

# Town Hall Meeting to Discuss COVID-19 Regulatory Relief for Medical and Other Materials Licensees

November 17, 2020

Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Material Safety and Safeguards  
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# Today's Meeting

- The purpose of today's meeting is to summarize existing regulatory relief available to NRC medical and other materials licensees, and to obtain licensee and industry feedback to inform additional relief that is being considered for future development.

# Agenda

- Important documents
- Prior public meetings
- COVID-19 regulatory relief
  - Medical licensees
  - Other materials licensees
  - 10 CFR Part 37 requirements
- Additional relief being considered
- Feedback and questions

# Important Documents

- **April 7, 2020 NMSS “All Licensees” letter** regarding methods for regulatory relief ([ML20094G166](#))
- **Expedited exemption guidance letters**
  - Parts 30 and 34 licensees ([ML20133K127](#))
  - Part 35 licensees ([ML20126G386](#) and [ML20233B145](#))
  - Part 37 requirements ([ML20134H934](#))
- **Enforcement Guidance Memorandum (EGM) 20-002** ([ML20083K794](#))
  - Attachment 2 for 10 CFR Parts 30-36, and 39 requirements for licensees who have shut down ([ML20136A085](#))
  - Attachment 3 for compliance with radiological emergency response plans ([ML20143A066](#))
- **NRC Enforcement Policy** ([ML19352E921](#))

# Early Public Meetings on COVID-19 Regulatory Relief

- April 22 for Part 35 licensees ([ML20135G471](#))
- April 23 for Parts 30 and 34 licensees ([ML20136A218](#))
- May 5 for Part 37 licensees ([ML20134H965](#))
- Advisory Committee on the Medical Uses of Isotopes meeting ([ML20140A357](#)) and report ([ML20125A148](#)) on potential regulatory relief measures for medical uses licensees during the COVID-19 public health emergency

# Continued Regulatory Relief

- The NRC recognizes that due to the ongoing COVID-19 public health emergency, licensees may continue to experience challenges in meeting certain regulatory requirements.
- There continue to be multiple methods for providing temporary relief from requirements while continuing to maintain safety and security.

# Available Regulatory Relief

- See the April 7 “All Licensees” letter at [ML20094G166](#)
- Temporary exemptions to regulations and amendments for license conditions or technical specifications
- EGM 20-002, Attachment 2: Enforcement discretion for requirements under 10 CFR Parts 30-36, and 39, where licensees have suspended the use of licensed material and placed material in safe storage
- EGM 20-002, Attachment 3: Enforcement discretion for violations of emergency preparedness regulations
- Emergency regulatory relief
  - During off-hours, call the Headquarters Emergency Operations Center at 301-816-5100

# Expedited Exemption Guidance

- May 5 letter to 10 CFR Part 35 licensees regarding requests for temporary exemption from certain requirements ([ML20126G386](#)) and August 18 updated table of requirements eligible for expedited exemption review ([ML20233B145](#))
- May 15 letter to Part 30 and 34 licensees regarding requests for temporary exemption from certain requirements and tables of requirements eligible for expedited exemption review ([ML20133K127](#))
- May 20 letter regarding requirements under Part 37, Security for Category 1 and 2 Radioactive materials and expedited requests for temporary exemption ([ML20134H934](#))

# Approved Temporary Exemptions

- To date, the staff has reviewed and approved temporary exemptions for 35 nuclear material user licensees or master materials licensees and one NRC–recognized medical specialty board.
- Exemption requests and approvals are listed at <https://www.nrc.gov/about-nrc/covid-19/materials/med-indust-academic.html>.

# Approved Temporary Exemptions

- Temporary exemptions for timeliness of certain radiation safety tasks:
  - Instrument calibrations
  - Area surveys
  - Material inventories
  - Sealed source leak tests
  - Security checks
  - Protocol renewals
  - Environmental sampling
  - Personnel dosimetry exchanges
  - Irradiator security device testing and calibration
  - Package receipt inspections
  - Annual reviews of radiation protection programs
  - Quarterly Radiation Safety Committee meetings
  - Program audits, etc.
- Temporary exemptions for some training requirements:
  - Annual radiation safety instruction related to patient release
  - Annual operational and safety instructions to operators
  - Supervised work experience training for generator elutions

# 10 CFR Part 37 Regulatory Relief for Security of Category 1 and 2 Radioactive Materials

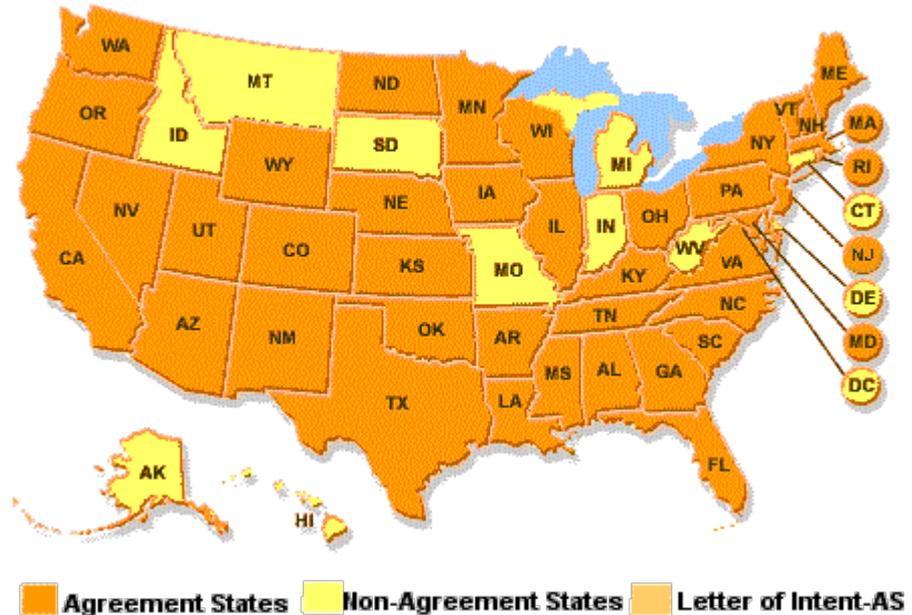
- To date, the NRC has received and granted two requests for temporary exemptions related to annual training (10 CFR 37.43(c)(3))
- NRC staff does not anticipate issuing an EGM for Part 37
- NRC staff continues to conduct inspection oversight and review the impact of the COVID-19 public health emergency on implementation of Part 37

# Additional Relief Being Considered

- The staff is considering development of an EGM for licensees that have continued, or are restarting, operations
  - Medical
  - Radiography
  - Irradiators
  - Other?
- Continue to update expedited exemption tables as needed

# Agreement State Licensees

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



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

# Discussion

- The NRC is interested in any feedback regarding the available relief, or any unanticipated challenges you have experienced, such as:
  - Has the current relief met your needs?
    - Expedited exemptions?
    - Enforcement discretion?
  - Are there any additional areas where COVID has presented a challenge to meeting the requirements?