Penn Medicine
Lancaster General Health

Office of Radiation Safety & Medical Physics

April 20, 2020

Pennsylvania Department of Environmental Protection
Bureau of Radiation Protection
Rachel Carson State Office Building
P.O. Box 8469
Harrisburg, Pennsylvania 17105-8469

RE: Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

To Whom It May Concern:

Lancaster General Health would like to request a temporary suspension of regulatory requirements and/or permit conditions. These regulations or conditions refer specifically to the use of ionizing radiation for medical use, as found in **Title 25, Environmental Protection**, and **Article V, Radiological Health**.

The following documents are attached in support of our request:

1) DEP form "COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions", completed and signed.

2) Attachment A, which details the regulations and/or conditions for which we request suspension, and provides information requested on the aforementioned DEP form. This form lacked sufficient space for the information requested.

3) The document, "Medical Licensee Temporary Exemptions During the Emergency Caused by the COVID-19 Pandemic", from the U.S. Nuclear Regulatory Commission (NRC). This document is submitted as evidence that the federal agency under which the PA Bureau of Radiation Protection operates as an "Agreement State" has issued a precedent for suspension of the regulations for which we request the same.

Thank you for your assistance in this matter. If you have need of any further information, please contact me using the information below.

Sincerely,

Anthony D. Montagnese

Anthony D. Montagnese, M.S., DABR

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pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

In accordance with Governor Wolf's Proclamation of Disaster Emergency of March 6, 2020 and the Governor's powers pursuant to the Emergency Management Code, 35 Pa.C.S. §7301, the Governor has authority to suspend regulatory obligations and other legal obligations within his jurisdiction where strict compliance will prevent, hinder, or delay necessary action in coping with the COVID-19 emergency.
*If you are requesting suspension of a Federal requirement, under only Federal authority, please contact US EPA Region III and refer to the US EPA March 26, 2020 Memorandum (COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program). To the extent the request relates to a federal program delegated to Pennsylvania, Pennsylvania will review requests submitted in this format.

Submit completed and signed requests to the email resource account:
RA-EPCOVID19SuspReq@pa.gov

Background
A. Identify the Regulated Entity or Permittee, including an address for the location of the permitted or regulated activity (if no address, DEP Permit No. can be used), and a point of contact for this request with email and phone number. Lancaster General Hospital, 555 N. Duke Street, Lancaster, PA 17604; Lancaster General Suburban Outpatient Pavilon, 2100 Harrisburg Pike, Harrisburg, PA 17604. Other outpatient facilities.
B. Describe what permitted or regulated activity you are engaged in. Use of byproduct material and radiation-producing machines for medical purposes.
C. If you were issued a permit by DEP for the permitted or regulated activity described above, identify the type of permit and permit number. Please list the DEP Office, Conservation District, Oil and Gas District Office, or District Mining Office that issued the permit or authorization. Radioactive materials license PA-0233. Certificates of Registration for Radiation-Producing Machines: 10-03909; 10-44017; 10-44022; 20-48034; 20-48205; 20-49448; 20-49619; 20-48718; 20-49037; 02-40062; 20-48708; Linear accelerator License: AC10-44017
D. Identify what regulatory requirement(s) or permit condition(s) or other requirement(s) you seek a temporary suspension of. Please cite the specific regulatory requirement(s), condition(s) and/or other requirement(s). Please see Attachment A.

Reasons for Requested Suspension
For each regulatory requirement or permit condition or requirement listed above, please state clearly why you are seeking the temporary suspension, addressing at least the following in detail:
A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be as specific as possible.

COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

Please see Attachment A
B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension? Please see attachment A
C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements? Please see attachment A
D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted? Please see attachment A
E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history. Please see attachment A
F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s) or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020. Please see attachment A
G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance. Please see attachment A

Evaluate Risk to Public Health and the Environment
A. Will the temporary suspension, if granted, result in an increase in the risk of additional pollution (e.g. increased emissions, increased concentrations of any pollutant and/or releases of new or more pollutants) and/or will it result in less monitoring, reporting, and/or supervision of pollution incidents, accidents or equipment failures? No. The radiation risk associated with delaying compliance with these activities is negligible.
(i) If yes, please identify what pollutants and the nature of the risk.

COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

(ii) If yes, please identify the potential extent of increased pollution, including any increases in risk to human health, safety or the environment.

(iii) If no, explain how increased pollution will be avoided.
Once the COVID-19-related social distancing and other restrictions are lifted, we will immediately begin returning to full compliance.

B. What public health and/or safety benefits will result if the temporary suspension is granted?
Reduction/minimization of the risk of COVID-19 spread to staff, patients, and the general public.

C. Is the restriction on your ability to comply generally applicable to others engaged in your industrial classification or industry? If no, please explain why your situation is unique.
Yes

D. Would you possess a unique advantage over your competitors, or others in the same industry, if a suspension is granted?
No

E. What would be the negative consequences to your operation if the temporary suspension is not granted? What would be the negative consequences to the Commonwealth's response to the COVID-19 emergency if your requested temporary suspension is not granted?
If required to comply as normal, staff will be required to put themselves at heightened risk of COVID-19 exposure, either due to the gathering of multiple persons in one location or coming into a health facility with known COVID-19 patients to perform a regulated task or to meet a regulatory deadline.

CERTIFICATION

Pursuant to the prohibition against unsworn falsification to authorities, 18 Pa.C.S.A. §4904, I am an authorized representative of the requestor and have personal knowledge of the facts set forth in this temporary suspension request.

I hereby certify that the information provided herein is true and accurate.

Anthony D Montagnese 4/20/20
Signature and title of Certifier Radiation Safety Officer

COVID-19-Emergency Request to Temporarily Suspend Regulatory Requirements and/or Permit Conditions

Anthony D. Montagnese, M.S., DABR, Radiation Safety Officer
Print Name and Title

Submit completed and signed requests to the email resource account:
RA-EPCOVID19SuspReq@pa.gov

Attachment A
Regulatory Exemptions Requested and Reasons for Requested Suspension

I. Calibration of Instrument Used to Measure Activity of Unsealed Byproduct Material
Regulatory Requirement or Permit Condition (all from Title 25, Environmental Protection
§ 224.10 (incorporating 10 CFR § 35.60 by reference)

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be specific as possible.
Since some clinical areas are shut down to protect staff and patients from COVID-19 spread, strict adherence to this regulation would require workers to come into the clinic for the sole purpose of performing a QC check on an instrument not currently in use.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?
As a general safety practice, unnecessary staffing and activities are being discouraged to minimize the health risk of contact with the virus.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?
Most of our outpatient clinics and services are either shut down completely or severely limited to minimize the risk of close-in contact between staff, patients, and the general public. We are not requesting any suspensions or waivers from other government agencies.

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?
Compliance with this regulation requires on-site presence of a worker. There is no alternate means to comply with it.

E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history.
We do not believe cost gouging or supply hoarding is negatively effecting our ability to comply.

F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s), or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020.
We will be unable to comply as long as regulatory and advisory agencies recommend minimizing staffing and social distance due to the risk of COVID-19 spread. We request suspension until at least June 30.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.
In records documenting the testing and calibration of the applicable instruments, a note will be made regarding the date of suspension of testing and/or calibration.

II. Safety Instruction

Regulatory Requirement or Permit Condition (all from Title 25, Environmental Protection

§ 224.10 (incorporating 10 CFR § 35.310(a) by reference)

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be specific as possible.

This regulation requires radiation safety instruction at least annually to personnel caring for patients who cannot be released under 10 CFR 35.75. Current recommendations discourage the assembly of groups of people for the purpose of social-distancing. Since our training program for this subject cannot be applied remotely or electronically, it is not possible to deliver a "live" training of personnel and comply with social distancing.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?

As stated above, restrictions on the gathering of large groups of people prohibit large-scale instruction, as evidenced by school closures.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?

Most of our outpatient clinics and services are either shut down completely or severely limited to minimize the risk of close-in contact between staff, patients, and the general public. We are not requesting any suspensions or waivers from other government agencies.

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?

On-line, electronic presentations could be explored to meet compliance; however, they are not currently developed and may not be in time to comply with the annual component of the regulation cited above. In addition, some training requires a live, "hands-on", component.

E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history.

We do not believe cost gouging or supply hoarding is negatively effecting our ability to comply.

F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s), or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020.

We will be unable to comply as long as regulatory and advisory agencies recommend minimizing staffing and social distance due to the risk of COVID-19 spread. We request suspension until at least June 30.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.

In records documenting annual staff retraining, we will note the reason for the delay in complying with the annual time frame.

III. Safety Instruction

Regulatory Requirement or Permit Condition (all from Title 25, Environmental Protection

§ 224.10 (incorporating 10 CFR § 35.410(a) by reference)

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be specific as possible.

This regulation requires radiation safety instruction at least annually to personnel caring for patients receiving brachytherapy. Current recommendations discourage the assembly of groups of people for the purpose of social-distancing. Since our training program for this subject cannot be applied remotely or electronically, it is not possible to deliver a "live" training of personnel and comply with social distancing.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?

As stated above, restrictions on the gathering of large groups of people prohibit large-scale instruction, as evidenced by school closures.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?

Most of our outpatient clinics and services are either shut down completely or severely limited to minimize the risk of close-in contact between staff, patients, and the general public. We are not requesting any suspensions or waivers from other government agencies.

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?

On-line, electronic presentations could be explored to meet compliance; however, they are not currently developed and may not be in time to comply with the annual component of the regulation cited above. In addition, some training requires a live, "hands-on", component.

E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history.

We do not believe cost gouging or supply hoarding is negatively effecting our ability to comply.

F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s), or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020.

We will be unable to comply as long as regulatory and advisory agencies recommend minimizing staffing and social distance due to the risk of COVID-19 spread. We request suspension until at least June 30.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.

In records documenting annual staff retraining, we will note the reason for the delay in complying with the annual time frame.

IV. Safety Instruction

Regulatory Requirement or Permit Condition (all from Title 25, Environmental Protection

§ 224.10 (incorporating 10 CFR § 35.610(d) by reference)

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be specific as possible.

This regulation requires radiation safety instruction at least annually to personnel who operate a remote afterloader unit. Current recommendations discourage the assembly of groups of people for the purpose of social-distancing. Since our training program for this subject cannot be applied remotely or electronically, it is not possible to deliver a "live" training of personnel and comply with social distancing.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?

As stated above, restrictions on the gathering of large groups of people prohibit large-scale instruction, as evidenced by school closures.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?

Most of our outpatient clinics and services are either shut down completely or severely limited to minimize the risk of close-in contact between staff, patients, and the general public. We are not requesting any suspensions or waivers from other government agencies.

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?

On-line, electronic presentations could be explored to meet compliance; however, they are not currently developed and may not be in time to comply with the annual component of the regulation cited above. In addition, some training requires a live, "hands-on", component.

E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history.

We do not believe cost gouging or supply hoarding is negatively effecting our ability to comply.

F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s), or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020.

We will be unable to comply as long as regulatory and advisory agencies recommend minimizing staffing and social distance due to the risk of COVID-19 spread. We request suspension until at least June 30.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.

In records documenting annual staff retraining, we will note the reason for the delay in complying with the annual time frame.

V. Calibrations of Particle Accelerators Used in the Healing Arts
Regulatory Requirement or Permit Condition (all from Title 25, Environmental Protection
§ 228.75(a)(1)

A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be specific as possible.
This regulation requires that medical-use particle accelerators be calibrated at intervals not to exceed 1 year. As a precautionary measure, half of our medical physics staff has been directed to stay at home as a "team" in the case that the COVID-19 virus infects one or more members of the other team. In this way, if one team has to suddenly self-quarantine at home, the at-home team can come in to perform patient treatment functions. Since this preventative approach reduces our on-site physics staff in half, their priorities will be directed toward patient care; thus, we will lack necessary physics staff to perform a full calibration of a medical accelerator.

B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension?
As stated above, strategic staff planning reduced our on-site physics staff to just performing treatment-specific functions.

C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?
Most of our outpatient clinics and services are either shut down completely or severely limited to minimize the risk of close-in contact between staff, patients, and the general public. We are not requesting any suspensions or waivers from other government agencies.

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?
The full calibration of a particle accelerator must be done on-site. We do not want to risk exposure of one of our at-home physicists for this activity at this time.

E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history.
We do not believe cost gouging or supply hoarding is negatively effecting our ability to comply.

F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s), or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020.
We will be unable to comply as long as regulatory and advisory agencies recommend minimizing staffing and social distance due to the risk of COVID-19 spread. We request suspension until at least June 30, with the calibration not exceeding 90 past its anniversary date.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.
In records documenting calibrations, we will note the reason for the delay in complying with the annual time frame.

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

Completed by: Katie Tapp
Reviewed By: Lisa Dimmick

Date: 04/08/2020

Regulation	Description of Exemption	Safety Basis	Exemption Language
Subpart C – General Technical Requirements			
35.60(b)	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. *(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.)*	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.	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.

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

Regu-lation	Description of Exemption	Safety Basis	Exemption Language
		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

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

Regu-lation	Description of Exemption	Safety Basis	Exemption Language
	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 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.	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.
Subpart H – Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery (GSR) Units			
35.610(d)(2)	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.	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	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

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

Regu-lation	Description of Exemption	Safety Basis	Exemption Language
		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.	instruction during the emergency caused by the COVID-19 pandemic.
35.630(a)	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).	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	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

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

Regu-lation	Description of Exemption	Safety Basis	Exemption Language
		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.	
35.635(a)(3)	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.	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	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.