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APPLICATION GUIDELINES

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

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A. PURPOSE OF GUIDELINES

These guidelines describe the information needed by New York State Department of Environmental Conservation (Department) staff in the Radiation Control Permit Section to commence review of an application for a permit to emit licensed radioactive material to the environment via ventilation or exhaust systems. This type of permit is provided for under Subpart 380-3 of 6 NYCRR Part 380, "Rules and Regulations for Prevention and Control of Environmental Pollution by Radioactive Materials."

The Department normally issues a single Part 380 Radiation Control Permit to cover all emission points at a facility. Separate permits are not normally issued to different emission points unless the facility has both a permitted exhaust system and a separate cyclotron facility. In such instances, the exhaust system and the cyclotron facility will each be issued separate permits. Separate application guidelines are available for radioactive waste incinerators.

Carefully study the Department's Part 380 regulations, these guidelines, and all enclosed supplementary guidance documents before preparing the letter of application for a Radiation Control Permit. The application must demonstrate that your facility has developed procedures that will ensure operations comply with Part 380 requirements. The Department will request additional information when necessary to provide reasonable assurance that you have established a permit compliance program adequate to minimize and track radioactive emissions to the environment and to ensure that radiation doses to the public resulting from those emissions will meet regulatory limits and be maintained as low as reasonably achievable (ALARA). The documents submitted in support of the application, once approved, will be made part of the permit. Therefore, once the permit is issued, you must keep copies of those documents on file with the permit, and implement the procedures described therein, to prevent operating in violation of the Part 380 regulations or the specific conditions of the radiation control permit.

B. APPLICABLE REGULATIONS

The regulations pertaining to this type of radiation control permit are found in Title 6, Chapter 4, Part 380 of the New York Code of Rules and Regulations (6 NYCRR Part 380). The statutory authority for the rules and regulations is found in the New York State Environmental Conservation Law (Articles 1, 3, 17, 19, 27, 29, and 37). Section 380-3.2, Permit Applications, outlines the information required for a permit application to be considered complete for the purpose of commencing review. Until all the required information in Section D of the guidelines (see below) has been submitted, the application will not be considered complete and the permit cannot be issued.

The information submitted in the application will be subject to Public Access to Records (6 NYCRR Part 616), which includes Section 616.7 regarding management of records containing trade secrets. An applicant may not declare an entire document to be "confidential" or "proprietary information." Under the New York State Freedom of Information Law (FOIL) and its implementing regulations (Part 616), all information submitted to the Department is subject to public review by request. Under this regulation, permit applicants submitting information to the Department may request that certain discrete information contained in the submission be excepted from public disclosure at the time the document is submitted. The relevant portions of the submission must be clearly identified (by page) as "trade secret," "confidential commercial information," or "critical infrastructure information." Such a request must include the reasons why the specified information should be considered excepted from public disclosure. After such an exception request is made, should the Department subsequently receive a FOIL request for that information, a determination will then be made whether or not the information can be withheld from public disclosure.

The administration of the permit, including modifications to any conditions therein, will be subject to Uniform Procedures (6 NYCRR Part 621). The application will also be subject to State Environmental Quality Review (6 NYCRR Part 617). Each of these regulations are available on the Department's website.

C. FILING AN APPLICATION

Your letter of application for a Part 380 radiation control permit must provide all the information requested in these guidelines. A complete application for a permit must contain information which thoroughly describes the proposed radioactive materials use, release, treatment, monitoring, and recordkeeping procedures.

Mail an original and a copy of the dated and signed letter of application to the Department's Regional Permit Administrator at the appropriate Regional Office (see last page of this guide). The Regional Permit Administrator will forward a copy of the application to each involved program within the Department for technical review.

For Part 380 radiation control permits, the Radiation Control Permit Section (located in Albany) is usually the only Department program involved. At the same time, you are urged to send another copy of the submitted application directly to the Radiation Control Permit Section, so we will be immediately aware that you have submitted a permit application to the Regional Permit Administrator.

You must retain one copy of the letter of application, with all attachments, since the permit will require as a condition that you follow the statements and representations set forth in the application, and any supplements to it. When issued, the permit will contain a condition requiring all commitments and procedures described in the application to be implemented. This means that, upon permit issuance, the detailed commitments and operating procedures described in the application become regulatory requirements, as part of the permit. Failure to follow any procedure described in the approved permit application (including any supplementary documents) would constitute a violation of the permit.

If you have any questions regarding the preparation of the Part 380 permit application, contact the Department's Radiation Control Permit Section for assistance at (518) 402-9625. For new permits, plan for adequate time to complete the application process; submit the permit application 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; the Regional Permit Administrator can advise you of such requirements. Applicants are encouraged to 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, and to learn about the operational and design plans of your new facility.

Facilities whose radioactive emissions could exceed the exemption in Section 380-3.4 must obtain both the required radiation control permit (from the Department) as well as the required radioactive material license (from the appropriate agency) before operations can commence. Apply for the needed permit and license simultaneously.

D. CONTENTS OF THE APPLICATION

The Part 380 Radiation Control Permit application should follow the format outlined below. Number all pages. If a requested item has already been provided elsewhere in the application, identify the location of that information by page /section. A complete application for a permit must satisfy the requirements of Section 380-3.2. Therefore, the application must contain the following information:

1. <u>General Information and Identification of Applicant</u>

- a. Applicant name and address (identify the facility owner's name, mailing address, and telephone number, and if applicable, also include the facility operator's name, address, telephone number, email, and hours of operation)
- b. Location/address of project/facility (if facility location is different from the facility's mailing address)
- c. County, village, town or city
- d. Contact person for the permit (usually the facility radiation safety officer or regulatory compliance officer). Identify the individual who can answer questions about the application (and eventually, the permit) and include a telephone number and email, and identify who should be contacted in that person's absence. State that the Department will be notified if the person assigned to this function changes.
- e A detailed area map showing roadways from a major state highway to the project/facility location
- f. A copy of the applicant's radioactive materials license that show the
 - license number and expiration date
 - list of radioactive materials authorized to possess
 - description of authorized use of radioactive material

If the radioactive materials license has not yet been obtained, confirm that the above information will be submitted to the Department when the license is received.

g. Organizational chart which identifies the chain-of-command from the organization's president/CEO to the facility radiation safety officer

2. <u>Source and Nature of Radioactive Emissions</u>

For each radionuclide in the effluent, provide a general description of

- a. The process involving that radionuclide that generates, or has the potential to generate, a release to the environment
- b. The properties of the emissions, including isotopic and chemical composition, and physical characteristics (i.e., nature of the gas or aerosol, or size of particles)

3. <u>Emission Points</u>

Provide the location and identity of each emission point, with a simple diagram of the entire exhaust system through which radionuclides are released. If the diagram is not drawn to scale, indicate the distance between points of interest in the exhaust system. The diagram should indicate the location of all components of the exhaust, effluent treatment, and effluent monitoring systems (if applicable). The submitted diagram must accurately represent the actual layout of the radionuclide effluent exhaust system (and effluent treatment and monitoring system, if applicable). Generic system diagrams are not acceptable; scaled engineering diagrams are acceptable, but not required. Applicants for a new facility that has not yet been constructed may submit a conceptual diagram; in this case, the application must state that a final, as-built drawing will be submitted at the conclusion of facility construction. In this case, the permit will include a condition requiring the submission of as-built drawings for review and approval.

Also provide a diagram of the rooftop which identifies the location of the emission point and any other components of the exhaust, treatment, and monitoring systems that are located on the roof. Also identify the location of all air intakes on the building. Provide dimensions (length, height, and width) of all buildings upon which exhaust stacks are mounted, include dimensions of setbacks. Indicate the distance from each emission point to all air intakes on the building (and on adjacent buildings that could be impacted by the exhaust plume), the nearest air intake, the nearest unrestricted area in the environment, the site boundary, and the nearest residence, shown on a map or sketch.

If a fume hood is used, indicate if the exhaust stack serving that hood is dedicated to that hood, or if the stack serves multiple hoods. Specify the type of hood (conventional, bypass, auxillary). Indicate if the fume hood is equipped with an air flow compensator and if so, describe the effect the position of the sash has on the compensator. Exhaust stacks should be as tall as possible, and not use rain caps. The exhaust system must be accessible to safely inspect and maintain all critical system components (filters, monitors, etc.). If ladders are used to access any portions of the exhaust systems, ensure ladders are OSHA compliant.

4. <u>Effluent Flow Rates</u>

a. State the minimum volumetric flow rate that will be maintained through each emission point. The minimum flow rate must be sufficient to maintain effluent concentrations ALARA.

Note: the permit will require that the minimum flow rate stated in the application be maintained at all times.

b. Indicate if effluent flow rate measurements will be performed by in-house staff, or by a contractor. If facility staff will be performing these measurements, submit a copy of the procedures to be used for determining the volumetric flow rate through each emission point. These procedures should include a complete description of

(i) How the linear velocity will be measured, how the average linear velocity will be determined (fpm), and how the average volumetric flow rate will be determined (cfm). If flow rates will be measured at the face of a fume hood, or in a fume hood exhaust duct, indicate the height of the fume hood sash opening at the time this measurement was taken, and the height of the sash during normal operations.

(ii) The measuring equipment used and the frequency it is calibrated (annually at a minimum, unless a primary standard is used)

(iii) The frequency of flow rate measurements (annually at a minimum, and after any changes to the ventilation system)

(iv) Calculations performed to determine total annual volume of the effluent (ml/yr) from flow rate measurements

(v) How records of flow rate checks and volumetric flow rate calculations will be reviewed and maintained

Note: a flow rate measurement must be taken at the emission point / exhaust stack prior to startup; state in the application that this will be done. If flow rate measurements are to routinely be taken elsewhere in the exhaust system (e.g., at the face of a fume hood) then a confirmatory stack measurement should be taken annually, to confirm the other measurements. State in the application that this will be done.

c. If there are instruments in place to measure the effluent flow rate in real time, confirm if there is an alarm; if so, specify the alarm set point. The alarm should be set at a rate higher than the minimum flow rate.

5. <u>Effluent Treatment</u>

Effluent treatment should be used whenever possible to maintain radioactive emissions ALARA. Engineering controls must include routine maintenance to ensure continued effectiveness, as well as periodic checks to ensure the system remains effective. Describe the emission treatment systems, if any, that will be used to minimize the release of radionuclides to the environment, including

- a. A detailed diagram of the treatment system(s)
- b. The date of installation
- c. The location of the system
- d. The removal efficiency of the system (as a function of flow rate) and a description of how it was determined
- e. The treatment capacity of the system
- f. How the system will be maintained, including, if applicable, how the pressure drop across filters is checked
- g. The established frequency of filter changes <u>and</u> the performance criteria that will dictate when filters will be changed
- h. How wastes produced during treatment will be disposed of
- Note: Certain medical patient radiopharmaceutical delivery and containment systems (such as xenon traps and aerosol nebulizers used in medical imaging studies) are considered *containers* rather than effluent treatment systems.

6. <u>Radionuclides to be Released</u>

For each emission point, submit a list of all radionuclides to be released. Provide a prospective estimate of the total activity and annual average concentration of each radionuclide in the effluent that will be released in a year. Include all calculations and assumptions used to support this estimate (e.g., radioactive material throughput/production and releases, filter efficiency, minimum flow rate through each permitted emission point).

If an effluent treatment system will be used to minimize the release of radionuclides in effluents (as addressed in item 5 above), provide an estimate of radionuclide releases both before and after treatment.

Note: The radionuclide release estimates provided in the application will be used to establish annual radionuclide release limits in the permit. Emission estimates should reflect realistic projections and material handling scenarios that could result in emissions. For example, based on production / usage volume, indicate if the potential exists for an occasional spill and the magnitude of emissions that may result from such an event. Note: Use the calculation sheet provided in the enclosed supplementary guidance document, "Demonstrating Compliance with the Public Dose Limits in Part 380," to provide prospective emission estimates.

7. <u>Evaluation of Emissions</u>

Subpart 380-6 requires you to perform surveys that are necessary to demonstrate compliance, and are reasonable to evaluate radiation levels in the environment and concentrations or quantities of radioactive materials in effluents. Subpart 380-6 also requires that instruments and equipment used for quantitative radiation measurements and effluent flow rates be calibrated annually.

"Survey" is defined in Subpart 380-2 as an evaluation of the radiological conditions incident to the presence of radioactive material, and, when appropriate, includes measurements, monitoring, or calculations of levels of radiation, concentrations, or quantities of radioactive material present. Thus, "survey" can include keeping track of discharges through inventory of radioactive material throughput, real-time effluent monitoring, and continuous effluent sampling.

Section 380-6.1 requires you to track the total activity and average concentration of radionuclides released to the environment, by isotope and emission point, using one or more appropriate methods to evaluate radionuclides in effluents. Depending on the isotope, form, and quantity of radioactive emissions, one or more of the survey methods listed below may be appropriate for your facility.

Specify the survey method(s) to be used to evaluate releases (e.g., mass balance, real-time monitoring, effluent sampling), and submit a copy of the effluent survey procedures to be used. Your procedures should include the following:

a. If the **mass balance method** is to be used, include a description of the radioactive material accounting procedures:

(i) Describe how the mass balance is determined (this is your survey). Your procedures should incorporate the source term, release fraction, and release totals (before and after effluent treatment, if any). Indicate how records of this determination (your survey results) will be maintained. Explain how these results will be used to estimate radionuclide activity and concentration in the effluent, including all calculations.

(ii) Indicate how frequently records of mass balance determinations and emission calculations will be generated and reviewed. Your procedures should ensure that a running total of the quantity and average annual concentration of radionuclide emissions is maintained, and that this record undergoes timely review to ensure that permit limits will not be exceeded. b. If the **real-time monitoring method** is to be used (i.e., a continuous monitoring method in which samples are analyzed as they are collected, with a continuous readout), include a description of the effluent monitoring system:

(i) Identify the in-line instrument to be used, detector type, range, sensitivity, frequency of calibration, alarm set point, how the instrument readout is recorded, and the location of the monitor, with diagram. Specify how the instrument is calibrated. Confirm that stack detector calibrations will be performed annually.

(ii) Describe how effluent monitoring data will be collected and maintained, and how these results will be used to determine radionuclide activity and concentration in the effluent, including all calculations.

(iii) Indicate how frequently records of effluent monitoring results and emission calculations will be generated and reviewed. The procedures for maintaining records of surveys should ensure that a running total of the quantity and average concentration of each radionuclide released is maintained, and that this record undergoes appropriate and timely review to ensure that permit limits will not be exceeded.

c. If the **effluent sampling method** is to be used (e.g., collection of samples for later analysis), the method chosen should be capable of obtaining a representative sample from the exhaust duct or other outlet. The volume of air sampled and the quantity of contaminant in the sample must be accurately determined in order to accurately assess the concentration of radioactive material in the effluent. The choice of method of analysis should also be carefully considered. This includes choice of filter medium to us in the air sampler, air flow rates, and choice of counting techniques. These factors should be selected to ensure that the desired monitoring sensitivity, expressed as a lower limit of detection (LLD), is achieved. In general, the appropriate LLD should not exceed 10 percent of the value to which compliance is to be demonstrated. Provide a detailed description of the effluent sampling system:

(i) Identify the location of the sampling probe and all other components of the sampling system, with diagram

(ii) Indicate at what frequency samples will be collected (i.e., continuous, intermittent, grab)

(iii) Identify the effluent sample collection method to be used. If a pump is to be used to collect the effluent sample, identify the manufacturer and the name and model number of the pump (or its equivalent), the pump flow rate, and the frequency of gauge calibration. If the sample pump is calibrated in-house, describe the calibration method and calibration instrument used, and how frequently it is calibrated (annually, if not a primary standard). If the flow rate meter is sent out for calibration, describe the backup instrument to be used. For sampling of particulates in the effluent, describe how the effluent stream will be sampled to ensure representative (isokinetic) sampling. Records must be maintained of all calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration, and should include the appropriate correction factors to be used. Confirm that all components of the sample collection system will be calibrated annually.

(iv) Describe the medium to be used to collect samples, its efficiency for the isotope and chemical form collected (as a function of sampling flow rate), and the frequency at which the collection medium will be changed.

(v) Describe the method of sample analysis. Indicate whether the sample is analyzed in-house or is sent out to a contracted analytical laboratory. If effluent samples are analyzed in-house, identify the detector used, its efficiency and minimum detectable activity (MDA), the equation used to calculate the MDA, and describe how the instrument is calibrated. Confirm that calibration sources are NIST-traceable and that the sample counting detector will be calibrated annually.

(vi) Describe how records of sample analysis results are generated and maintained, and how these results will be used to determine radionuclide activity and concentration in the effluent; provide all equations and calculations. Attach a sample of the effluent sample analysis results worksheet / form to be used.

Note: sample results should be listed as "MDA" if no activity is detected (a zero or negative value is not an acceptable result). The term "not detected" or similar terms should not be used. Each reported result should either be a value and its associated standard deviation, or an indication that the result was below the stated value of the lower limit of detection. (vii) Indicate how frequently records of effluent sampling results and emission calculations will be generated and reviewed. The procedures for maintaining records of surveys should ensure that a running total of the quantity and average concentration of each radionuclide released is maintained, and that this record undergoes appropriate and timely review to ensure that permit limits will not be exceeded.

8. <u>Dose Limits to Members of the Public</u>

Subpart 380-5 establishes radiation dose limits for individual members of the public and a 10 mrem dose constraint. It also requires you to conduct surveys of radiation levels in unrestricted areas in the environment and of radioactive materials in effluents released to unrestricted areas in the environment. The results of these surveys will be the basis for demonstrating that your operations are conducted in such a way that public dose limits are met.

Subpart 380-5 also requires that compliance with the public dose limits be demonstrated by one of two methods. The two methods are described in section 380-5.2; you must select one of these two methods to demonstrate how your facility will comply with the dose limits. Regardless of which method is used, the application must provide the results of that demonstration based on the conservative assumption that radioactive emissions will occur at the maximum level requested and authorized in the permit (annual emissions = permit limits).

The simplest method is outlined in section 380-5.2(b)(2), which states that if the average annual concentration of radionuclides in effluents at the emission point is less than the effluent concentration value listed in Column 1, Table II of section 380-11.7, and if the external dose rate limit is met, you have demonstrated compliance. This method for demonstrating compliance with public dose limits should be used whenever effluent concentration are less than Table II values.

For those facilities whose discharges exceed the effluent concentration value in Column 1, Table II of section 380-11.7, the method outlined in section 380-5.2(b)(1) must be used to demonstrate compliance with public dose limits. This means your application must provide a dose assessment to determine public dose, based on the requested level of radionuclide releases (permit limits).

You must clearly indicate which of the following two methods will be utilized to demonstrate compliance:

a. <u>Method 1 - section 380-5.2(b)(2) - Emissions < Table II</u>

Demonstrating that--

(i) the annual average concentration of licensed material in effluents to air at the emission point does not exceed the concentration values specified in Column 1, Table II of Subpart 380-11; and

(ii) if an individual were continually present in an unrestricted area (in the environment), the dose from external sources would not exceed 2 millirems in an hour and 50 millirems in a year.

Included in (i) above is the requirement that, if more than one radionuclide is released from the same emission point, the sum of the ratios between the concentration of each radionuclide in the effluent and the concentration for that radionuclide listed in Column 1, Table II of Subpart 380-11 must not exceed unity, as determined by the "sum-of-ratios" method described in Subpart 380-11.

Submit a demonstration (prospective estimate) that emissions will be less than Table II values to demonstrate compliance with the public dose limits, based on the requested permit limits and the minimum flow rate. Describe how survey results will be used to confirm this demonstration.

- Note: Review the enclosed supplementary guidance document, "Demonstrating Compliance with the Public Dose Limits in Part 380" and complete its enclosed calculation sheet to provide this demonstration. (This emission calculation sheet is also discussed in item 6 above.)
- b. <u>Method 2 section 380-5.2(b)(1) Emissions > Table II</u>

Demonstrating by measurement or calculation that the total effective dose equivalent (TEDE) to an individual member of the public likely to receive the highest dose from radioactive effluents does not exceed the annual 100 millirem dose limit and the 10 mrem dose constraint.

Submit a demonstration (prospective estimate) that the maximum potential public dose resulting from radioactive emissions from your facility will be in compliance with the public dose limit and the 10 mrem dose constraint, based on the requested permit limits and the minimum flow rate. Describe how surveys results will be used to confirm this demonstration.

Note: Review the enclosed supplementary guidance document, "Demonstrating Compliance with the Public Dose Limits in Part 380" and complete its enclosed calculation sheet to determine if a dose assessment will be needed. Also review the enclosed additional supplementary guidance document, "Review of Atmospheric Transport and Dispersion Models" before performing a dose assessment in response to this item.

9. <u>Release Minimization Program</u>

Section 380-5.1 requires that the release of licensed material to the environment be limited so that, in addition to meeting public dose limits, doses to individual members of the public are ALARA. Towards that end, Subpart 380-7 requires all permittees to develop, document, and implement a release minimization program for maintaining releases of licensed material to the environment ALARA. (Note: this program was formerly known as the Discharge Minimization Program.)

The release minimization program should be commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with Part 380. It is recognized that facilities are required to develop and implement a radiation protection program (ALARA program) by their licenses. Your release minimization program could be a part of your overall radiation protection program, or it can be maintained separately. In either case, the release minimization program should specifically address radioactive emissions to the environment.

To ensure compliance with Subpart 380-7, your release minimization program should contain the following program elements:

- a. Management's formal policy commitment to maintaining public doses due to environmental releases ALARA, including the establishment of investigational levels for radionuclide emissions
- b. Analysis of trends in radionuclide usage and their effect on actual emission levels, to evaluate adequacy and operation of process equipment, emission control equipment, and operating procedures
- c. Establishment of personnel qualifications and worker training requirements adequate to ensure that staff are competent to perform duties necessary to maintain compliance with the Part 380 regulations and the conditions of the permit
- d. Establishment of survey and effluent monitoring programs appropriate for the facility's emissions

e. Review of procedures, engineering controls, and process controls, including

(i) An analysis of the processes that result in radioactive releases, to identify the steps in the process during which radioactive materials enter the effluent stream

(ii) An evaluation of procedures used and equipment involved to identify what improvements could be made to reduce radioactive emissions

(iii) An evaluation of the option of installing effluent treatment equipment to reduce radionuclides in effluents; or, if such equipment is already installed, an evaluation of the effectiveness of the equipment maintenance program, the current performance of the equipment, and an estimate of when the equipment will need replacement

(iv) For each improvement and effluent treatment equipment identified under (ii) and (iii) above, an identification of the modifications to operating and maintenance procedures, equipment, and facilities that have been considered, a determination of what modifications have been made, and a justification of any modifications that have been recommended but not implemented

- f. Annual review of the release minimization program content and implementation, and documentation of the results of that review
- Note: A copy of the U.S. Nuclear Regulatory Commission's Regulatory Guide 8.37, "ALARA Levels for Effluents at Materials Facilities," is enclosed to provide additional guidance on designing an acceptable program for maintaining radioactive effluents ALARA.

10. Records

Subpart 380-8 requires records to be maintained of (a) all radioactive releases, (b) the results of surveys, (c) all demonstrations of compliance with public dose limits, and (d) the release minimization program. Provide a copy of the record keeping procedures that will be used to comply with Subpart 380-8.

All records should be signed and dated by the person generating the record, and again later by the person conducting a secondary review. All electronic records must be available for review, and provided in hard copy form upon Department request per section 380-8.6(c).

11. <u>Reporting Requirements</u>

Subpart 380-9 contains reporting requirements. Confirm that you will submit an annual emission report to the Department by the end of each March of the following year, in accordance with Section 380-9.1. Also confirm that you will comply with the notification requirements in Section 380-9.2.

Note: the list of reportable events in Section 380-9.2 has significantly expanded, and now includes events such as equipment failure, uncontrolled releases, an exceedance of the annual release limit established in a permit, missing radioactive materials, fire or explosion, etc.

12. State Environmental Quality Review Act (SEQR) Requirements

The permit application and review process must comply with SEQR. This means that potential environmental impacts from the requested action (i.e., the release of radioactive material at the maximum level requested in the permit application) must be evaluated. If you are applying for a new permit, or for the modification or renewal of an existing permit where there will be a material change (i.e., an increase in radionuclide emissions), complete and sign Part I of the enclosed Short Environmental Assessment Form (SEAF) and submit it with the application. Respond to questions on the status of required licensing approvals.

Applications for permit renewals or modifications with no change in the magnitude of radionuclide emissions do not require the resubmission of a SEAF.

13. Signature

The letter of application must be dated and signed by both the facility's designated contact person for the permit (usually the radiation safety officer or regulatory compliance officer) and the managerial agent. The managerial agent must be a representative of the corporation or legal entity who is authorized to make binding commitments on behalf of the applicant* and must certify that the application contains information that is true and correct to the best of the signor's knowledge and belief. Section 380-10.7 requires all submissions to be complete and accurate in all material respects. As such, a signature by the managerial agent acknowledges management's knowledge about the contents of the permit application, the statements and commitments made in the application, and management's commitment to ensure that all procedures described therein will be fully implemented. Unsigned applications will be returned for proper signature.

*Note: The positions of the persons signing the application should be shown on the organizational chart submitted in response to item 1.

E. PERMIT MODIFICATIONS

Once your facility has been issued a permit, you must conduct the approved permit compliance program in accordance with the statements, representations, and procedures contained in the permit application and supporting documents (which are referenced in the permit). Therefore, before making any changes in facility operations (e.g., approved facilities, equipment, procedures, or radioactive emissions), you must first obtain a permit modification. This means that before changes can be made to the level of radioactive releases, emission points, procedures, or scope of operations, the Department must first modify the permit to reflect and authorize those requested changes.

The permit does not need to be modified when equipment is replaced-in-kind, or when upgrading equipment with functionally equivalent components. Permit modifications are also not needed when increasing the frequency of internal monitoring, reporting, or maintenance activities. Contact the Radiation Control Permit Section to discuss your plans and to obtain a determination regarding the need for a permit modification when contemplating such changes.

Your letter of application for a permit modification should identify the permit by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific, and must identify the pertinent information by date, page, and paragraph.

When preparing a permit modification request, you must answer all relevant questions outlined in Section D of these guidelines. Requests to increase the level of emissions authorized in the permit, or to add a new emission point, must include a description of the effluent treatment to be used (where appropriate), the survey method to be used to evaluate discharges, and an updated demonstration that public doses will be met, as outlined in Section D.

The requirements of SEQR must also be met as described in item 12 of Section D. Permit modification applications must be signed as described in item 13 of Section D and dated. You should retain one copy of the application for permit modification, since the statements made in the application will be made part of the modified permit. File your application as directed in Section C of these guidelines.

Changes in facility ownership require the permit to be formally transferred to the new owner. Contact the Regional Permit Administrator to obtain a permit transfer form.

F. PERMIT RENEWALS

Under the Uniform Procedures regulations (6 NYCRR Part 621), the permit will remain in effect after the expiration date only if the application for permit renewal has been submitted to the appropriate Regional Permit Administrator and determined to be sufficient at least 90 days prior to the expiration date. If this criteria is met, the existing permit will qualify for SAPA continuance (i.e., "timely renewal status") and will remain in effect in the event the permit renewal process has not been completed by the permit expiration date. Therefore, the letter of application for permit renewal must be filed well before this 90-day deadline. If the Department finds the permit renewal application needs to be supplemented with additional clarifying information, this will allow enough time to prepare and submit the required information well before the expiration date is reached.

Renewal applications should contain up-to-date information about your current program, and must meet all regulatory requirements in effect at the time of renewal. If there have been any changes in your program since the last renewal of the permit, a detailed description of these changes must be submitted with the renewal application. Normally, permit holders will be required to prepare and submit an entirely new permit application for permit renewal, in accordance with Section D of this guide. This will serve to update the application and the permit, when renewed.

The permit renewal application must meet the requirements of SEQR as described in item 12 of Section D. Applications must be signed as described in item 13 and dated. You should retain one copy of the renewal application, since the statements made in the application will be made part of the permit renewal. File your application as directed in Section C of these guidelines.

G. REQUESTS FOR PERMIT DISCONTINUANCE

When emissions of radioactive material to the environment cease, or if you believe that emissions have decreased to such a level that a permit is no longer required (see section 380-3.4), you should request that the permit be discontinued. Although an expired permit is no longer valid (i.e., emissions are no longer authorized), the Department will not formally discontinue the permit until appropriate actions are taken to close out the permit. Permits will not be formally discontinued by the Department until the permittee has demonstrated that (1) all potential sources of radionuclide discharges to the environment have been eliminated, or (2) that a permit is no longer needed for your level of discharges.

Your letter of request for permit discontinuance must be signed as described in item 13 of Section D of this guide and dated. The request should include survey results indicating the residual contamination levels of all components of the radioactive material exhaust and/or treatment systems, or, if you believe a permit is no longer needed, survey results demonstrating your current level of radionuclide emissions. Identify the disposition of all potential sources of radioactive material emissions. File your request for permit discontinuance as directed in Section C of these guidelines.

The request for permit discontinuance must include a final report providing all the information required by Section 380-9.1 and your permit, in lieu of an annual report. Under Section 380-10.4, permittees must notify the Department of intent to vacate at least 30 days prior to relinquishing possession or control of premises that may have become contaminated with radioactive materials.

Note: If any planned decontamination and demolition activities have the potential to release radioactive materials to the environment, the permit may need to be modified *prior* to the final permit discontinuance, in order to address potential environmental releases that could occur during decontamination operations. In such instances, a letter of application for permit modification must be prepared in accordance with Section E of this guide, submitted, deemed complete, and the permit issued to authorize such releases prior to initiating decontamination and demolition procedures.

Enclosures:

- 1) NRC Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for licensees other than Power Reactors"
- 2) NRC Regulatory Guide 8.37, "ALARA levels for Effluents from Materials Facilities"
- 3) NYSDEC Short Environmental Assessment Form
- 4) NYSDEC Guide, "Demonstrating Compliance with Public Dose Limits in Part 380"
- 5) NYSDEC Guide, "Review of Atmospheric Transport and Dispersion Models"

Cyclotron facility applicants will also be provided with the additional NYSDEC guide,6) "Supplement to the Air Guide for Cyclotron Facilities."

Additional References:

ANSI/AIHA/ASSE Z9.5-2012, <u>Laboratory Ventilation</u>, American Industrial Hygiene Association, Falls Church, VA (2012)

ANSI/HPS N13.1-2011, <u>Sampling and Monitoring Releases of Airborne Radioactive</u> <u>Substances from the Stacks and Ducts of Nuclear Facilities</u>, American National Standards Institute, New York, NY (2011) ANSI/ASHRAE 110-1995, <u>Method of Testing Performance of Laboratory Fume Hoods</u>, American Society of Heating, Refrigerating and Air Conditioning Engineers, Atlanta, GA (1995)

ANSI/ASHRAE/ACCA 180-2012, Standard Practice for Inspection and Maintenance of Commercial Building HVAC Systems, American Society of Heating, Refrigeration and Air Conditioning Engineers, Atlanta GA (2012)

ANSI N42.18, <u>Specification and Performance of On-site Instrumentation for</u> <u>Continuously Monitoring Radioactivity in Effluents</u>, American National Standards Institute, New York, N.Y. (2004)

ANSI N323C-2009, <u>Radiation Protection Instrumentation Test and Calibration – Air</u> <u>Monitoring Instruments</u>, American National Standards Institute, New York, NY (2009)

ACGIH, <u>Air Sampling Instruments</u>, Ninth Edition, American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio, 2001

ASME N509-2002, <u>Nuclear Power Plant Air Cleaning Units and Components</u>, American Society of Mechanical Engineers, 345 East 47th Street, New York, N.Y. 10017, (2002)

ASME AG-1-2012, <u>Code on Nuclear Air and Gas Treatment</u>, American Society of Mechanical Engineers, 345 East 47th Street, New York, N.Y. 10017, (2012)

ASTM Standard D3803-91, <u>Standard Test Method for Nuclear-Grade Activated Carbon</u>, American Society for Testing and Materials, Philadelphia, Pennsylvania, (2014)

<u>Industrial Ventilation: A Manual for Recommended Practice</u>, Twenty-third Edition, American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio (1998)

OSHA Technical Manual, Section III, Chapter 3, "Ventilation Investigation" (www.osha.gov)

USEPA, 40 CFR 61, Appendix A (Test Methods 1 & 2) (Revised July 1, 1991)

USNRC Regulatory Guide 8.25, <u>Air Sampling in the Workplace</u>, United States Nuclear Regulatory Commission, Washington, D.C. 20555 (Revision 1, June 1992)

USNRC Regulatory NUREG 1400, <u>Air Sampling in the Workplace</u>, United States Nuclear Regulatory Commission, Washington, D.C. 20555 (September 1993)

DEC Regions and Counties

Region 1 Nassau and Suffolk

Region 2 New York City

<u>Region 3</u> Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, Westchester

<u>Region 4</u> Albany, Columbia, Delaware, Green, Montgomery, Otsego, Rensselaer, Schenectady, Schoharie

<u>Region 5</u> Clinton, Essex, Franklin, Fulton, Hamilton, Saratoga, Warren, Washington

<u>Region 6</u> Herkimer, Jefferson, Lewis, Oneida, St. Lawrence

Region 7 Broome, Cayuga, Chenango, Cortland, Madison, Onondaga, Oswego, Tioga, Tompkins

<u>Region 8</u> Chemung, Genesee, Livingston, Monroe, Ontario, Orleans, Schuyler, Seneca, Steuben, Wayne, Yates

<u>Region 9</u> Allegany, Cattaraugus, Chautauqua, Erie, Niagara, Wyoming

Regional Permit Administrator

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