

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.
 A list of DEP Permit Numbers and License Numbers affiliated with the University of Pennsylvania is listed in section C below. The contact person for this request is Eileen Normoyle, Radiation Safety Officer, normoyle@ehrs.upenn.edu, 215-651-0543
- B. Describe what permitted or regulated activity you are engaged in. We are a University Medical Center with a Broad Scope Radioaactive Materials License, an Irradiator License, several Accelerator Licenses (medical and non-medical), and many energized equipment Permits.
- 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.

Commonwealth of Pennsylvania, Bureau of Radiation Protection

Accelertor Licenses:

Chestnut Hill Acc (AC20-48973)

Cyclotron (AC40-06037)

Doylestown (AC20-49138)

MiniTandem (AC40-56080)

PCAM EBX (EBX10-05800)

PCAM (AC20-48901)

PCAM Proton Accelerator (PAC20-48901)

Pennsylvania Hosp Acc (AC10-04077)

Presbyterian Acc (AC10-01632)

Radnor Acc (AC20-49837)

Valley Forge Acc (AC20-49276)

Vet Accelerator (AC06-38658)



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

Broad Scope License (PA-0141) Irradiator License (PA-0141A

X-ray facility Registration Numbers and addresses

40-06037 University of Pennsylvania 3160 Chestnut St, Suite 400 Philadelphia, PA 19104

20-49645 Chester County Hospital at Exton 7600 W Lincoln Hwy Exton, PA 19341

20-49646 Chester County Hospital at Fern Hill 915 Old Fern Hill Rd, Suite 400 West Chester, PA, 19380

20-49647 Chester County Hospital at Kennett Square 402 McFarlan Rd, Suite 204 Kennett Square, PA 19348

10-44147 Chester County Hospital 701 E. Marshal St West Chester, PA 19380

20-49648 Penn Medicine Southern Chester County 455 W. Woodview Rd West Grove, PA 19390

20-49840 Penn Radiation Oncology at Chestnut Hill 8835 Germantown Ave Philadelphia, PA 19118

20-49587 CHOP Specialty Care & Surgery Ctr Brandywine Valley 819 Baltimore Pike Glen Mills, PA 19342

20-48521 Unit of PA CHOP Bucks Specialty Care 500 W. Butler Ave



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

Chalfont, PA 18914

20-48390 Univ of PA CHOP Specialty Care Exton 481 John Young Way Exton, PA 19341

20-49944 CHOP Urgent Care Haverford 663 W. Lancaster Ave Bryn Mawr, PA 19010

20-49577 CHOP King of Prussia Specialty Care 550 S. Goddard Bvd King of Prussia, PA 19406

10-06038 Children's Hospital of Philadelphia 3400 Civic Center Blvd Philadelphia, PA 19104

20-49138 Univ of PA Health System Doylestown Oncology Facility 599 W. State St, Suite 103 Doylestown, PA 18901

10-05800 Hospital of the University of Pennsylvania 3400 Spruce St Philadelphia, PA 19104

40-56179 University of PA School of Dental Medicine 240 S. 40th St Philadelphia, PA 19104

01-15326 Penn Dental at University City 3737 Market St, 10th floor Philadelphia, PA 19104

02-30210 Penn Orthopaedics Exton 479 Thomas Jones Way, Suite 300 Exton, PA 19341

02-31321



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

Penn Orthopaedics West Grove 105 Vineyard Way, Suite 101 West Grove, PA 19390

20-49812 Penn Urgent Care South Philadelphia 1930 S. Broad St, Unit 28 Philadelphia, Pa 19145

10-01632 UPHS Penn Presbyterian Medical Center 51 N. 39th St Philadelphia, PA 19104

20-49276 University of PA Radiation Oncology at Valley Forge 1001 Chesterbrook Blvd Berwyn, PA 19312

20-49129 Penn Radiology Valley Forge 1001 Chesterbrook Blvd Berwin, PA 19312

20-48425 Univ of PA Health Sys Division of Community Radiology Radnor 250 King of Prussia Rd Radnor, PA 19087

02-30185 Univ of PA Health Sys Division of Community Radiology Langhorne 777 Township Line Rd, Suite 150 Yardley, PA 19067

02-30655 Univ of PA Health Sys Division of Community Radiology King of Prussia 491 Allendale Rd, Suite 104 King of Prussia, PA 19406

20-49325 Penn Radiology Paoli 250 W Lancaster Ave Paoli, PA 19301

10-04077 Pennsylvania Hospital 800 Spruce St Philadelphia, PA 19107



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

10-44065 PA Hospital Tuttleman Center 1840 South St Philadelphia, PA 19146

04-34778 PA Orthopaedics Farm Journal 230 W. Washington Square Philadelphia, PA 19106

20-49435 Penn Medicine Washington Square Urology 800 Walnut St, 19th floor Philadelphia, PA 19107

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).

Pennsylvania Department of Environmental Protection regulations that are specified by the incorporation of Nuclear Regulatory Commission regulations in 25 PA Code 215.1(e) are hereafter referred to by the Code of Federal Regulations reference.

- 25 PA Code 217.143 and 10 CFR 31.5(c)(2): tests for leakage of radioactive material and of proper operation of on-off mechanism and indicator of devices that are generally licensed under 25 PA Code 217.143 or 10 CFR 31.5 will be delayed, if necessary, until after the emergency has ended. Any missed tests will be completed as soon as practicable after the end of the emergency.
- 25 PA Code 218.12: Failure to pay fees in a timely manner should not be subject to civil and criminal penalties, nor revocation of licenses or registrations for the duration of the emergency and for a reasonable period thereafter to allow for preparation of the payments.
- 25 PA Code 219.61 and License No. PA 131, Amendment No. 51, Condition 18: tests for leakage of radioactive material from sources that are specifically licensed will be delayed, if necessary, until after the emergency has ended. Any missed tests will be completed as soon as practicable after the end of the emergency.
- 25 PA Code 221.35a(c): The frequency of QMP evaluations of fluoroscopic equipment will be extended, if necessary, beyond 14 months. A QMP evaluation will be performed on any such systems as soon as practicable after the emergency ends.
- 25 PA Code 221.35a(c)(1): dosimetry systems will have been calibrated within a period of 2 years plus the duration of the emergency plus six months. The period allows for possible later emergencies at the location of calibration facilities and for the



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

expected backlog of dosimetry systems needing calibration when the emergency ends.

- 25 PA Code 221.35a(d)(1): review of established procedures for FGI studies will be extended, if necessary, beyond 12 months. Any such reviews will be performed as soon as practicable after the emergency ends.
- 25 PA Code 221.38a(c): output measurements of fluoroscopic systems with high level control will be extended, if necessary, beyond the annual requirement. Any such reviews will be performed as soon as practicable after the emergency ends.
- 25 PA Code 221.50. Facilities using CR or DR. (c) Facilities other than dental, podiatric and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer or the Department. Any missed tests will be completed as soon as practicable after the end of the emergency
- 225 PA Code 221.64(a): The radiation measurements of CBCT systems described in this section will be extended, if necessary, beyond the annual requirement. Any such systems will be calibrated as soon as practicable after the emergency ends.
- 225 PA Code 221.64(a): performance evaluation of a CBCT system will be extended, if necessary, beyond 14 months. A performance evaluation will be performed on any such system as soon as practicable after the emergency ends.
- 225 PA Code 21.65: performance evaluation of a CT system used solely to calculate attenuation coefficients of for image registration in nuclear medicine studies will be extended, if necessary, beyond 14 months. A performance evaluation will be performed on any such system as soon as practicable after the emergency ends.
- 225 PA Code 21.74(a): calibration of an X-ray system will be extended, if necessary, beyond 12 months. Any such systems will be calibrated as soon as practicable after the emergency ends.
- 25 PA Code 221.74(c): dosimetry systems will have been calibrated within a period of 2 years plus the duration of the emergency plus six months. The period allows for possible later emergencies at the location of calibration facilities and for the expected backlog of dosimetry systems needing calibration when the emergency ends.
- 221.204(a)(3): performance evaluation of a CT X-ray system will be extended, if necessary, beyond 14 months. A performance evaluation will be performed on any such as soon as practicable after the emergency ends.
- 25 PA Code 221.204(a)(4)(x): dosimetry review will be extended, if necessary, beyond 14 months. Any such reviews will be performed as soon as practicable after the emergency ends.
- 25 PA Code 221.204(a)(6): dosimetry systems will have been calibrated within a period of 2 years plus the duration of the emergency plus six months. The period



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

allows for possible later emergencies at the location of calibration facilities and for the expected backlog of dosimetry systems needing calibration when the emergency ends.

- 25 PA Code 225.101(e) The frequency of testing on-off switches, interlocks, and safety devices on cabinet and baggage/package x-ray systems will be extended if necessary, beyond the annual requirement. Such evaluations will be performed as soon as practicable after the emergency ends.
- 25 PA Code 227.11a(h)3 The frequency of testing safety and warning devices on open-beam analytical x-ray equipment devices will be extended if necessary, beyond the annual requirement. Such evaluations will be performed as soon as practicable after the emergency ends.
- 25 PA Code 227.12a(d)(1) The frequency of radiation surveys on analytical x-ray equipment will be extended if necessary, beyond the annual requirement. Such evaluations will be performed as soon as practicable after the emergency ends.
- 25 PA Code 227.12a(e) The frequency of testing and inspecting safety and warning devices on analytical x-ray equipment will be extended if necessary, beyond the annual requirement. Such evaluations will be performed as soon as practicable after the emergency ends.
- 25 PA Code 228.75(c)(2): dosimetry systems will have been calibrated within a period of 2 years plus the duration of the emergency plus six months. The period allows for possible later emergencies at the location of calibration facilities and for the expected backlog of dosimetry systems needing calibration when the emergency ends.
- 10 CFR 20.1501(c): established frequencies for calibration of instruments and equipment used for quantitative radiation measurements will be extended if necessary until after the end of the emergency. Any missed calibrations will be completed as soon after the emergency as is practicable.
- 10 CFR 35.60(b): Any tests of instruments used to measure the activity of unsealed byproduct material may be delayed beyond the period specified by the national standard and will be completed as soon as practicable after the emergency ends.
- 10 CFR 35.61(a): calibration of survey meters used to comply with 10 CFR Parts 20 and 35 may be delayed and will be completed as soon as practicable after the emergency ends.
- 10 CFR 35.67(b)(2): leak tests of sealed sources for medical use may be delayed and will be completed as soon as practicable after the emergency ends.
- 10 CFR 35.620(a): A calibrated dosimetry system will have been calibrated using the standards and procedures specified in 10 CFR 35.620(a)(1) within a period of 2 years plus the duration of the emergency plus six months. The period allows for possible



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

later emergencies at the location of calibration facilities and for the expected backlog of dosimetry systems needing calibration when the emergency ends.

10 CFR 37.25(c): reinvestigations of individuals who have access to Category 1 and Category 2 material that are required to be completed before one month after the end of the emergency will be delayed. Any delayed reinvestigations will be completed as soon as practicable after the emergency ends.

10 CFR 37.33(a): review of the access authorization program will be delayed and will be completed as soon as practicable after the emergency ends.

10 CFR 37.43(c)(3): refresher training on the security procedures will be delayed, if necessary, until the emergency ends. It will be completed as soon as practicable thereafter.

10 CFR 37.55(a): review of the security program will be delayed and will be completed as soon as practicable after the emergency ends.

License No. PA 131, Amendment No. 51, Condition 32 as follows: If the emergency causes shutdown of normal operations of the Radiation Safety Staff for more than 30% of any quarter, the Radiation Safety Committee may skip the next regular meeting after that quarter and defer items that would have been covered in that meeting to the next regular meeting.

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. The University of Pennsylvania is closed to all personnel except essential personnel. Healthcare facilities and clinics have prioritized urgent and emergency visits. These actions can preserve staff personal protective equipment (PPE) and patient care supplies; ensure staff and patient safety; and expand available hospital capacity.
- 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?
 - The University of Pennsylvania is closed to all personnel except essential personnel. Healthcare facilities and clinics have prioritized urgent and emergency visits. These actions can preserve staff personal protective equipment (PPE) and patient care supplies; ensure staff and patient safety; and expand available hospital capacity.
- 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



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

suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements?

We are not requesting waivers from other government agencies. The Health System is seeking a waiver under 1135 of the Social Security Act for relief from various CMS conditions of participation, not necessarily associated with radioactive materials or radiation producing machines.

- D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?
 There are no alternate compliance options.
- 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. We are requesting relief until as soon as practicable after the emergency ends.
- G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.
 Reporting obligations will continue when the emergency has ended.

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
 - (i) If yes, please identify what pollutants and the nature of the risk.
 - (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.



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

B. What public health and/or safety benefits will result if the temporary suspension is granted?
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? Use of PPE by Radiation Safety staff would divert availablilty for essential medical staff. Additional risk of our staff contracting the virus. Additional community spread.
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.
Elen Normay: Radiation Safety Officer Signature and title of Certifier
Signature and title of Certifier
Eileen Normoyle, Radiation Safety Officer Print Name and Title

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