

**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

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

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

Materials Licensee Letter – April 7, 2020

- 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

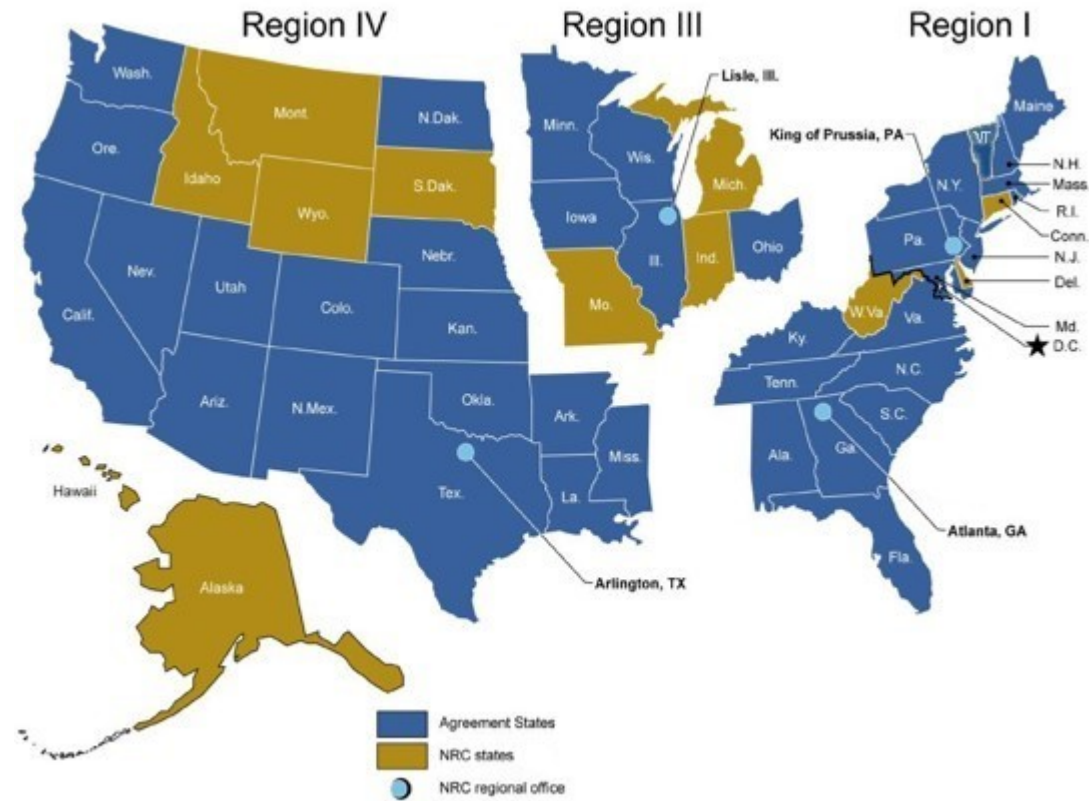
- Exemptions are expected to be temporary.
- The expiration date of the exemption and/or any extension of deadlines to comply with regulatory requirements will be specified.
- Should additional time beyond the exemption be needed, the NRC would consider an exemption based on a subsequent request that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

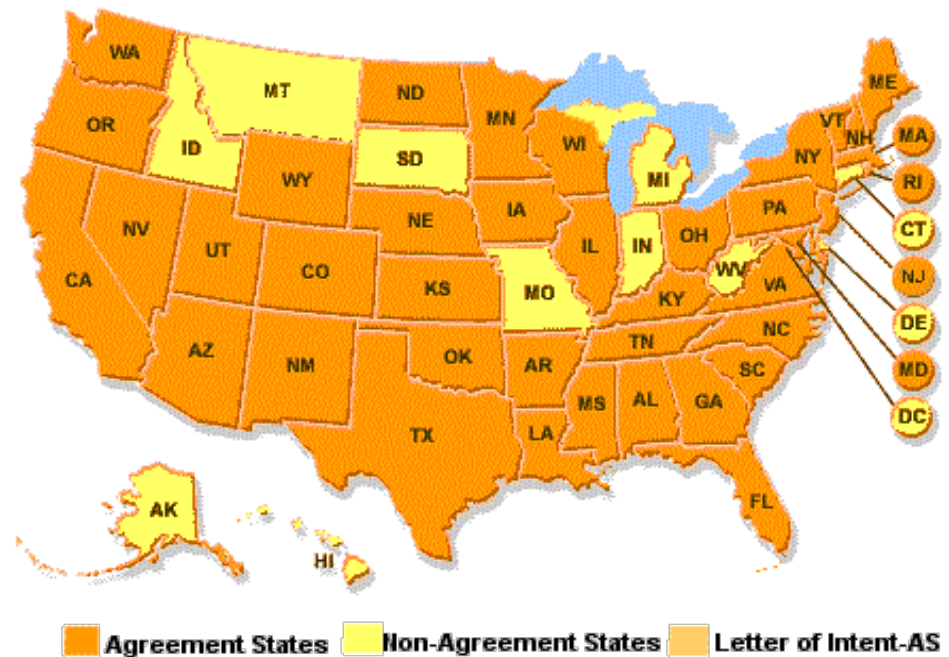
Points of Contact for Regulatory Relief

- Region I
James Trapp, Director
James.Trapp@nrc.gov
- Region III
David Pelton, Director
David.Pelton@nrc.gov
- Region IV
Mary Muessle, Director
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Agreement State Licensees

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



<https://www.agreementstates.org/covid-19-response.html>

Exemption Request Overview

Penny Lanzisera, Senior Health Physicist
Division of Nuclear Materials Safety, NRC Region I

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 requests
- 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