



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

June 5, 2020

David Pelton, Director
Division of Nuclear Materials Safety
Nuclear Regulatory Commission (NRC) Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA – Request for temporary authority to grant exemptions from NRC regulations in 10 CFR Parts 30 and 35.

Dear Mr. Pelton:

In accordance with 10 CFR 30.11(a), we request the VA be granted temporary authority to provide exemptions under limited conditions due to COVID-19 impacts. Pursuant to Item 5.A. of the VA-NRC Letter of Understanding, we request temporary authority to grant exemptions from a number of NRC regulations and facility permit conditions during the COVID-19 emergency. The NRC-suggested exemptions are listed in the enclosures below; the license conditions listed in the table will be applied to individual MML permittees.

Our intent is to use these exemptions selectively as needed during the emergency. We do not intend to use all the exemptions at all VA medical facilities with radioactive materials permits.

We request the authority to grant each exemption for a 90-day time period, with the option to extend it an additional 90 days not to go past the end of Calendar Year 2020. Exemptions granted to permittees will be reported quarterly to the NRSC for oversight and we will keep an auditable record of any exemptions granted.

The request for relief from the listed regulations is due to VA, local, State, and National restrictions (including social distancing and travel) in place as a result of the COVID-19 pandemic. These regulations cannot be safely met without increasing the possibility of exposing NHPP staff, the permittees' employees, contractors, patients, or members of the general public to the COVID-19 virus. This request will not endanger life or property or the common defense and security and is otherwise in the public interest.

Please contact Edwin M. Leidholdt, Jr., Ph.D., at 501-257-1571; Clinton Abell, MSHP, at 501-708-5013; or Joseph Stanley Bravenec, MS, at 281-224-6133, if you have questions about this request.

Sincerely,

David Bushnell

David L. Bushnell, M.D.
Chair, VHA National Radiation Safety Committee

Enclosures

Material Licensee Generic Exemptions During the Emergency Caused by the COVID-19 Pandemic

04/13/2020

Regulation	Description of Exemption	Safety Basis (Open)	Safety Basis (Closed)	Exemption Language
10 CFR 30.34 Terms and conditions of licenses				
10 CFR 30.34	The requirement in License Condition [number] to perform a physical inventory every 6 months;	This exemption is relatively short compared to the required 6-month interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required 6-month interval. Additionally, the extension of inventory time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using these instruments.	From the date of issuance of this letter for a period of 90 days, the licensee is exempt from the requirement in license condition [number] to perform a physical inventory of licensed material every 6 months. Inventories shall be completed within 30 days following the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform leak testing every 6 months or at the frequency specified in the SSD; <i>Note: The leak testing requirements specified in the SSD range from 6 months to 3 years.</i>	This exemption is relatively short compared to the required leak testing interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required leak testing interval. Additionally, the extension of the leak test time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using these sources.	From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempt from the requirement in license condition [number] to perform leak tests every 6 months. The licensee shall perform the required leak tests within 30 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform surveys <i>Note: for companies who are still operating, make</i>	This exemption is relatively short compared to the required survey interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety	This exemption is relatively short compared to the required survey interval. Additionally, the extension of survey time does not constitute a significant increase in risk to public health and safety, because the licensee suspended	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the survey time interval required by license condition [number] . The licensee shall perform the required surveys within 7 days

Material Licensee Generic Exemptions During the Emergency Caused by the COVID-19 Pandemic

	<i>sure that this exemption is needed</i>		operations and is not using these instruments.	of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to exchange dosimetry	This exemption is relatively short compared to the required dosimetry exchange interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required dosimetry exchange interval. Additionally, the extension of dosimetry exchange time does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using equipment that would lead to accumulated dose.	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the dosimetry exchange requirement in license condition [number] . The licensee shall make the required dosimetry exchanges within 7 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to provide radiation safety refresher training at intervals not to exceed 12 months	This exemption is relatively short compared to the required refresher training interval. The NRC notes that the licensee must continue to provide initial radiation safety training to each radiation worker. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required refresher training interval. Additionally, the extension of time between training does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.	From the date of issuance of this letter until for a period of 90 days, the licensee is temporarily exempted from the refresher training frequency requirement in license condition [number] . The licensee shall provide the required refresher training within 90 days of the expiration of this exemption.
10 CFR 30.34	The requirement in License Condition [number] to perform instrument calibration	This exemption is relatively short compared to the required calibration interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.	This exemption is relatively short compared to the required calibration interval. Additionally, the extension of time between instrument calibrations does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not using the instruments for which calibration is required.	From the date of this letter for a period of 90 days, the licensee is temporarily exempt from the calibration time interval requirement in license condition [number] . The licensee shall perform the required calibration within 7 days of the expiration of this exemption.

Material Licensee Generic Exemptions During the Emergency Caused by the COVID-19 Pandemic

<p>10 CFR 30.34</p>	<p>The requirement in License Condition [number] to hold Radiation Safety Committee meetings at intervals not to exceed [X] months;</p> <p><i>Note: this exemption should only be used for licensees that have suspended licensed activities.</i></p>	<p>[Do not issue this exemption for companies that are still acting under the authority of their licenses]</p>	<p>The extension of time between Radiation Safety Committee meetings does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.</p>	<p>From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in license condition [number] to perform Radiation Safety Committee meetings at intervals not to exceed [X] months. The licensee shall hold the required meeting within 30 days of the expiration of this exemption.</p>
<p>10 CFR 30.34</p>	<p>The requirement in License Condition [number] to complete an annual program review at intervals not to exceed 12 months;</p>	<p>This exemption is relatively short compared to the required annual program review interval. Therefore, the exemption does not constitute a significant increase in risk to public health and safety.</p>	<p>This exemption is relatively short compared to the required annual program review interval. Additionally, the extension of time between annual program reviews does not constitute a significant increase in risk to public health and safety, because the licensee suspended operations and is not acting under the authority of its license.</p>	<p>From the date of issuance of this letter for a period of 90 days, the licensee is temporarily exempted from the requirement in license condition [number] to perform an annual program review at intervals not to exceed 12 months. The licensee shall perform the annual program review within 90 days of the expiration of this exemption.</p>

Medical Use Licensee Temporary Exemptions

During the Emergency Caused by the COVID-19 Public Health Emergency

Updated: May 8, 2020

This table provides a list of 10 CFR Part 19, 20, 30, and 35 requirements for the which the NRC may consider expedited requests for temporary exemption. Licensees may seek a temporary exemption from these requirements to address the challenges licensees may face during the COVID-19 Public Health Emergency (PHE). This table may be updated as the NRC identifies additional requirements for which the NRC may consider expedited requests for temporary exemption.

Regulation	Description of Regulation
35.60(b)	The requirement in 10 CFR 35.60(b) that the licensee calibrate the instrumentation required in 10 CFR 35.60(a) in accordance with nationally recognized standards or the manufacturer's instructions. <i>(Note: this exemption should only be applied to instrumentation for which nationally recognized standards or manufacturer's instructions require calibration at time intervals of a month or longer. Exemptions from § 35.60(b) should not be issued for other instrumentation without further review. In addition, this exemption should not be combined with extensions in calibrations intervals recommended by nationally recognized standards due to COVID-19 emergency.)</i>
35.61(a)	The requirement in 10 CFR 35.61(a) that the licensee calibrate survey instruments used to show compliance with 10 CFR Parts 20 and 35 annually.
35.67(b)(2)	The requirement in 10 CFR 35.67(b)(2) that the licensee test sealed sources and brachytherapy sources for leakage at intervals not to exceed 6 months at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.
35.67 (g)	The requirement in 10 CFR 35.67(g) that the licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession.
35.310(a)	The portion of 10 CFR 35.310(a) that requires licensees to provide radiation safety instruction at least annually to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.
35.410(a)	The portion of 10 CFR 35.410(a) that requires licensees to provide radiation safety instruction at least annually to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75.
35.610(d)(2)	The portion of 10 CFR 35.610(d)(2) that requires licensees to provide operational and safety instructions at least annually to individuals who operate the unit at the facility.
35.630(a)	The requirement in 10 CFR 35.630(a) that the licensee perform calibration on the dosimetry system in accordance with the conditions in paragraph (a)(1) or paragraph (a)(2).
35.633(a)(3)	The requirement in 10 CFR 35.633(a)(3) that the licensee perform calibration at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days.

Medical Use Licensee Temporary Exemptions

During the Emergency Caused by the COVID-19 Public Health Emergency

Updated: May 8, 2020

Regulation	Description of Regulation
35.633(a)(4)	The requirement in 10 CFR 35.633(a)(4) that the licensee perform full calibration at intervals not exceeding 1 year for low dose-rate remote afterloader units.
35.635(a)(3)	The requirement in 10 CFR 35.635(a)(3) that the licensee perform full calibration at intervals not exceeding 1 year for gamma stereotactic radiosurgery units.
35.655(a)	The requirement in 10 CFR 35.655(a) that the licensee shall have each teletherapy unit or gamma stereotactic unit fully inspected and serviced at intervals not to exceed 5 years for each teletherapy unit/7 years for each gamma stereotactic radiosurgery unit.
35.3045(d)	The requirement in 10 CFR 35.3045(d) that the licensee submit a written report to the appropriate regional office within 15 days after discovery of a medical event.
20.1101(c)	The requirement in 10 CFR 20.1101(c) that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.
19.13(b)	The requirement in 10 CFR 19.13(b) that each licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or (2) The individual requests his or her annual dose report.
30.34 (Annual Radiation Safety Training License Condition)	The requirement in License Condition [number] to comply with the commitment in the letter dated XXXX to provide annual radiation safety refresher training as described in NUREG-1556, Volume 9.

Song, Taehoon

From: Leidholdt, Ed <Edwin.Leidholdt@va.gov>
Sent: Monday, June 08, 2020 7:09 PM
To: Parker, Bryan
Cc: Bushnell, David L.; Abell, Clinton E.; Bravenec III, Joseph S (HOU); Edwards, Mark W.; Kidwell, Calvin B
Subject: [External_Sender] Request for temporary authority to grant exemptions to specific NRC regs
Attachments: Letter MML Regs Exemp Req Final w Encl.pdf

Bryan:

Please find attached the VA's request for temporary authority to grant exemptions to some NRC regulations.

Would you please reply to this message to acknowledge receipt?

Please call me at 916 833-8415 if you have questions about this request.

Thank you.

Ed

Edwin M. Leidholdt, Jr., Ph.D., FACR
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