.....	3
Scope.....	3
Reference.....	3
Definitions/ Acronyms.....	3
Prerequisites	4
Responsibilities	4
Process Description	8
Introduction	8
Records and Attachments.....	27
Records.....	27
Attachment.....	27

<p>Uncontrolled Document when printed. Verify current revision prior to use.</p>	<p>Signature on file.</p>	<p align="right">Page 1 of 27</p>
	<p>_____ Matthew Daut Process Owner Signature / Date</p>	
	<p>_____ Robert Verburgt QA Rep. Signature / Date</p>	

CX RC-US Authorized User Radiation Protection Program	2608-1
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Change History

Revision Level	Effective Date	Page	Description of Change
1	03/06/15	All	Initial release to document management system. Training Required.

CX RC-US Authorized User Radiation Protection Program	2608-1
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Document Support

Purpose The purpose of this document is to provide guidance for:

- Siemens employees to work with radioactive material
- Provide general radioactive material license information
- Siemens Authorized User Radiation Protection Program
- Emergency Instructions
- Radiological Survey Guidance

Scope This SOP applies to all Siemens Medical Solutions USA Inc. personnel who work with or handle radioactive material while performing service operations.

Reference 10 CFR 20.20
 NUREG 1556, Volume 18

Document Number	Document Title
E131	Environmental Health and Safety Guide
E032	CX RC-US Personnel Dose Monitoring
0733	CX RC-US Declaration of Pregnancy
2607	CX RC-US Radioactive Material License Assessment

**Definitions/
 Acronyms**

Word / Acronym	Definition
AU	Authorized User: Customer Service Engineers who meet all requirements to handle and use radioactive material.
CRSO	Chief Radiation Safety Officer
CSE	Customer Service Engineer
DRSO or LRSO	District or Local Radiation Safety Officer
LCL	Local Control Level
MI	Molecular Imaging
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RGM	Radiation Generating Machine
RML	Radioactive Material License
RSM	Regional Service Manager
RSO	Radiation Safety Officer

CX RC-US Authorized User Radiation Protection Program	2608-1
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SAP	Software used to track service
SPECT	Single Photon Emission Computed Tomography
WBD	Whole Body Dosimeter

Prerequisites

Type	Column Title Here

Responsibilities

Function Name	Responsibility
Executive Management	Executive Management is responsible for providing the staffing and resources necessary to ensure the effective implementation and application of the Radiation Safety program as well as overall compliance to requirements for RML and RGM.
Director of Service Quality	Director of Service of Quality is responsible for providing an effective Radiation Safety Program, RAM licensing, RGM registration and radiation exposure monitoring for Siemens Medical Solutions USA, Inc. Service Group.
Chief Radiation Safety Officer	<p>CRSO is responsible for:</p> <ul style="list-style-type: none"> • Obtaining and maintaining radioactive material service or vendor licenses (RMLs) in the United States with the federal government and Agreement States where service/vendor licenses are required. • Obtaining and maintaining radiation generating machine (RGM) registrations in states with this requirement. • All Aspects of the Radiation Safety Program <p>General Radiation Program Management Including:</p> <ul style="list-style-type: none"> • ALARA • Identifying radiation safety problems • Initiating, recommending, or providing

	<p>corrective actions</p> <ul style="list-style-type: none">• Developing training and radiation safety programs as required by Siemens policy and to ensure it will meet or exceed Federal and Agreement State license conditions.• Verifying implementation of corrective actions• Stopping unsafe activities• Ensuring compliance with the regulations and compliance with the terms and conditions of the license and commitments contained therein• Prohibiting the use of radioactive material by employees who do not meet the necessary requirements• Ensure the Personnel Dosimetry Program is maintained in compliance with state and federal requirements• Halting operations when it is justified by radiation safety concerns• Designation of Authorized Users where required by RML licenses conditions.• Ensuring the timely completion of all required RML and RGM audits. <p>Dosimetry Program for AUs including:</p> <ul style="list-style-type: none">• Providing a quarterly review of badge results• Providing an annual dosimetry report for each employee• Ensuring all AUs are issued WBDs• Ensuring all AUs are issued at least one Ring Dosimeter• Ensure WBDs are read or exchanged at least quarterly• Endure Ring Dosimeters are exchanged at least quarterly• Ensure personnel are notified if they exceed a Siemens Local Control Level• Ensure Dose Investigations completed or completed to the fullest extent possible within the period specified within this SOP. <p>Radiation Safety Training Program:</p> <ul style="list-style-type: none">• The CRSO will ensure Regional Service
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	<p>Managers are Training Status Reports for personnel designated as AU.</p>
<p>Regional Service Managers</p>	<p>Regional Service Managers are responsible for direct supervision of CSEs and their compliance to the licensing or registration requirements for all RMLs used in that region.</p> <p>RSMs must immediately notify the CRSO of the following :</p> <ul style="list-style-type: none"> • Any direct report personnel are to be trained as AUs. • When a monitored individual changes modalities effecting their dosimetry or radiation safety training requirements • When a radiation worker moves into a different state or to a location (even within the same state) that is governed by a different RML. • Change in job status for a CSE or other monitored worker to include medical leave, disability, retirement or termination. <p>RSMs are responsible to ensure that work is only conducted where Siemens is currently licensed.</p> <p>RSMs shall ensure that all AUs:</p> <ul style="list-style-type: none"> • Successfully complete initial radiation safety training prior to handling sources • Maintain required radiation safety training • Are assigned appropriate dosimetry for handling radioactive material <p>RSMs are responsible to ensure their personnel maintain ALARA principals, timely completion of radiation safety training and for knowledge o f</p> <p>RSMs that allow AUs to assist other geographical areas of the United States the contact the CRSO prior to ensure there are no radioactive material licensing concerns.</p>
<p>Local or District Radiation Safety Officer</p>	<p>The Local (LRSO) or District Radiation Safety Officer (DRSO) is responsible for administration of the radiation safety program in the assigned</p>

CX RC-US Authorized User Radiation Protection Program	2608-1
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	<p>local area or state. This includes being the technical resource for licensing, registration and dosimetry within their coverage area.</p> <p>LRSO and DRSO serve as a local contact for state regulators where required.</p> <p>LRSO and DRSO are delegated by Executive Management to carry out all aspects of the Radiation Safety Program including:</p> <ul style="list-style-type: none"> • identifying radiation safety problems • initiating, recommending, or providing corrective actions • verifying implementation of corrective actions • stopping unsafe activities • ensuring compliance with the regulations and compliance with the terms and conditions of the license and commitments contained therein • including prohibiting the use of radioactive material by employees who do not meet the necessary requirements • halting operations when it is justified by radiation safety concerns. <p>LRSO and DRSO assist the CRSO or proxy in maintaining RGM and RAM licenses, audits and compliance to the radiation safety program.</p>
Individual AUs	<p>All individuals qualified as an AU are required to know which RMLs they are working under when performing service operations using radioactive material and understand the licensing requirements for each.</p> <p>AUs are responsible for the safe use and control of a customer's licensed material while performing service operations. The AUs are responsible for:</p> <ul style="list-style-type: none"> • ALARA • Understanding the basic contents of a radioactive material license. • Handling all radioactive material in accordance with applicable license conditions and this SOP

	<ul style="list-style-type: none"> • Notifying the CRSO/DRSO or LRSO if an issue of non-compliance or safety with an applicable RML arises • Ensuring all Radiation Safety Program Training is kept current • Wearing, reading and exchange dosimetry in accordance with dosimetry policies • Being familiar with Radiological Survey instruments, methods and documentation • Demonstrating where to find the most current copy of all applicable RMLs, SOPs, Emergency procedures and required Radiation Safety Postings • Recognizing unsafe or unlicensed activities and report those activities to the CRSO and supervisor <p>For states that require names of specific AUs to be listed a license condition; ensure that no licensed activities (to include adding an AU's) are performed until all state requirements are met.</p>
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Process Description

Introduction This instruction is designed to provide guidance and support for personnel who handle radioactive material as part of service operations for Siemens Medical Solutions USA, Inc.

1.0 Radioactive Material Service Licenses (RML) Radioactive material can only be used under the authority of a radioactive material license. Most states and the NRC require Siemens to have a radioactive material vendor license. For Siemens, radioactive material licensing is required when:

- Performing unsupervised work with licensed material.
- Performing service on devices that contain or store radioactive material (performing modification issued by the factory on registered devices).
- Performing service with regulated material that is not authorized under the customer's radioactive material license (source exchanges).

NRC – Nuclear Regulatory Commission has authority under the Atomic Energy Act of 1954 to regulate and provide oversight for the safe use of byproduct material. The NRC regulates 13 states, District of Columbia, United States Territories and all government facilities throughout the United States.

Agreement States are US States that have been granted the responsibility of regulating licensed radioactive material in their own state. An agreement state agency has the authority for regulation with the exception of those sites located on federal territories with the state or sites within the states with unusual needs. (VA and Military Hospitals, Native American Lands).

Authorized Users and supervisors should have a thorough understanding of the conditions and requirements specified in Radioactive Material Licenses.

1.1 Radioactive Material License Contents: While there are differences in structure and some content between licensing authorities, most of them have common requirements or “tie-downs” Siemens must follow in order to continue licensed operations. Under all circumstances, Siemens will follow the requirements of the most conservative licensing authority for each location and apply those tie-downs in each state to avoid confusion.

1.2 Radioactive Material Authorized and Maximum Quantity Authorized

- A RML will list each radionuclide AUs are authorized to handle and the maximum amount we are allowed to use at any one location. It is important to understand what material is authorized for use. If a customer requests the use of any material not listed on the state or federal license or the quantity exceeds what is allowed for use, the AU must to refuse.
- Siemens provides all licensing bodies a list of all potential sources that could be used on the equipment serviced.

1.3 Radioactive Material Use:

- Radioactive material used for service for installation, testing, repair, routine and non-routine maintenance, source exchange, equipment demonstration and calibration services for diagnostic imaging equipment. No other use is implied or authorized. Authorized Users cannot use the material for purposes not listed on the license – such as shipping, receipt or relocation outside the facility.

1.4 Designation of the Radiation Safety Officer:

- The RSO is the individual who is responsible for the organization to meet the requirements of the radioactive material conditions and oversee all aspects of the radiation safety officer. The Chief Radiation Safety Officer fulfils this role for the majority of RMSLs Siemens maintains, however, some states require a local radiation safety officer be listed. AU’s should know the name of

CX RC-US Authorized User Radiation Protection Program	2608-1
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the Radiation Safety Officer listed on the license under which they are currently working.

1.5 Authorized Users:

- Some states require that Siemens list the CSEs that will work in that state. It is not permissible to allow even fully qualified individuals to perform licensed work in states requiring this designation if they were not currently listed on that license. Individuals can be added to the AU list; however, a RML amendment will have to be submitted and approved before the new AU can perform work. Current states that require the approval of AU's are posted on the Radiation Safety Officer website.
- Some RMLs require the RSO to designate AUs, in this case, the RSO will designate in writing those personnel who meet the requirements for AUs for the applicable RMLs.

1.6 Training:

- Siemens training requirements for AUs meets or exceeds the training outline in NUREG 1556 Vol. 18 Appendix H. The training requirements listed below is a condition for all of our licenses and registration. Any deviation from this Siemens approved training requires approval from our licensing bodies via the amendment process. The following are AU training conditions:

Course	Method of Instruction	Frequency
Initial Source Handling and Emergency Training (for new AUs)	Hands On With Documented Practical Demonstration	Initially prior to handling radioactive sources
Annual Radiation Safety Refresher for Authorized Users	Web Based and Media	Annually

NOTE: An individual is not authorized to perform licensed activities if they do not meet the training requirements listed above – including annual refresher training.

- Regional Service Managers will be responsible for ensuring their AU designated personnel maintain their current training. RSMs will not authorize or dispatch unqualified personnel to perform licensed activities.
- Other Siemens Business Partners or Units working under Chief Radiations Safety Officer Service License are required to ensure their training program meet the requirements of NUREG 1556 Vol.18 or ensure their AUs are trained as above. Those entities following the

Chief Radiation Safety Officer License training for AUs will be required to provide training information if requested.

Initial, hands on source handling training for personnel who were previously qualified as radioactive material source handlers (prior to establishment of the Authorized User Program) was completed by previous classes where sources handling was integrated into the program. All AUs will have historical record of this training to verify initial radioactive source handling.

1.7 Dosimetry:

All Authorized Users will be required to wear whole body dosimetry and at least one ring dosimeter at all times while handling sources.

- Whole body dosimetry can either be Instadose or Thermoluminescent Dosimeters (TLDs). These are currently provided by Mirion Dosimetry Services.
- Ring TLDs are also currently provided by Mirion Dosimetry Services.
- Rings and TLDs will be exchanged quarterly and Instadose dosimeters will be read at least quarterly during scheduled read cycles.
- All dosimetry providers and devices must be NVLAP Accredited.

Whole body dosimeters will be worn on the front portion of the body somewhere between the chest and waist. If possible, dosimeters should be double captured and secured to prevent unintentional movement and reduce the risk of loss.

1.8 Radioactive Material Assessments

Radioactive Material Audits are required to be performed at least annually for each state. These audits will be performed by someone knowledgeable of the radioactive material program and the requirements for state licensure. Assessments will be documented on the CX-RC US Radiation Safety Assessment Form (2607) available in the Quality Documents. Audits will be kept in accordance with state or federal requirements.

1.9 Operating and Emergency Procedures:

Regional Service Managers and Authorized Users are required to have a thorough understanding of Siemens Operating and Emergency procedures. A review of these procedures is required by all RSMs and AUs annually or after significant changes. All radioactive material licenses incorporate the current

Radiation Safety and Emergency SOPs as part of the license tie-down conditions. Any changes to SOP scope or practice must be submitted to ALL licensing authorities for review and acceptance.

1.10 Radiological Surveys: Emergency Procedures require familiarization and use with general radiation detection equipment. Familiarization training has been incorporated into the Annual Radiation Safety Training for Authorized Users and the 8-hour Triennial Radiation Safety Class. Siemens does not maintain radiation survey detection meters for our CSE's. If a circumstance arises where a survey is required, it is expected that AU will borrow a meter from the facility. The facility should have a meter with the proper range and response to detect the isotope in question – as is required by their radioactive material license conditions. Siemens has either communicated this expectation with facility RSO's via a Memorandum of Understanding or as part of their Service Contract to ensure meters will be available for use.

1.11 Customer Agreements: Siemens will submit a memorandum of understanding between existing customers that outlines Siemens responsibility when performing service operations at a customer's facility. This same language shall be incorporated into new service contracts and new purchase agreements that specify the use of radioactive material.

2.0 Exposure Limits: The following occupational ionizing radiation limits are listed in 10 CFR 20.1201 and 10 CFR 20.1208.

Area of Concern	Annual Dose Limit	Dose Equivalent
Whole Body	50 mSv (5 rem)	Total effective dose equivalent (TEDE)
Lens of the Eye	150 mSv (15 rem)	Eye dose equivalent (EDE)
Extremities	500 mSv (50 rem)	Shallow dose equivalent (SDE)
Skin	500 mSv (50 rem)	Shallow dose equivalent (SDE)
Embryo/Fetus	5 mSv (500 mRem)	Total effective dose equivalent (TEDE)

The total effective dose equivalent (TEDE) is the sum of the deep dose equivalent (DDE) from external radiation added to the committed effective dose equivalent (CEDE) from the internal uptake of radioisotopes. This dose limit is based on a stochastic limit for a risk based occurrence, such as cancer.

Siemens AUs are monitored for whole body, fetal (when applicable) and extremity doses.

Radiation Workers who decide to declare their pregnancy shall follow the policy in SMS Declared Worker Policy 0734. Dose to the embryo/fetus is calculated for the duration of the pregnancy. Familiarization with this policy is required for all employees and radiation workers.

2.1 Local Control Levels: in order to ensure Siemens Service employees never reach the limits listed above and to ensure ALARA practices and policies are adhered to, the following whole body local control levels are established:

Area of Concern	Annual Control Level	Quarterly Control Level
Whole Body	1 mSv (100 mrem)	.20 mSv (20 mrem)

Workers and supervisors shall make every effort to ensure their workers do not exceed the annual and quarterly local control levels. If a worker is anticipated to exceed their annual control level due to a planned evolution, the Chief Radiation Safety Officer shall be notified prior to work.

Supervisors should monitor of Radiation Workers exposures and make attempts to reduce their exposures if at all possible. Some methods to reduce exposures are listed as follows:

- Distribute work involving potential exposure to other qualified workers if possible
- Review work practices and procedures to ensure Radiation Workers are employing ALARA principals to the maximum extent possible.
- Perform frequent work site monitoring and surveillances to ensure Radiation Workers are following proper controls and good ALARA practices.

Personnel who are close to exposure goals may consider more frequent reads if using Instadose dosimetry.

2.2 As Low As Reasonably Achievable (ALARA): Siemens is committed to maintaining radiation exposures As Low As Reasonably Achievable (ALARA). This commitment from Siemens management provides the basis for the radiation safety practices described in the Radiation Safety Manual and in associated Standard Operating Procedures (SOP's). In addition, Siemens sets an ALARA dose limit for Authorized Users at a lower level than those dictated by regulatory agencies.

Siemens Customer Service Engineers, Applications Specialists and other staff who may be exposed to ionizing radiation in the course of their work should not exceed an annual cumulative dose of greater than 1 mSv (100 mrem). While this goal is not a limit, good engineering controls and ALARA practices should make this goal attainable for every Radiation Worker.

To help Radiation Workers and their managers proper assess their worker's radiation exposure and plan work accordingly the following ALARA Notifications and Investigations will be used.

2.3 ALARA Notification: If an individual receives more than .20 mSv (20 mRem) during any read cycle an ALARA Notifications shall be automatically generated and sent to the individual, their supervisor, the local Radiation Safety Officer and the Chief Radiation Safety Officer.

The purpose of this notification is to provide information to the individual that their exposure may exceed the Siemens goal of 1 mSv (100 mrem). No further action is required unless the individual is trending towards exceeding an annual control level. The supervisor shall be cognizant of the current annual whole body exposures for their subordinates.

2.4 ALARA LEVEL 1 Investigation: If an individual receives more than 1 mSv (100 mrem) whole body exposure during any read cycle a LEVEL 1 ALARA Notification shall be automatically generated and sent to the individual, their supervisor, the local Radiation Safety Officer and the Chief Radiation Safety Officer.

The Chief Radiation Safety Officer shall initiate a Dose Investigation. The target goal for completion of the investigation is 5 working days.

It is important the individual work with the Chief Radiation Safety Officer or Local Radiation Safety Officer to complete this investigation. Special attention shall be given to travel and work performance.

2.5 ALARA LEVEL 2 Investigation: If an individual receives more than 5 mSv (500 mrem) whole body exposure during any read cycle a LEVEL 2 Notification shall be automatically generated and sent to the individual, their supervisor, the local Radiation Safety Officer and the Chief Radiation Safety Officer.

The individual shall **cease any and all work associated with ionizing radiation** until the Chief Radiation Safety Officer completes the dose investigation. The Chief Radiation Safety Officer shall initiate a Dose Investigation. The target goal for completion of the investigation is 2 working days.

It is critical that the individual work with the Chief Radiation Safety Officer or Local Radiation Safety Officer to complete this investigation. Special attention shall be given to travel and work performance. If the Chief Radiation Safety Officer assigns this dose as occupational exposure after the investigation, further notification may be required as some regulatory bodies require notification any time an individual exceeds 10% of their occupational limits.

3.0 Authorized User Program

3.0 Authorized User Program: Customer Service Engineers or Applications Specialists that handle radioactive material as part of their normal work will undergo a formal training program that will provide them with the basic knowledge needed to handle these items safely.

Radioactive Material Use: Radioactive source use is defined as licensed material used for service for:

- Installation
- Testing
- Repair
- Routine
- Non-routine maintenance
- Source exchange
- Equipment demonstration
- Calibration services for diagnostic imaging equipment.

No other use is implied or authorized.

Siemens Medical Solutions USA Inc. does not own or possess radioactive material while performing service operations at customer facilities; all licensed material is owned by the customer. All training requirements must be completed prior to an authorized user to be allowed to handle radioactive material.

Siemens Authorized Users will use the customer's material under the license of the customer facility with the following controls:

- For each use of these sources, the Siemens CSE shall ensure that the sources are protected from damage, theft, and loss while they are being used and ensure that a customer representative will be available for return of the source(s) that are used at the customer's facility or arrangements are made to return the sources to a secure location identified by the customer.
- Unsealed sources used for tuning and peaking will be prepared by the customer only. Authorized Users **cannot** and are **not authorized** to prepare unsealed sources.
- All sources must be returned to the customer after use, storage of sources in areas that are not designated is not permitted. Authorized Users need to coordinate source use and return prior to accepting responsibility for use.
- Authorized Users may not use a source that exceeds the maximum amount authorized or that is not listed on the applicable radioactive materials license.
- All sealed and unsealed sources should be handled with protective gloves.
- Siemens does not dispose of radioactive material.

Use not Authorized: Our radioactive material licenses do not allow AUs to do any of the following:

- Order radioactive sources for a customer

- Receiving incoming source shipment
- Unboxing incoming shipment of radioactive material
- Performing leak test for new or old sources
- Inventorying sources for a licensee
- Storing material in any way other than described within the customer's radioactive material license.
- Making usable dilution of liquid source by changing from one vessel to another or adding solution
- Filling any phantom or mix solutions with liquid sources for testing
- Boxing sources for shipment
- Filling out shipping paperwork
- Transporting sources other than room to room at the same facility
- Removing sources from a facility
- Disposal of radioactive material
- Packaging sources or in any way participating in preparation of sources for transportation
- Shipping packaged sources
- Accepting unlabeled sources

3.1 Safe Use of Radioactive Material: Customer Service Engineers that handle radioactive sources will always follow ALARA practices.. Some general precautions are listed below:

- Ensure survey meters are available at the facility and they are in good working order and calibrated prior to commencing licensed activities.
- Always wear gloves when handling sources and check gloves frequently for holes or damage
- Use tongs when possible and appropriate while handling sources
- Keep radioactive material in storage containers or shielded containers when not in use
- Ensure a ring dosimeter is on the hand using the radioactive source and the chip is facing the material
- Ensure whole body dosimetry is worn properly
- Visibly inspect unsealed sources for evidence of leakage prior to use
- Ensure sources for use are listed on the correct Siemens Radioactive Material license and the activity is less than the maximum allowed.
- **Never** leave licensed material unattended in an unlocked or unguarded room
- Do not eat, drink, smoke or apply makeup or lip balm while handling radioactive material
- Notify the Facility RSO or Technicians if you suspect a problem with a source
- Never try to force a sealed source into a container or device. Investigate the problem and resolve it – if the problem cannot be resolved contact the facility RSO or Technician for assistance.
- Always return sources to their proper storage containers after use – ensure you make arrangements with the customer if performing

- licensed activities after normal hours of operation.
- When radioactive sources are present while performing service operations ensure that doors are shut or monitored to prevent unauthorized entry.
- When using a customer's radioactive material Siemens AUs are required to maintain positive control. Siemens shall not leave licensed material in an unlocked room or container even for a short break. Sources shall be returned return to their original storage locations after use or a prearranged storage location prior to departure by the Siemens employee.
- Any defects with a radioactive source or device that stores radioactive material shall be reported to the facility RSO and Siemens Chief Radiation Safety Officer upon discovery in accordance with 10 CFR 21.21(a).
- AUs need to be cognizant of the temporary work areas and ensure members of the general public are restricted from exposure from sources used by Siemens AUs.

3.2 Incident Notifications: Siemens will use the reporting requirements of NUREG 1556, Volume 18 - Table 8.4 for incident notification when applicable.

3.3 Qualification as AU: Prior to being classified as an Authorized User, personnel must meet all of the training requirements or maintain them if previously qualified to handle or use radioactive material. The CRSO approves all new AUs.

A flow path to qualification is detailed as follows, note that most AUs will not be direct hires and are part of the Siemens team and training experience prior to work with Molecular Imaging (MI) equipment:

- If not already current, the RSM/CSE enrolls the individual for initial Radiation Safety Training found on Learn @ Siemens.
- Upon completion if the initial Radiation Safety Training the CRSO orders ring dosimetry for the AU candidate.
- The individual will complete Initial Source Handling and Emergency Situation Training located at the Cary Campus. This class is designed to familiarize and provide initial safety training for source handling and emergency situations. A practical demonstration and written examination will be given at the end of the class. Upon successful completion of the course a certificate will be issued by the CRSO.
- CRSO will maintain a copy of all training certificates for AUs and provide training status for RSMs
- Authorized Users will complete Annual Radiation Safety Refresher Training.

**4.0
Emergency
Procedures:**

Authorized Users must have a thorough understanding of the immediate actions they are required to take in the event of an emergency. While emergencies cannot be predicted nor can procedures cover every possible scenario the emergencies an Authorized User is most likely to encounter are

listed below.

The CSE is expected to work with the customer and the customer RSO as necessary to ensure any actions which were the result of Siemens service work are completed in accordance with the site's license conditions. All emergency situations should be reported to the CRSO as soon as practical.

These emergency procedures are general in nature and cannot account for every situation possible at temporary work locations. A customer's emergency actions may be more detailed or differ from the actions detailed in the following emergency actions; AUs need to follow customer's instructions and report any differences to the CRSO soon as practical.

4.1 Medical Emergencies: There are **no** radioactive sources that Siemens Service employees are licensed to work with which pose an immediate danger to life or health. In every instance, **a medical emergency will take precedence over any radiological concern that a CSE may have.** Ignore all radiological precautions if a situation occurs that involves providing immediate lifesaving medical assistance to someone who may potentially be radioactively contaminated.

4.2 Fire, Flooding or Life Threatening Situations: As with medical emergencies if there is a situation that requires immediate evacuation – follow the protocols of the site location. Do not let concern for radiological controls to impede immediate evacuation when faced with a life threatening situation.

4.3 Radioactive Material Spills or Contamination Discovered at a Temporary Work Location:

If an AU encounters contamination at a work location or inadvertently causes a minor spill of radioactive material or contamination at their work site. Regardless of the source of the spill, the actions remain the same. These procedures are designed to prevent radioactive material entry into the human body by inhalation or ingestion, to limit exposure to radiation sources, and to prevent further spread of radioactive contamination.

Radioactive material can easily be spread outside the spill area by the movement of personnel involved with the spill or cleanup effort. Prevent spreading of radioactive material and contamination by restricting movement of personnel in the spill area until they have been monitored and found to be free of contamination.

Initial Actions:

1. Stop the spread of contamination; keep the contamination to the smallest area of confinement possible.
 - a. If not already worn, don rubber gloves.
 - b. Cover the liquid with absorbents.

2. Warn Others – ask for help from technicians the facility, call the facility RSO or Security if after hours, and ensure everyone in the room/location is aware of the spill.
3. Isolate the Area – do not leave the scene of the spill keep others away from any contaminated areas or liquid. Assist the facility with placing additional absorbents or initial wipe downs of the spill area and equipment.
4. Minimize Exposure – maximize your distance from any source of radiation and wear protective clothing if you must assist.

Supplementary Actions:

1. Prior to leaving the area you must check to ensure you do not have any contamination on your body. Work with the facility RSO, Security or a Nuclear Medicine Technologist to perform a frisk of your whole body using a frisker or similar instrument. Follow the instructions of the radiation safety personnel to ensure you are properly egressed from the spill area.
2. Surveys of the area need to be obtained or performed if the spill was directly related to service work performed by the CSE. Survey requirements are detailed later.
3. Call the Chief Radiation Safety Officer as soon as possible if you are involved in any spill of radioactive material.

Whom to Contact:

- Local or District Radiation Safety Officer
- Regional Service Manager
- Chief Radiation Safety Officer

4.4 Skin Contamination: If radioactive contamination is detected or during a frisk or if you have visible liquid on your clothing please ensure the facility staff are aware of the situation. The facility RSO will assist you during any decontamination event. The hospital will have decontamination procedures that you will have to follow. All contaminated clothing may be stored for decay and returned with the activity reaches background.

Initial Actions:

1. Request Help – if not already contacted request assistance from facility technicians. If you cannot locate anyone in the immediate area contact the facility's Security Department
2. Stand Fast – contamination spreads easily when moving about. Do not touch your eyes, face or any other uncovered part of your body.
NOTE: Make sure you notify the staff if you touched doors or communication devices so they can be isolated and evaluated.
3. Remove contaminated clothing – when directed don gloves if not already worn and remove wetted or contaminated clothing and place in

- controlled area such as chucks pad or plastic bag.
4. Decontaminate Skin – contamination on the skin should be removed using tepid water and a mild abrasive (Lava/pumice soap). Survey contaminated areas with frisker and record the results of each attempt. Continue decontamination until the contamination is no longer present or no change in counts is observed. **NOTE: if decontamination attempts cause redness or skin irritation, stop decontamination.**

Supplemental Actions:

1. The facility RSO may request that you perform a bioassay (depending on the radioisotope and amount); you should comply with that request.
2. Ensure you get a copy of any paperwork that details your contamination levels and all decontamination efforts.
3. Read your Instadose or arrange for an immediate exchange of all dosimetry worn.
4. Contact the CRSO as soon as possible if you had any skin contamination. This is a reportable event in almost every state.

Whom to Contact:

- Local or District Radiation Safety Officer
- Regional Service Manager
- Chief Radiation Safety Officer

4.6 Stuck Source: Refer to stuck source procedures detailed in individual equipment manuals. Immediately notify site RSO and CRSO if this occurs. Do not leave the exposed source unattended or unlocked.

- Never attempt to forcefully extract or insert a source into its device holder.
- A radiation survey will be required if the issue cannot be corrected immediately.

Whom to Contact:

- Local or District Radiation Safety Officer
- Regional Service Manager
- Chief Radiation Safety Officer

4.7 Ruptured Sealed Source If in the unlikely event a sealed source is ruptured when performing a service evolution stop all work immediately. Notify site RSO and CRSO take action for spill outlined above.

- Perform actions for a Spill

If the source ruptured while in the device holder, work with the site RSO to remove ruptured source from equipment:

- Ensure that you have appropriate protective equipment on:
 - Gloves
 - Shoe covers (if appropriate)
 - Face Shield (if appropriate)
- Care should be taken to ensure that contamination is not spread to equipment internals.

NOTE: None of Siemens' radioactive material licenses allow CSEs to perform decontamination of equipment or spaces. If the customer is licensed to perform decontamination of equipment, the CSEs can assist with dismantling equipment so that site radiological specialists can perform decontamination. Siemens employees cannot perform any decontamination on equipment or spaces. A third party may have to be contacted to perform decontamination services; contact CRSO for guidance.

Whom to Contact:

- Local or District Radiation Safety Officer
- Regional Service Manager
- Chief Radiation Safety Officer

4.8 Loss of Control of Radioactive Material: Radioactive material under the physical custody of a Siemens employee is lost or stolen.

- Contact the site technician and/RSO immediately
- Search the immediate area
- Retrace steps, search work bags
- Depending on the source and facility's survey meter sensitivity a search with a sensitive meter may help locate some types of sources. Contact CRSO or facility RSO for guidance.
- If the source cannot be located after initial searches contact **CRSO immediately.**

Whom to Contact:

- Local or District Radiation Safety Officer
- Regional Service Manager
- Chief Radiation Safety Officer

4.9 Emergency Contact Information:

Chief Radiation Safety Officer: Matthew Daut

Office: (919) 319-2952
Mobile: (919) 208-3026
Email: radiationsafetyofficer.healthcare@siemens.com

5.0 Radiological Surveys:

Siemens AUs may be required to perform a radiation or contamination survey in support of licensed material work. AUs need to be familiar with survey detection equipment and how to perform and document a radiological survey if the need arises.

Contamination Surveys

- With the exception of I-131 and Tl-201 > 20 mCi, the amount of activity in the unsealed radioactive sources used for tuning, peaking and calibration of nuclear medicine cameras is below the threshold to perform surveys after use. See NUREG 1556 Vol 18 Chapter 8.
- Because AUs work independently and in many cases, when facility assistance is not available, the AU may have to egress from a spill area or check to ensure their equipment is not contaminated. Anytime an AU must perform a contamination survey they should contact the facility RSO and Siemens CRSO.

Radiation Surveys

- Radiation surveys using radiation detection meter is required in the event such as a stuck source as detailed in the appropriate service procedures. At the AU requests, the facility will provide an appropriate meter to verify radiation levels. Contact the CRSO if there are any problems during source installation or exchange.

5.1 Contamination Surveys and Meters: The amount of activity in most radioisotopes used by Siemens employees during service operations is below the activity levels required for daily surveys; however occasions may occur where a contamination survey may be required. Siemens will be responsible to conduct contamination surveys of the worksite during the following circumstances:

- Siemens requires the use of I-131 or Tl-201 > 20 mCi to perform service operations.
- Leakage is suspected or noticed while using any unsealed source
- A sealed source is ruptured during service operations
- A spill of licensed material is suspected or caused by an AU from Siemens

Count rate meters are used in the event that contamination is suspected for detecting for low levels of radiation. These meters generally display Counts Per Minute (CPM) and have a multiplier setting x1, x10, x100 or x1000 f. The meter may be digital or analog, digital meters will read out as is and will have automatic range adjustments. Analog meters may have a scale reads out in 0-500 CPM if the needle indicates 200 on the scale and the multiplier setting is x100 then the actual counts are 20000 (200 x 100) – each scale works similarly.

Prior to meter use the following checks shall be performed:

- Physical Inspection – prior to energizing the meter ensure it is in good condition with no holes or tears in the probe or any attached cables
- Verify Calibration Dates – the meter should be calibrated annually and have a sticker on it from the calibration facility with the most recent date of calibration. NOTE: if the meter is not calibrated it can still be used during emergent situations – notify the CRSO if the meter is out of calibration
- Battery Response – verify the battery is operational.
- Source Check (if possible) – If the source check has not been performed for that day it can be checked against any available source for response. This check is to ensure that the meter is identifying changes in radiation levels.

Documentation: Every contamination survey performed by Siemens AUs will have the following information:

- A diagram of the area surveyed
- A list of items or equipment surveyed
- Specific locations where areas were frisked or surveyed
- Contamination levels with appropriate units
- Make and model of instrument used
- Background levels
- Name of person performing the survey along with the date

All surveys should be documented on Record of Radiological Survey (Form 2606). If not, other forms may be used, or drawn out.

Record Background – note if background counts are greater than 100 CPM it is difficult to distinguish background results from real contamination. Background counts need to less than 300 CPM – ideally less than 100 CPM if possible.

First find an area nearby where radiation or contamination is not present to determine background count rates for the meter. This level should be recorded on the radiological survey map.

Each Survey shall contain:

- Name of person performing the survey
- Date/time of survey
- Meter model and serial number
- Date of last calibration
- Diagram of the area surveyed – it does not have to be elaborate
- A list of all of the items surveyed in on the map

Steps to follow:

- Document the background for each item

- Survey the item and record the highest counts.
- Subtract the background from recorded counts and document in the Net Counts space.
- The activity is generally net counts divided by the efficiency (1% for most GM pancake probes) – record this as DPM.

Example:

Item	Reading CPM	BKG CPM	Net CPM	Activity DPM
Camera Bed Cover	25	25	0	0
Right Camera Detector Cover	200	25	175	[REDACTED]
Left Camera Detector Cover	25	25	0	0

The meter should have some type of probe that usually has a mylar window used for beta detection – sometimes referred to as a pancake probe. To survey an area:

- Move the probe over the area within approximately ½” of the surface. Care should be taken not to contaminate the probe.
- Keep the probe movement to approximately 1-2” per second.
- If there is an audible response it should be on during the frisk. The audible response will respond sooner than the meter.
- Slow frisking rates if noticeable increasing counts are detected.
- Allow time for meter stabilization when the highest counts are detected. If analog, switch meter scales if the meter is nearly to the next scale (unless max scale achieved).
- If contamination is present contact the Facility technician or RSO to confirm evaluation.

All surveys must be documented.

5.2 Radiation Surveys and Meters: Area Radiation surveys would not normally be performed with a hand-held instrument during routine service operations. Proper source installation is verified using the Molecular Imaging Device. There may be situations where the AU is required to perform a radiation survey such as:

- Failure to verify proper source installation using the Molecular Imaging Device
- Source is stuck out of its holder
- Anytime there is a question or concern about radiation levels from a source
- If a source is lost while being used by a Siemens AU (search)

NOTE: This list is not all inclusive

General Guidance: Most radiation survey meters are used to measure the

strength of radiation fields or beams. They generally read out in R or mR/hr (roentgens or milli-roentgens) and either come with a directional probe or a probe contained within the meter casing. Like the contamination meters, analog meters will have a multiplier knob to switch scales. Many of the sources used for Siemens equipment will barely be detectable using a common radiation survey meter (depending on the model and multiplier settings). When performing a radiation survey two readings are normally recorded, "on contact levels" and a level at some distance away (ambient).

"On contact" readings are taken with the meter's probe directly on the highest level of the radiation source being measured. Results are normally recorded directly on the survey map where the item was measured.

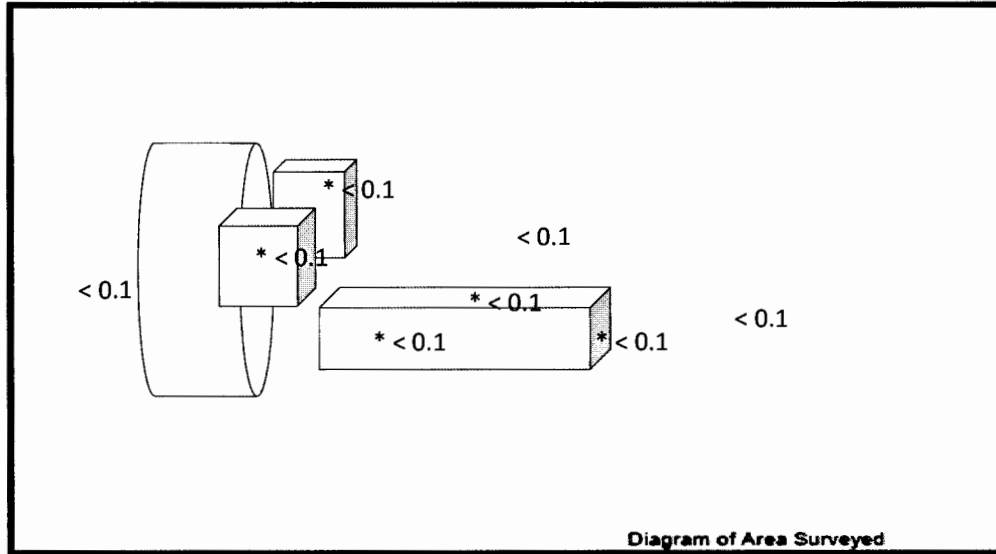
Prior to meter use please perform the following checks when applicable:

- Physical Inspection – prior to energizing the meter ensure it is in good condition with no holes or tears in the probe or any attached cables.
- Verify Calibration Dates – the meter should be calibrated annually and have a sticker on it from the calibration facility with the most recent date of calibration. NOTE: if the meter is not calibrated it can still be used during emergent situations – notify the CRSO if the meter is out of calibration.
- Battery Response – most meters have some indication that the installed batteries are still working.

Documentation: Every radiation survey performed by Siemens AUs will have the following information:

- A diagram of the area surveyed
- A list of items or equipment surveyed
- Specific locations where areas were frisked or surveyed
- Radiation levels with appropriate units
- Make and model of instrument used
- Background levels
- Name of person performing the survey along with the date and time

All surveys should be documented on Record of Radiological Survey (Form 2606). If not available, the survey may be documented on a page of paper to include the same information.



Comments

- Ambient radiation levels should be taken with the meter probe held at waist high while moving slowly along a path.
- Usually background for a radiation survey meter is lower than the lowest meter indication (unless digital). In those cases where the meter indicates zero the result should be documented as "less than (<) the lowest level of detection (< 0.1, <0.01 etc.).
- When increased activity is observed slow the meter movement rate until stabilized. If performing ambient surveys, the surveyor should rotate their body frequently to ensure their body does not shield the probe.
- Some surveys may require AUs to perform surveys at a distance, ensure the distance is annotated on the survey diagram.

NOTE: All surveys performed must be documented and a copy sent to CRSO.

**CX RC-US Authorized User Radiation Protection
Program**

2608-1

Records and Attachments

Records

The records section lists the specific records that are created from the instructions detailed in this document. This section also lists any special disposal requirements for the records.

Record Identification	Record Location	Record Owner	Retention Period

Attachment

This instruction contains no attachments

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

5/12/15, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (32-35165-01)
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** 586974.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader