

Medical Licensee Temporary Exemptions During the Emergency Caused by the COVID-19 Pandemic

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Regulation	Description of Exemption	Safety Basis	Exemption Language
Subpart C – General Technical Requirements			
35.60(b)	<p>The regulation from which [the licensee] is requesting an exemption is 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></p>	<p>The extension of calibration time does not constitute a significant increase to the risk of failure of these instruments or to public health and safety. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	<p>For instrumentation that, in accordance with the requirement in 10 CFR 35.60(b), is due to be calibrated between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the calibration time interval required by 10 CFR 35.60(b). The licensee may instead extend the required time interval for calibration of the instrumentation by [the requested extension, up to 90 days]. If the instrumentation exhibits signs that it might be malfunctioning, the licensee must suspend use of the instrumentation until it can be calibrated. This exemption does not apply to any instrumentation for which nationally recognized standards or manufacturer’s instructions require calibration more frequently than once per month. In addition, this extension must not be combined with extensions in calibrations intervals recommended by nationally recognized standards due to the COVID-19 emergency. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate instrumentation as soon as is safely possible. [The licensee] requested to extend the required time interval for calibration during the emergency caused by the COVID-19 pandemic.</p>

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35.61(a)	<p>The regulation from which [the licensee] is requesting an exemption is 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.</p>	<p>The regulation in 10 CFR 35.61(a) requires licensees to calibrate survey instruments used to show compliance with 10 CFR Parts 20 and 35 before first use, annually, and following repair. This exemption would only be from the requirement to perform annual calibrations, not to the requirement to perform calibrations before first use and following repair. The extension provided by this exemption is relatively short compared to the one-year time period between calibration of survey instruments. This relatively short extension does not constitute a significant increase in risk to public health and safety. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds</p>	<p>For instrumentation that, in accordance with the requirement in 10 CFR 35.61(a), is due to be calibrated between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the calibration time interval required by 10 CFR 35.61(a) and may instead extend the required time interval for calibration of the instrumentation by [the requested extension, up to 90 days]. If the instrumentation exhibits signs that it might be malfunctioning, the licensee must suspend use of the instrumentation until it can be calibrated. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate instrumentation as soon as is safely possible. [The licensee] requested to extend the time interval for calibration during the emergency caused by the COVID-19 pandemic.</p>

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		that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.	
35.67(b)(2)	The regulation from which [the licensee] is requesting an exemption is 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.	The extension provided by this exemption is relatively short. In addition, licensees must still perform leak tests if the sources exhibit signs that the source might be leaking, such as increased dose rates of the patient following procedures, which would indicate significant leakage. Therefore, this exemption does not constitute a significant increase in risk to public health and safety. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and	For sealed sources or brachytherapy sources that, in accordance with the requirement in 10 CFR 35.67(b)(2), are due to be leak tested between the date of this letter and [up to 90 days after issuance] , [the licensee] is temporarily exempt from the requirements of 10 CFR 35.67(b)(2) and may instead extend the required time interval for leak testing of the sources by [the requested extension, up to 90 days] . If the source exhibits signs that it might be malfunctioning, the licensee must suspend use of the source until it can be leak tested. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to leak test sources as soon as is safely possible. [The licensee] requested to extend the leak test interval required by paragraph (b)(2) of this section for [brachytherapy and/or sealed sources] during the emergency caused by the COVID-19 pandemic.

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		security and is otherwise in the public interest.	
Subpart E – Unsealed Byproduct Material – WD Required			
35.310(a)	The regulation from which [the licensee] is requesting an exemption is 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.	The relatively short period delay of annual instruction does not constitute a significant increase in risk to public health and safety. The licensee must continue to provide initial radiation safety instruction to staff caring for patients or human research subjects who cannot be released. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.	From the date of issuance of this letter until [90 days after issuance] , the licensee is temporarily exempted from the requirement in 10 CFR 35.310(a) that the licensee must provide annual instruction to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75. The purpose of this exemption would be to allow [the licensee] to delay this annual instruction during the emergency caused by the COVID-19 pandemic.
35.410(a)	The regulation from which [the licensee] is requesting an exemption is the portion of 10 CFR 35.410(a) that requires licensees to	The relatively short period delay of annual instruction does not constitute a significant increase in risk to public health and safety.	From the date of issuance of this letter until [insert the date of the requested extension, up to 90 days after issuance] , the licensee is temporarily exempted from

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	<p>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.</p>	<p>The licensee must continue to provide initial radiation safety instruction to staff caring for patients or human research subjects who cannot be released. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	<p>the requirement in 10 CFR 35.410(a) that the licensee must provide annual instruction to personnel caring for patients or human research subjects who cannot be released under 10 CFR 35.75. The purpose of this exemption would be to allow [the licensee] to delay this annual instruction during the emergency caused by the COVID-19 pandemic.</p>
<p align="center">Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery (GSR) Units</p>			
<p>35.610(d)(2)</p>	<p>The regulation from which [the licensee] is requesting an exemption is 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.</p>	<p>The relatively short period delay of annual instruction does not constitute a significant increase in risk to public health and safety. The licensee must continue to provide initial radiation safety instruction to individuals who operate the unit at the facility and must also continue to provide</p>	<p>From the date of issuance of this letter until [90 days after issuance], the licensee is temporarily exempted from the requirement in 10 CFR 35.610(d)(2) that the licensee must provide operational and safety instructions at least annually to individuals who operate the unit at the facility. The purpose of this exemption would be to allow [the licensee] to delay this annual</p>

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		<p>instruction in accordance with 10 CFR 35.610(d)(1). The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	<p>instruction during the emergency caused by the COVID-19 pandemic.</p>
<p>35.630(a)</p>	<p>The regulation from which [the licensee] is requesting an exemption is 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).</p>	<p>The requested extension is relatively short compared to the 2-year interval in paragraph (a)(1) or 4-year interval in paragraph (a)(2) and does not constitute a significant increase in risk to public health and safety. Further, if the licensee chooses to calibrate its systems in accordance with the conditions in 10 CFR 35.630(a)(1), then the requirement to perform calibrations after any servicing that may have affected system</p>	<p>For systems that, in accordance with the requirement in 10 CFR 35.630(a), are due to be calibrated between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the 2-year and 4-year calibration time intervals required by paragraphs (a)(1) and (a)(2), respectively, and may instead extend the required time interval for calibration of the system by [the requested extension, up to 90 days]. If the system exhibits signs that it might be malfunctioning, the licensee must suspend use of the system until it can be calibrated. Notwithstanding the</p>

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		<p>calibration will continue to apply. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	<p>regulatory relief provided by this exemption, the licensee should try to calibrate the system as soon as is safely possible. [The licensee] requested to delay performance of the calibration during the emergency caused by the COVID-19 pandemic.</p>
<p>35.633(a)(3)</p>	<p>The regulation from which [the licensee] is requesting an exemption is 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.</p>	<p>The requested extension is relatively short compared to the 1 quarter interval and does not constitute a significant increase in risk to public health and safety. Further, the licensee will still be required to perform periodic spot checks and full calibrations following replacement of sources or any repairs in accordance with 10 CFR 35.633(a)(2). The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities</p>	<p>For units that, in accordance with the requirement in 10 CFR 35.633(a)(3), are due to be calibrated between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the calibration time interval required by 10 CFR 35.633(a)(3) and may instead extend the required time interval for calibration of the unit by [the requested extension, up to 30 days]. If a unit exhibits signs that it might be malfunctioning, the licensee must suspend use of the unit until it can be calibrated. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate units as</p>

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		<p>increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	<p>soon as is safely possible. [The licensee] requested to delay performance of the calibration during the emergency caused by the COVID-19 pandemic.</p>
<p><u>35.633(a)(4)</u></p>	<p>The regulation from which [the licensee] is requesting an exemption is 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.</p>	<p>The requested extension is relatively short compared to the 1-year interval and does not constitute a significant increase in risk to public health and safety. Further, the licensee will still be required to perform periodic spot checks and full calibrations following replacement of sources or any repairs in accordance with 10 CFR 35.633(a)(2). The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19</p>	<p>For units that, in accordance with the requirement in 10 CFR 35.633(a)(4), are due to have a full calibration between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the full calibration time interval required by 10 CFR 35.633(a)(4) and may instead extend the required time interval for full calibration of the unit by [the requested extension, up to 90 days]. If a unit exhibits signs that it might be malfunctioning, the licensee must suspend use of the unit until it can be fully calibrated. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to fully calibrate units as soon as is safely possible. [The licensee] requested to delay performance of the full calibration during the emergency caused by the COVID-19 pandemic.</p>

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		<p>virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.</p>	
<p><u>35.635(a)(3)</u></p>	<p>The regulation from which [the licensee] is requesting an exemption is 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. [The licensee] requested to delay performance of the full calibration by [requested extension] during the emergency caused by the COVID-19 pandemic.</p>	<p>The requested extension is relatively short compared to the 1-year interval and does not constitute a significant increase in risk to public health and safety. Further, the licensee will still be required to perform periodic spot checks and full calibrations as required by 10 CFR 35.635(a)(2). The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common</p>	<p>For units that, in accordance with the requirement in 10 CFR 35.635(a)(3), are due to have a full calibration between the date of this letter and [90 days after issuance], [the licensee] is temporarily exempt from the calibration time interval required by 10 CFR 35.635(a)(3) and may instead extend the required time interval for full calibration of the unit by [the requested extension, up to 90 days]. If a unit exhibits signs that it might be malfunctioning, the licensee must suspend use of the unit until it can be fully calibrated. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to calibrate units as soon as is safely possible. [The licensee] requested to delay performance of the full calibration during the emergency caused by the COVID-19 pandemic.</p>

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		defense and security and is otherwise in the public interest.	
35.655(a)	The regulation from which [the licensee] is requesting an exemption is the requirement in 10 CFR 35.655(a) that the licensee shall have each [teletherapy unit/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] .	The requested extension is relatively short compared to the [5-year/7-year] interval and does not constitute a significant increase in risk to public health and safety. The NRC staff notes that, absent the proposed exemption, [additional staff would be required to come into the medical facilities increasing the possibility of exposing licensee’s employees, contractors, patients, or members of the general public to the COVID-19 virus and/or the medical facilities would not be able to provide patient care.] Therefore, the NRC staff finds that the proposed exemption will not endanger life or property or the common defense and security and is otherwise in the public interest.	For units that, in accordance with the requirement in 10 CFR 35.655(a), are due to be inspected and serviced between the date of this letter and [90 days after issuance] , [the licensee] is temporarily exempt from the inspection and service time interval required by 10 CFR 35.655(a) and may instead extend the required time interval for calibration of the unit by [the requested extension, up to 120 days] . If a unit exhibits signs that it might be malfunctioning, the licensee must suspend use of the unit until it can be inspected and serviced. Notwithstanding the regulatory relief provided by this exemption, the licensee should try to have the units inspected and serviced as soon as is safely possible. [The licensee] requested to delay performance of this inspection and servicing during the emergency caused by the COVID-19 pandemic.