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SUPPLEMENT
TO
APPLICATION GUIDELINES FOR RADIATION CONTROL PERMITS FOR EMISSION OF RADIOACTIVE MATERIAL IN EFFLUENTS TO AIR

FOR CYCLOTRON PRODUCTION FACILITIES

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This Supplement is an addendum to the Department's *Application Guidelines for Radiation Control Permits for Emission of Radioactive Materials in Effluents to Air*. It describes specific factors affecting radioactive effluent monitoring and controls that need to be considered when designing a cyclotron facility for the production of PET-imaging agents. This supplementary guidance is provided to facilitate the process of applying for a Part 380 Radiation Control Permit to release radioactive material to the air via associated cyclotron facility exhaust systems. All items listed below are keyed to the *Application Guidelines* for reference. You should carefully consider each factor discussed in this Supplement when designing your cyclotron facility and preparing your Part 380 permit application.

General Considerations

Plan for adequate time to complete the application process. The application process for obtaining a Part 380 permit can be complex; therefore, applicants should allot adequate time for the permitting process prior to the projected date of facility startup. You should submit the permit application to the Department four to six months prior to the expected date of commencement of operations. This will allow time for revisions to be made to the application, should they be found necessary. If the facility will be newly constructed, other local and Department permits may be required.

Schedule a pre-application meeting. Applicants should meet in person with Radiation Control Permit Section personnel prior to the submission of the application. Doing so will provide staff the opportunity to explain the application process in detail, discuss the many technical subtleties of cyclotron emission treatment and monitoring, and how to maintain operations in compliance with regulatory requirements. Contact the Radiation Control Permit Section to arrange a meeting at your convenience.

General Regulatory and Technical Considerations

All Part 380 permit holders must meet the10 millirem (mrem) constraint (Section 380-5.1(b)). This requirement states that a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, must be established such that the individual member of the public likely to receive the highest dose will not be expected to receive a total dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions.

Therefore, Part 380 permit applicants must demonstrate that the potential annual radiation dose to the public (at the location of the nearest identified receptor, which could be an individual, a rooftop air intake or a window) that could result from exposure to radioactive emissions is less than 10 mrem per year.

Cyclotron facilities often need to emit multi-curie quantities of radionuclides to the air; as a result, some cyclotron facilities may find the 10 mrem constraint challenging to meet. Accordingly, when designing facility ventilation systems, applicants need to carefully consider how specific design choices regarding ductwork, effluent treatment systems, flow rate, and height and placement of exhaust stacks can impact effluent concentrations and the resulting radiation exposures to members of the public. Applicants must also be able to demonstrate, through effluent monitoring, that permit limits and the 10 mrem constraint will be met.

Expanded Discussion of Specific Items in Application Guide

Section D.3 Emission Points

Exhaust stacks should be as tall as reasonably possible. Cyclotron facility exhaust stacks should be located as far as possible from the nearest locations where emissions could potentially be re-entrained into the building (windows, doors, air intakes). Good exhaust stack design can greatly reduce the potential annual dose to the nearest public receptor, which is often a nearby air intake.

Do not install rain caps on exhaust stacks. Exhaust systems are generally designed to operate continuously, and exhausted airflow of reasonable velocity will keep rain out of the stack. If heavy rainfall is a problem in your area, install an offset stack with a provision for drainage. Rain caps are not optimal for radioactive emissions, as they redirect airflow downward.

Section D.4 Effluent Flow Rates

Provide a sufficient exhaust flow rate. Radionuclide concentrations and resultant doses to potential public receptors are generally proportional to airflow through the exhaust system. Therefore, deciding what constitutes a sufficient exhaust flow rate should be carefully considered when designing your system. Flow-boosting auxiliary exhaust fans located at exhaust points add significantly to throughput and to flow loft; these fans are always worth considering, as they are cost effective, and are especially worth considering for use in densely populated urban areas.

Utilize real-time flow rate monitoring. Real-time flow rate monitoring is standard practice, and is usually provided as a standard feature of emission monitoring packages for insertion into the exhaust system ductwork. For systems utilizing Pitot tubes (use of which is standard practice) note that, while Pitot tubes are primary standards, they are usually attached to solid-state transducers for automated flow logging; these devices can vary in response, and systems will therefore require annual calibration. As particulates (aerosols) are not usually generated at cyclotron facilities, measurement capability for particulates is generally not required unless chemistries utilized are expected to produce them.

Section D.5 Effluent Treatment

Effluent treatment is a requirement. Applicants must demonstrate that radioactive emissions are maintained ALARA (As Low As Reasonably Achievable). Therefore, radioactive effluents should be held up and/or contained for decay, and removed via treatment/filtration, whenever practical to do so. Methods of treatment of cyclotron emissions containing filterable and nonfilterable compounds have become well established; these include carbon filtration, product holdup via gas compression or gas capture, and ancillary filtration in hot cells and on synthesis units. You should plan to discuss the current effluent treatment options that are under consideration during the pre-application meeting.

Section D.7 Evaluation of Emissions

Monitoring. Section 380-6 requires appropriate surveys of all environmental releases. Due to the high concentration of radionuclides in effluents that can be released from cyclotron operations, and the fact that these facilities rely heavily on effluent treatment to reduce emissions, the Department requires cyclotron facilities to use real-time monitors to continuously measure radioactive emissions. There are several vendors supplying turnkey packages for cyclotron monitoring. Please note: Carbon filter housings should be located well away from detectors, and detectors should be shielded if necessary to reduce background signal. Detectors should not be positioned near radiation sources (such as filters), to reduce background interference and prevent degradation of detector response characteristics. Some systems are remote draw; there are advantages and disadvantages to such systems, but background obviously may be reduced to some extent by their use.

Calibration. Section 380-6.2 requires that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated at least annually for the radiation measured, and that instruments used to measure effluent flow rates also be calibrated annually. In-situ calibration of real-time effluent monitoring systems must therefore be conducted on a yearly basis. In recent years, cyclotron exhaust product detection systems have evolved considerably, and systems appropriately designed for this purpose are now readily available. Detectors themselves now often contain microprocessor-controlled linearity adjustment, which has eliminated much of the nonlinear response problems previously encountered. Nevertheless, detector response for all types of stack monitors remain highly dependent upon exhaust system materials, flow rates and geometries.

Experience has shown that manufacturer assurances that systems are "precalibrated" are misleading. Such statements are not reliable indicators of response in situ and are not acceptable in lieu of hard data. Manufacturer-derived calibrations (calibrations performed off-site) do not demonstrate actual performance of stack monitors in situ. It merely establishes that, given a particular calibration procedure under controlled circumstances, a detector has a certain, reproducible response, when used in conjunction with a calibration factor. While under controlled circumstances factory calibration may establish a workable baseline of performance for a particular detector, the detector response in situ is representative of a number of site-specific factors (e.g., ductwork material and design, detector design and placement, the rate of radioactive gas release, flow rate related performance issues, problems with associated electronics, such as breakdown of cables and capacitance issues). Hence the use of a factory calibration protocol would be considered as an adjunct to, not a replacement for, stack monitor gas calibrations. Therefore, stack monitoring systems will require at least an initial in situ calibration using multiple releases of gaseous boluses of representative radionuclide(s). Note: because of dependence of detector response upon site-specific factors, button-source calibrations are not acceptable as primary calibrations of detectors (although button sources may be used as constancy checks).

Methods. In order to calibrate stack monitors over the range of effluent concentrations that may be encountered, calibrations should be performed using a range of release activities. Generally, three activity releases are adequate. The low activity release should be representative of the minimum detectable activity of the system, while the high activity release should be representative of a likely major release, and be high enough in activity so that linearity (or nonlinearity) of response can be well demonstrated. Typically, releases are made in the 1-5, 20-30 and 60-100 mCi ranges; these values may vary with system specifications. While many currently marketed systems will respond in a relatively linear fashion, some may not, and will require that a calibration factor be applied to releases to adjust not just for the system's response characteristics, but for linearity as well. Additionally, failure of internal microprocessors or of primary detector components is always a possibility, and some annual method of assuring repeatability of response is necessary. Releases should be plotted along with the resultant calibration curve, and the permit will require that the results of initial calibrations be reported to the Department for review.

Section D.8 Dose Limits to Members of the Public

Section 380-5.1 establishes a public radiation dose limit of 100 mrem per year and an external dose rate limit of 2 mrem in any hour. In addition, for radioactive emissions to the air, the 10 mrem dose constraint must also be met.

Discussion. Applicants must demonstrate that all applicable public dose limits will be met. The application must specify, and justify, the prospective estimated total activity and annual average concentration of each radionuclide that will be released as a result of routine operations, including radionuclides used for stack monitor calibrations. (These estimates will be used to develop the release limits that will appear on the permit, when issued.)

Before the Department can approve the requested level of emissions, the applicant must demonstrate that the public dose that could result from the requested level of emissions will meet the 100 mrem public dose limit, the 10 mrem dose constraint, and be ALARA. A detailed explanation of how applicants can demonstrate compliance with the public dose limits is provided in a separate guidance document, *Demonstrating Compliance with the Public Dose Limits in Part 380*. If the average annual concentration of the effluent will exceed the concentration values listed in Table II of Section 380-11, a dose assessment must be included in the permit application. Most cyclotron facilities will be required to perform a dose assessment. Please review that guide for further details.

Specific radionuclides. In 2018, the tables in Section 380-11 were expanded to add two accelerator-produced isotopes that were not previously listed: nitrogen-13 and oxygen-15. The Table 2 Effluent Concentration Values for Air for both of these isotopes is 2E-8 uCi/ml, which is larger than the "default" value of 1E-9 for short-lived radionuclides not otherwise listed. Please note that, if unmaintained software such as USEPA's COMPLY is utilized to perform dose assessments, that software will utilize the older, more restrictive dose conversion factors.

Be aware that if a cyclotron facility shares its building with other tenants or occupants, its rooftop may be accessible to others (i.e., a public area). In this case, the 2 mrem in any hour public dose rate limit applies to the rooftop. This dose rate limit may be difficult to meet unless the rooftop areas with detectable dose rates are designated and maintained as restricted areas under the radioactive materials license. Filter assemblies at active facilities become significant (if intermittent) radiation sources, and care must be taken to ensure that workers, repair and maintenance personnel, etc., are excluded from potential areas of public dose rate limit exceedance.

Direct Measurement of Dose

Site environmental dosimetry is required. Dose modeling is ultimately a best guess at maximum exposure to public receptors. In many (or most) cases, a well-designed modeling effort will substantially overestimate actual dose to the most affected receptor—modeling should be a conservative exercise, and while realistic assumptions are desirable, conservative estimates are mandatory in the absence of operational data. Additionally, it is to be remembered that no model accurately reflects actual “microconditions” at the site being considered. Environmental dosimeters are inexpensive and easily emplaced and accessed. Dosimeters provide valuable pre-operational environmental exposure data and can serve to confirm that the public dose limit (100 mrem/yr) is being met during operations.

Environmental dosimetry of sufficient sensitivity for regulatory purposes is currently easy to perform and relatively inexpensive given the availability of environmental-level thermoluminescent dosimeters (TLDs), as long as appropriate placement is possible. A variety of vendors produce environmental-level TLDs that are suitable to the purpose; offerings registering minimum detectable dose of nominal 0.1 mrem ambient dose equivalent, having reasonably linear responses, and suffering reproducible fading are available for minimal cost investments. Other methods for environmental dosimetry are, of course, available, but given their costs (in terms of money, tradeoffs and effort) they are often impracticable.

Whenever measuring low levels of man-made radiation in the ambient radiation field, one must deal with the fact that background radiation levels are sizeable in comparison with measured dose. The collection of pre-operational data is therefore critical. If background could be counted upon to be uniform, even small doses to receptors would be apparent, but background measurements with high-sensitivity TLDs are subject to considerable variation. Interpretation needs to consider many factors, some of which change unpredictably. Most terrestrial background radiation comes from K-40, from radionuclides in the uranium and thorium decay chains, from radon daughters and cosmic and cosmogenic sources, and from radionuclides deposited as a result of nuclear weapons testing, not to mention facility-specific sources. Radiation levels can vary significantly due to geographic, temporal, meteorological and even astrophysical factors. Correct interpretation of measurements requires familiarity with these local factors, which can only be gained through the implementation of a well-planned, and unrushed, assessment of radiological background. Take efforts to avoid poor placement of measurement TLDs, and improperly placed control dosimeters. Given all of these potential difficulties, TLD readings must be regarded as confirmatory rather than quantitative, and cannot preclude dose modeling, but have been found useful, nevertheless.