

Tuesday, March 17, 2015

Mr. Daniel S. Collins,  
Director, Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission, Region 1  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406-2713

NC License No.  
092-0895-01

REC'D 10819 15M1032

**RE: Response to Apparent Violation in Inspection Report No. 15000032/2014001;  
EA-15-008**

Dear Mr. Collins,

Siemens Medical Solutions USA, Inc. realizes the importance of maintaining a comprehensive and effective radiation safety program. I would like the Nuclear Regulatory Commission to better understand how committed we are to maintaining license requirements, meeting our specific regulations and how we communicate requirements throughout our organization.

To ensure our radiation safety program remains an essential component to our service industry we provide licensing and regulatory training for our Senior Management, Zone Vice Presidents and their Directors. The most recent training occurred on 11 March, 2015, details of this training are included as Attachment (1).

Working closely with Directors, Regional Service Managers have the direct supervision and responsibility over all service operations and Authorized Users in their region. The Chief Radiation Safety Officer is invited to regional meetings where licensing information is presented directly to the Managers of Authorized Users. The most recent meeting occurred on 26 February, 2015; details of this meeting are included as Attachment (2).

Siemens maintains field Radiation Safety Officers (currently 22) to assist the Chief Radiation Safety Officer with managing our Radiation Safety Program throughout the United States and US Territories. Each Radiation Safety Officer is required to attend prerequisite Radiation Safety Officer Training and provided technical and regulatory guidance for the Radiation Safety Program each year at Radiation Safety Officer Meetings. The most recent meeting was hosted by Dade Moeller Training Academy from 23 to 27 February, 2015; meeting agenda and specific details are included as Attachment (3). To maintain program support and ensure effective communication between annual meetings, quarterly virtual meetings are facilitated by the Chief Radiation Safety Officer

To ensure Authorized Users are adequately trained our Annual Radiation Safety Training now includes essential regulatory and licensing requirements. Additionally, the Chief Radiation Safety Officer presents directly to the Authorized Users during recurrent management meetings. The goal is to reinforce regulations, licensing requirements and individual responsibilities and clarify any topics.

Siemens feels that involving our management with our radiation protection program will result in maintaining the highest level of safety and compliance. The Chief Radiation Safety Officer

routinely briefs Senior Management, in person, on the status of our material licenses and Radiation Safety Program. Siemens understands the importance maintaining strict compliance with regulations and conditions within our radioactive material licenses. Our Radiation Safety Officers have Management's 100% backing and authority to carry out program requirements or, if need be, halt operations.

If you have any questions regarding our response, please direct them either to me or to Matt Daut, our Chief Radiation Safety Officer.

With Best Regards,



Mike Guin  
Vice President of Service Operations  
221 Gregson Drive  
Cary, NC 27539  
(919) 468-7411



<b>Name</b>	<b>Attendance</b>	<b>Response</b>
Guin, Michael	Meeting Organizer	Accepted
Bowles, Lisa	Required Attendee	Accepted
Field, Ken	Required Attendee	Accepted
Katt, Eddie	Required Attendee	Accepted
Overcash, Ronald	Required Attendee	Accepted
Promenschenkel, Eric	Required Attendee	Accepted
Witschel, Michael	Required Attendee	Accepted
Parrella, Michael	Required Attendee	Accepted
Camela, Larry	Required Attendee	Accepted
Pellegrini, Ron	Required Attendee	Accepted
Werkmeister, Kenneth	Required Attendee	Accepted
Matthews, Jon C	Required Attendee	Accepted
Daut, Matthew	Required Attendee	Facilitator
Siebert, David	Required Attendee	Accepted
Hayes, Charmin	Optional Attendee	Accepted

Hans Beinke  
VP, US Head of Quality and EH&S

Mike Guin  
Sr. VP of National Service

Robert Verburgt  
Sr. Director Service Quality

Matt Daut  
CRSO

Ron Pellegrini  
West Zone VP

- MT— John Simmons
- WY— John Simmons
- ID— John Simmons
- OR— John Simmons
- WA— John Simmons
- UT— John Simmons
- AK— John Simmons
- CO— Bruce Bubacz
- CAN— Nader Khoury
- CAs— John Goossens
- AZ— John Goossens
- NV— John Goossens
- NM— John Goossens
- HI— John Goossens

Ron Pellegrini  
Midwest Zone VP

- ND— Todd Gornik
- SD— Todd Gornik
- IA— Nate Curtis
- NE— Chip Valentine
- KS— Chip Valentine
- MO— Chip Valentine
- KY— Rick Vanemon
- AR— Steve Cantrell
- MS— Steve Cantrell
- LA— Steve Cantrell
- OK— Matt Clark
- TX— Christian Rude

Mike Parrella  
Central Zone VP

- MI— Nate Curtis
- IL— Nate Curtis
- WI— Nate Curtis
- MN— Todd Gornik

Larry Camela  
Central Zone VP

- WV Seth Maniscalco
- PA— Joseph Ostrowski
- OH— Tim Morris
- IN— Rick Vanemon

Larry Camela  
Southeast Zone VP

- DE— Tridib Borkakoty
- MD— Tridib Borkakoty
- DC— Tridib Borkakoty
- VA— Tridib Borkakoty
- NC— Steve Tole
- SC— Steve Tole
- TN— Jack Finney
- GA— Randolph Wilson  
Steve Stasel
- AL— Randolph Wilson
- FL— Dan Sobeck

Mike Parrella  
Northeast Zone VP

- ME— Glen Caron
- NH— Glen Caron
- VT— Glen Caron
- CT— Dennis Buckley
- MA— Dennis Buckley
- RI— Dennis Buckley
- NY— Richard Longo
- NJ— Ray Plesnarski

# SIEMENS

## Healthcare

### Radiation Safety Program

<b>Title</b>	Managing Authorized Users	
<b>Date</b>	26 February 2015	<b>Duration</b> .5 Hours
<b>Instructor</b>	Matt Daut	
<b>Topics</b>	Regulatory Reasons for Service Licensing Current Status of Siemens Radioactive Material Licenses Overview of Device Registrations and Requirements Radioactive Material License Contents Management Responsibility Individual Responsibility Program Updates Management of The Radiation Safety Program	

<b>Attendees</b>	<b>Name</b>	<b>Comment</b>
	See Attached Spreadsheet	

<b>Name</b>	<b>Attendance</b>
Bernard, Barry	Attended
Bowles, Lisa	Attended
Chaffins, Brett	Attended
Farmer, Ben	Attended
Geertson, Richard	Attended
Goossens, John	Attended
Hauser, Tim	Attended
Hundtoft, Thomas	Attended
Jarrell, Steve	Attended
Kimball, Austin	Attended
Kruse, Brent	Attended
Leimpeter, Peggy	Attended
Matthews, Jon C	Attended
Ponsness, Kevin	Attended
Reed, Danny	Attended
Reynolds, Mikiola	Attended
Simmons III, John A	Attended
Taylor, Doug	Attended
Trunnell, Kristen	Attended
Tsoukalas, Georgios	Attended

### Radiation Safety Program Training RSO Conference

<b>Title</b>	Licensing Requirements and Application Submission	
<b>Date</b>	24 February 2015	<b>Duration</b> 2.5 Hours
<b>Instructor</b>	Matt Daut	
<b>Topics</b>	Regulatory Reasons for Service Licensing Current Status of Siemens Radioactive Material Licenses State by State review of license requirements Overview of Device Registrations and Requirements Radioactive Material License Application Contents Survey Requirements Duties and Responsibilities of the RSO Device Registries Management Responsibility Individual Responsibility Program Updates Management of The Radiation Safety Program	

<b>Attendees</b>	<b>Name</b>	<b>Comment</b>
	See Attached Spreadsheet	



## Agenda for Siemens RSO Meeting

### Monday

1115 to 1130	Early Lunch on-site	
1200 to 1230	Selected EH&S Overview	Hans Beinke
1230 to 1300	Opening Session	Sandy
	1. Welcome & Introduction- Matt Daut	
	2. Facility information	
	3. Risk Perceptions (public and customer experience)	
1300 to 1330	Message from VP Service Operations	Mike Guin
1330 to 1530	Siemens Forward Looking Topics	Friedhelm
1530 to 1630	Radiation Safety in X-ray Facilities (CT, C-arms, Angio, Mammo....interop?)	Brent
	1. What is a registration and what does it mean?	
	2. Basic X-ray unit safety	
	3. Shielding and X-ray survey general information	
	4. NOV's and Regulatory Concerns for X-ray users	
1800	RSO Night Out! Banquet TBD	

# Agenda for Siemens RSO Meeting

## Tuesday

0800 to 1000	<p>Health Effects and Sources of Radiation</p> <ol style="list-style-type: none"> <li>1. Hazards of radiation exposure</li> <li>2. Basics of radiation safety and benchmark numbers to remember</li> <li>3. Background Radiation Values and where they come from</li> </ol>	Brent
0800 to 1000	<p>Brief Regulatory Overview/Fundamentals of Radiation Safety</p> <ol style="list-style-type: none"> <li>1. 10 CFR 19, 20</li> <li>2. 10 CFR 31,32</li> <li>3. 10 CFR 35</li> <li>4. 10 CFR 40</li> <li>5. NUREG and Other guidance documents               <ol style="list-style-type: none"> <li>a. Characteristics of Radiation</li> <li>b. Units of Radiation Dose and Quantity of Radioactivity</li> <li>c. Levels of Radiation from Licensed Material</li> </ol> </li> </ol>	Sandy/ Brent
1000 to 12:00	<p>The Siemens RSO Experience</p> <ol style="list-style-type: none"> <li>1. Safety Culture for leadership</li> <li>2. RSO expectations (Matt D)</li> <li>3. Scenario discussions</li> <li>4. Time distance Shielding- ALARA</li> </ol>	Sandy
1200 to 1300	Lunch - Provided	
1300 to 1400	<p>Dosimetry</p> <ol style="list-style-type: none"> <li>1. Basics of Dosimetry (types of dosimeters and uses for each)</li> <li>2. Dosimetry oversight for RSO's</li> <li>3. What to do when (how to handle unusual dosimetry issues)</li> </ol>	Matt S.
1530 to 1600	<p>Hospital Sources of Radiation</p> <ol style="list-style-type: none"> <li>1. Where to find sources in a hospital</li> <li>2. When to report?</li> </ol>	Brent
1300 to 1430	Licenses/Auditing	Matt D.
1600 to 1700	Selected State Audits (Colorado) Simmons/Bubacz	Matt D.

# Agenda for Siemens RSO Meeting

## Wednesday

0800 to 0930	Emergency Response <ol style="list-style-type: none"> <li>1. When to act</li> <li>2. What does it mean for Siemens employees</li> <li>3. What does it look like for hospitals?</li> <li>4. Your Role in Emergencies</li> </ol>	Brent
0930 to 1200	Radiation Detectors <ol style="list-style-type: none"> <li>1. Basic detector information</li> <li>2. Uses for different detectors</li> <li>3. Basic Trouble shooting guide</li> </ol>	Matt S.
12:00 to 1300	Lunch (Provided)	
1300 to 1400	Radiation Surveys <ol style="list-style-type: none"> <li>1. Techniques</li> <li>2. Dos and Don'ts</li> </ol>	Matt S.
1400 to 1600	Radiation Survey Lab Activities	Matt S. Sandy Brent
1600 to 1700	PET/PET-CT/PET-MRI	Brent

## Thursday

0800 to 0900	Follow-up from 2014 RSO meeting	Sandy, Matt D.
0900 to 1030	Group Activities	Sandy, Matt D.
1030 to 1200	Operating and Emergency Procedures	Matt D.
1200 to 1300	Lunch (Provided)	
1300 to 1430	Therapy <ol style="list-style-type: none"> <li>1. Hazards from Linac Housing</li> <li>2. New Modalities</li> <li>3. ViewRay</li> </ol>	Brent
2:45- 4:00	Group Activity/TEST Certificates for course completion	Sandy, Brent
1600 to 1700	Selected Audits Washington (Nevada) Goossens	Matt D.

## Agenda for Siemens RSO Meeting

### Friday

0800 to 0900	CA North/CA South	Khoury
0900 to 1000	Hawaii	Goossens
1000 to 1100	Arizona	Goossens
1100 to 1200	New Mexico	Goossens
1200 to 1300	Utah	Goossens
1300 to 1400	Texas	Rude
1400 to 1700	Pennsylvania, West Virginia, Indiana, Michigan Ohio	Maniscalco

Complete as many audits as possible – subject to change and availability of personnel.

<b>Name</b>	<b>Attendance</b>	<b>Response</b>
Daut, Matthew	Meeting Organizer	Facilitated
Clark, William M	Required Attendee	Accepted
Goossens, John	Required Attendee	Accepted
Khoury, Nader	Required Attendee	Accepted
Maniscalco, Seth	Required Attendee	Accepted
Morris, Timothy	Required Attendee	Accepted
Ostrowski, Joseph	Required Attendee	Accepted
Reed, Jeff	Required Attendee	Accepted
Rude, Christian	Required Attendee	Accepted
Simmons III, John A	Required Attendee	Accepted
Sobeck, Dan	Required Attendee	Accepted
Stasel, Steven	Required Attendee	Accepted
Tole, Steve	Required Attendee	Accepted
Vanemon, Rick	Required Attendee	Accepted
Wilson, Randolph	Required Attendee	Accepted
Verburgt, Robert	Required Attendee	Accepted
Roberts, Jeffrey O	Required Attendee	Accepted
Hayes, Charmin	Required Attendee	Accepted
Guin, Michael	Optional Attendee	Accepted
Bubacz, Bruce	Required Attendee	Accepted
Curtis, Nathaniel	Required Attendee	Accepted
Gornick, Todd	Required Attendee	Accepted
Schreiber, Friedhelm	Optional Attendee	Accepted