Please stand by, the Meeting on Regulatory Relief for NRC Medical Licensees will begin shortly.

Please ensure you have called into the bridge line, it’s the only audio for today’s meeting:

Bridge Line: 888-452-5182
Pass Code: 2891351
Regulatory Relief Pathways for NRC Medical Licensees During the COVID-19 Public Health Emergency

April 22, 2020

Division of Materials Safety, Security, State, and Tribal Programs,
Office of Nuclear Material Safety and Safeguards
Division of Nuclear Materials Safety
NRC Region I
Purpose of Today’s Meeting

- Discuss available regulatory relief pathways for medical licensees during the COVID-19 public health emergency
- Discuss the process by which to submit requests for regulatory relief
- Hear from medical licensees on the types of regulatory relief they expect they might need
## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:00 p.m.</td>
<td>Introduction</td>
<td>Mike Layton, Director, Division of Materials Safety, Security, State, and Tribal Programs</td>
</tr>
<tr>
<td>2:05 p.m.</td>
<td>Meeting Logistics</td>
<td>Sarah Lopas, Facilitator</td>
</tr>
<tr>
<td>2:10 p.m.</td>
<td>Regulatory Relief Pathways</td>
<td>Chris Einberg, Chief, Medical Safety and Events Assessment Branch</td>
</tr>
<tr>
<td>2:20 p.m.</td>
<td>General Overview of Exemption Requests</td>
<td>Penny Lanzisera, Senior Health Physicist, Division of Nuclear Materials Safety, NRC Region I</td>
</tr>
<tr>
<td>2:30 p.m.</td>
<td>Comments from Medical Industry and Public</td>
<td></td>
</tr>
<tr>
<td>3:25 p.m.</td>
<td>Meeting Recap and Adjourn</td>
<td>Chris Einberg</td>
</tr>
</tbody>
</table>
Meeting Logistics

• Meeting audio is through the bridge line only (Bridge Line: 888-452-5182, Pass Code: 2891351)
• Participants are in listen-only mode until the public comment portion of the meeting
• Meeting materials include slides (ML20111A042), April 7 licensee letter (ML20094G166), and temporary exemptions table (ML20100D410)
• During the public comment portion of meeting, comment by phone or by submitting a message via WebEx Chat
Regulatory Relief Pathways

Chris Einberg, Chief
Medical Safety and Events Assessment Branch
This letter outlines the regulatory options for materials licensees to seek regulatory relief that may be necessary during the COVID-19 public health emergency.

- Exemptions to regulations and amendments for license conditions and tie downs
- Potential for NRC to issue enforcement discretion
- Emergency regulatory relief
- Accessible at ADAMS Accession No. ML20094G166
Temporary Exemption

- Exemptions are expected to be temporary.
- The expiration date of the exemption and/or any extension of deadlines to comply with regulatory requirements will be specified.
- Should additional time beyond the exemption be needed, the NRC would consider an exemption based on a subsequent request that updates all the information in the initial request.
NRC Preparation for Anticipated Relief Requests

- Created a template to allow NRC regions to quickly process anticipated exemption requests
- Developed guidelines for regional reviewers to quickly process anticipated requests
- Continually reviewing information received from medical professional societies and medical licensees regarding the impact of the COVID-19 emergency to prepare for anticipated requests
- Unanticipated requests will be evaluated but may take more time to process
Points of Contact for Regulatory Relief

- **Region I**
  James Trapp, Director
  James.Trapp@nrc.gov

- **Region III**
  David Pelton, Director
  David.Pelton@nrc.gov

- **Region IV**
  Mary Muessle, Director
  Mary.Muessle@nrc.gov
Agreement State Licensees

- See the Organization of Agreement States (OAS) Web site for links to Agreement State COVID-19 responses:

What to Include in COVID-19 Exemption Request

- Request to seek regulatory relief that may be necessary during the COVID-19 public health emergency
- Description of activities and parts of the facility that are shut down or where staff access is limited
- Description of activities and parts of the facility that are operational
- Description of any other COVID-19 related circumstances that affect the licensee’s ability to comply with certain regulatory requirements
- Regulations, license conditions, or license commitments for which licensee is seeking temporary relief
- Compensatory measures to ensure that licensed material is being stored and used safely
- Length of time shut down or restriction to facility is expected and actions to be taken when re-start occurs
Types of Requests Received in NRC Region I

• Licensee Mandated No or Limited Access to Facilities (e.g., only Essential Employees allowed access to portions of facility)
• Affects daily, weekly, monthly, quarterly, semi-annual, and annual commitments for Radiation Safety Program:
  – Area Surveys
  – Package Receipt Timelines
  – Equipment/Instrument Calibration and Testing
  – Dosimetry Exchange
  – Routine Inventories (sealed & unsealed)/Sealed Source Leak Tests
  – Routine Audits
  – Routine Training
  – Vendor activities (e.g., source exchange, preventative maintenance)
Emergency Relief Requests

• If necessary, licensees may request immediate exemptions via e-mail or phone
• Oral requests must be followed up within 24 hours with a written request
• Directors of the regional Divisions of Nuclear Materials Safety can provide oral authorization of the requested exemptions if immediate relief is needed and they deem appropriate
• In urgent, off-hours cases, call the Headquarters Emergency Operations Center at 301-816-5100
Medical Industry and Public Comments

• To make a comment over the phone, press “*” then “1” and follow the prompts.

• You can also submit shorter comments or questions by sending a WebEx chat message to “All Panelists”.
Questions for Licensees

• What hardships related to NRC regulations are you experiencing or expect to experience in the next 3 months due to the COVID-19 emergency?

• Are there any specific NRC regulations which you do not think you will be able to meet?

• How long do you believe exemptions might be necessary?

• To inform our approach regarding inspections: Are licensees able to support routine in-person inspections? What conditions would be necessary?
In Closing...

• For questions:
  – Contact your project manager (if known)
  or
  – E-mail “MedicalQuestions.Resource@nrc.gov”

• Send meeting format feedback to Sarah.Lopas@nrc.gov

• To subscribe to the Medical List Server, send an email to "Medical-GC.Resource@nrc.gov" with the word “subscribe” in the subject line