

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

All questions must be completed; if not applicable, type "N/A".

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), business mailing address, and a point of contact for this request with email and phone number.

Thomas Jefferson University Hospital 132 S 10th Street, Philadelphia, PA 19107

B. Describe what permitted or regulated activity you are engaged in

X-rays in the Healing Arts

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.

DEP Certificates of Registration for Radiation Producing Machines issued by Bureau of Radiation Protection (Harrisburg)

Registration ID No. 10-05719

Registration ID No. 10-01832

Registration ID No. 30-50242

Registration ID No. 01-16862

Registration ID No. 20-49877

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).

Title 25 Chapter 221.35a - annual fluoroscopy QMP evaluation Title 25 Chapter 221.35a - annual review of FGI procedures



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Title 25 Chapter 221.38a - annual measurement of fluoroscopic radiation output

Title 25 Chapter 221.64 - annual radiation measurements for CBCT

Title 25 Chapter 221.65 - annual performance evaluation of CT attenuation system

Title 25 Chapter 221.204 - annual peformance evauation of CT x-ray systems

Title 25 Chapter 221.204 - annual review of CT imaging protocols

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.

Gov Wolf's "Stay at Home" order requires individuals to stay at home except for certain essential activities and work to provide life-sustaining business and services. The activities needed for compliance with the above regulatory requirements are not life-sustaining services. Being physically present with the equipment in order to perform the required activities would require entering areas of healthcare facilities where sick patients are present, increasing the risk of virus spread.

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?

Achieving compliance requires individuals to be physically present at the location of x-ray imaging systems. These activities cannot be done while staying at home.

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?

Many aspects of our operation are currently suspended, primarily those involving elective or non-critical medical preocedure, including surgeries and routine/non-critical outpatient visits. Specific to x-ray use, for example, non-urgent imaging procedures such as screening mammography, screening for bone density, screening for lung cancer, and musculoskeletal imaging for non-urgent pain management have been suspended.

No waivers are being sought from other government agencies with respect to the use of x-rays in the healing arts.



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

The need for physical presence to perform equipment tests and measurements precludes other options.

The required activities can be completed after the Stay at Home order is lifted.

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.

No

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.

Requsting suspension until the Governor's order is lefted for the geographic areas within which the registered equipment is located.

Activities to achieve compliance will resume after the Stay at Home order is lifted and can be completed within 90 days from that date.

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

There are no specific reporting obligations within the regulations from which suspension of requirements is being sought. Relevant reports will be completed as soon as possible following the lifting of the Stay at Home order and will be available for inspection by the Bureau of Radiaiton Protection as is the usual practice.

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?

There are no pollutants associated with the use of x-ray equipment. There are also no equiment failure reporting obligations associated with the regulations from which suspenion of requirements is being requested.

There would be no direct testing of radiation-producing equipment during the suspension period.

Any accident reporting related to the use of x-ray producing equipment would not be affected by the requested suspension.

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(i) If yes, please identify what pollutants and the nature of the risk. There is no pollution in the sense of releasing hazardous substances to the environment. Any risk involves the exposure of patients and healthcare workers to x-ray radiation. (ii) If yes, please identify the potential extent of increased pollution, including any increases in risk to human health, safety or the environment. If an imaging system has become mis-calibrated and is non-compliant with safety requirements, delayed testing may lead to sub-optimal radiation exposure of patients during the suspension period. This may result in either more or less radiation exposure to patients and employees than intended for the medical imaging procedure. Image quality may also be affected, either positively or negatively depending on the nature of the deviation. However, radiation output calibation deviations are fairly rare. Therefore, history has shown that the risk of improper radiation exposure during the suspension period would be low, and the risk of a significant unintended radiation exposure would be extremely low. (iii) If no, explain how increased pollution will be avoided. Please see the preceding answers. X-ray operators would continue to utilize proper imaging techniques and would be able to report any significant problems with image quality that would necessitate using alternate available x-ray units. B. What public health and/or safety benefits will result if the temporary suspension is granted? Individuals who would have to enter multiple healthcare locations to perform compliance activities will be able to remain in isolation to prevent spread of the COVID-19 virus. 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



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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?

By having to enter multiple healthcare facility room locations and interact with essential staff, there would be unnecssary increased risk of community transmission of COVID-19 virus by increasing the opportunities for individuls to contract and spread the virus among the population in general, among the vitally important healthcare provider group, and to vulnerable patient populations.

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.

Signature and title of Certifier

Chief of Diag. Medical Physics

Eric L Gingold, Ph.D. Chief of Dig Medical Physics

Print Name and Title

Note: This form will not be accepted without a written signature. Electronic signatures are not accepted.

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