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. PA- 0988 Avid Radiopharmaceuticals 3711 Market Street Suite 710 Philadelphia PA 19104 Primary Contact Person: Nathaniel Lim, RSO, lim@avidrp.com, 215-298-0712
B. Describe what permitted or regulated activity you are engaged in. Per PA DEP License no PA-0988, Avid Radiopharmaceuticals is allowed to use differing quatities of specific radiosotopes to conduct research and development as defined in 10 CFR 30.4; acquire and use calibration/reference sources for calibration of intruments; hold certain amount of radioactive byproducts for decay in storage and storage prior to disposal.
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. PA DEP License no PA-0988 issued by Commonwealth of Pennsylvania, Department of Environmental Protection Bureau of Radiation Protection
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). Per application package for PA -0988, Avid Radiopharmaceuticals has committed to (1) perform a Radiation Safety Program audit at least annually. The program review is conducted pursuant to the requirements in Title 25 of the Pennsylvania Administrative Code Sections 219 which incorporates by reference U.S. Nuclear Regulatory Commission (NRC) regulations found in Title 10, Code of Federal Regulations (CFR), Part 20.1101(c). This NRC regulation requires radioactive

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

material licensees to "periodically (at least annually) review the radiation protection program content and implementation." ; (2) perform sealed source leak testing and inventory every 6 months; (3) conduct routine radiation monitoring badge issuance/re-issuance; (4) perform routine check of radiation safety equipment (e.g. meters, effluent release monitor).

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.
In order to conduct an effective program audit, a live onsite meeting is needed. Historically, the audit is conducted for about 3 days amongst 5 -6 individuals (auditor + Avid RSO/AUs). In support of social distancing, conducting the audit onsite would not be ideal as the practice will require personnel to be in the same room/area for 3 days. To perform sealed source leak testing and inventory (due May 2020), issue/re-issue radiation monitoring badge and perform routine radiation safety equipment checks, RSO/AU will need to commute to perform tasks onsite which would pose unwarranted risk of COVID-19 exposure.

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?
It will be difficult for Avid Radiopharmaceuticals to comply with the requirements to (1) conduct the audit as per schedule, (2) perform sealed source leak testing and inventory on schedule, (3) issue/reissue radiation monitoring badges and (4) perform routine radiation safety equipment checks since Avid Radiopharmaceuticals have scaled back operations significantly onsite since the outbreak. Only designated staff are allowed onsite on a periodic basis to do select essential work (e.g. check on mail deliveries, among others). Conducting the audit on schedule, performing sealed source inventory and leak testing, issuing/re-issuing radiation monitoring badges and performing routine radiation safety equipment checks will force RSO/AUs and auditor to commute and report for onsite work. This action is not in alignment with effort on helping to slow down risk and spread of COVID-19.

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?
Our site is currently in an idled state with no regular operations occurring at this time due to COVID-19. We have not requested (and do not plan to request) any suspensions or waivers from other government agencies.

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

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?
Avid Radiopharmacueticals has explored conducting remote/online audit. But upon review, the audit will not be effective since paper documentation related to the program are only available onsite. In addition, portions of NUREG 1556, Volume 7, Appendix L would not be conducted (e.g. site inspection, posting).
No other alternative was identified to comply with the requirements to (1) perform sealed source leak testing and inventory on schedule, (2) issue/re-issue radiation monitoring badges and (3) perform routine radiation safety equipment checks as these tasks require RSO/AUs to be physically present onsite.

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.
To the best of our knowledge, 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.
At the moment, threre is no clear indication yet when Avid will resume limited operation or full operation. While there is a possibility to resume limited operations within two to three months, full operation, which would allow an effective onsite audit will likely not happen until the third/fourth quarter this year. That being said, factors such as availability of onsite live testing, and availability of vaccine can reduce the timelines whereas a re-emergence of the virus in the cooler Fall weather might push the timeout further out. Therefore, a suspension to allow for a fourth quarter audit is being sought for now.
The tasks involving (1) performing sealed source leak testing and inventory, (2) issuing/re-issuinge radiation monitoring badges and (3) performing routine radiation safety equipment checks would resume once limited operations resume.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.
To the best of our knowledge, this is not applicable.

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?
To the best of our knowledge, no

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

(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.
Our site is currently in an idled state (i.e. no usage of radioactive material), therefore, risk of generating related pollution is not foreseen.

B. What public health and/or safety benefits will result if the temporary suspension is granted?
A temporary suspension facilitates and supports the overall cause of fighting this pandemic altogether as it eliminates the need for individuals to risk potential exposure through travel and/or congregation, therefore lessening the potential to contract and/or spread the 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.
To the best of our knowledge, industries operating with the same type of license and having also elected to limit or shut down operations will likely be facing the same situation as Avid Radiopharmaceuticals.

D. Would you possess a unique advantage over your competitors, or others in the same industry, if a suspension is granted?
To the best of our knowledge, 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 temporary suspension is not granted, Avid Radiopharmaceuticals will likely force an auditor and its RSO/AUs to come onsite to perform the audit and conduct other tasks identified above. This will result in an increased risk of exposure to the virus with the potential of spreading to their family or individuals they may contact later on.

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.

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

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

06/05/2020

Signature and title of Certifier

Nathaniel Lim, RSO

Print Name and Title

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