



**APPLICATION GUIDELINES FOR RADIATION CONTROL PERMITS
FOR USE OF RADIOACTIVE MATERIAL IN THE ENVIRONMENT**

August 2022

A. PURPOSE OF GUIDELINES

These guidelines describe the information needed by the New York State Department of Environmental Conservation staff to evaluate an application for a permit to use licensed radioactive material in the environment for studies and experiments of a specific, determinate duration. 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 use of radioactive material in the environment is considered an environmental release, and therefore is governed by the Part 380 regulations.

You should carefully study the Part 380 regulations and these guidelines before preparing the letter of application. The Part 380 regulations require you to develop and implement procedures that will ensure compliance with the applicable laws and regulations. The Department will request additional information when necessary to provide reasonable assurance that you have established a radiation safety program adequate to minimize radioactive releases to the environment. The documents you submit in support of your application 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.

B. APPLICABLE REGULATIONS

The regulations pertaining to this type of 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, and 29).

The administration of the permit, including modifications to any conditions therein, will be subject to Uniform Procedures (6 NYCRR Part 621). 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. The application will also be subject to State Environmental Quality Review (6 NYCRR Part 617).

For the purposes of maintaining compliance with the above-mentioned regulations, the definition of "annual" has been adopted from *Black's Law Dictionary* to

mean: **annual** *adj.* (14c) **1.** Occurring once every year; yearly <**annual** meeting>. **2.** Of, relating to, or involving a period of one year* <**annual** income>. (* According to *Merriam-Webster's* dictionary, one year is defined as **365 days**.) Therefore, all commitments/requirements with the frequency of “annual” will be expected to be performed no later the 365 days from the previous performance date.

C. FILING AN APPLICATION

Your letter of application for a Part 380 permit should 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, handling, and release procedures. According to Subpart 380-3, the submitted information must describe the proposed operations in sufficient detail to

(1) enable the Department to assess the nature and extent of any potential environmental impact;

(2) demonstrate that the proposed use of licensed material in the environment will comply with the requirements of Part 380; and

(3) provide adequate justification for the release of radioactive material to the environment.

The Department may approve the radioactive material use and release levels proposed in the letter of application if the applicant demonstrates the following:

(1) that radionuclide releases will be limited, as required by Subpart 380-5, so that radiation dose limits for individual members of the public will not be exceeded, and that doses will be maintained as low as reasonably achievable (ALARA); and

(2) that the applicant has made every reasonable effort to minimize the release of radioactive material to the environment, as required by Subpart 380-7.

Mail an original and two copies of the letter of application to the Department's Regional Permit Administrator at the appropriate Regional Office (see page 11). The Regional Permit Administrator will forward a copy of the application to each involved program area within the Department (e.g., the Radiation Control Permit Section).

You should 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. If the Department also requires you to obtain another type of permit for the proposed study, the Part 380 permit, when issued, will cross-reference that other permit.

If you have any questions regarding the preparation of the Part 380 permit application, you may contact the Department's Radiation Control Permit Section for assistance at (518) 402-8652.

D. CONTENTS OF THE APPLICATION

A complete application for a permit must satisfy the requirements of Sections 380-3.2 and 380-3.5. Therefore, the application should contain the following information:

1. General Information and Identification of Applicant

- a. Applicant name
- b. Mailing address
- c. Location/address of study/facility
- d. County & village
- e. Radiation Safety Officer's (RSO) name and telephone number, and who should be contacted in the RSO's absence
- f. A detailed area map showing roadways from a major state highway to the study/facility location
- g. A copy of those portions of the applicant's radioactive materials license that show the
 - license number and expiration date
 - list of radioactive materials authorized to possess
 - 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.

- h. Federal social security account number and/or federal employer identification number
- i. Organizational chart

2. Source and Nature of Radionuclide Release

Provide a general description of

- a. The study to be performed and its objectives

- b. The location and size of the study area
- c. The radionuclides to be used, including isotopic and chemical composition, and physical form
- d. The total activity of each radionuclide to be used
- e. Why radionuclides must be used for this study, rather than another method using non-radioactive material
- f. The process or method of application involving radionuclides that generates, or has the potential to generate, a release to the environment
- g. The probable fate of the radionuclides after use or application
- h. The potential for accidental releases, maximum quantities that could potentially be released, potential contamination consequences, and dose estimates
- i. Measures to be taken to control access to the study area, or an explanation of why this is unnecessary
- j. Decontamination procedures to be followed after the study is complete. Any residual contamination in soil resulting from the study must meet the guidelines in the Department's Cleanup Guidelines for Soils Contaminated with Radioactive Materials - Technical Administrative Guidance Memorandum 4003 (TAGM 4003).

3. Evaluation of Releases

Subpart 380-6 requires you to make surveys that are necessary to comply with the regulations and that are reasonable to evaluate radiation levels, concentrations, or quantities of radioactive materials. Subpart 380-6 also requires that instruments and equipment used for quantitative radiation measurements 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 or calculations of levels of radiation, concentrations, or quantities of radioactive material present. Thus, "survey" includes keeping track of releases through inventory of radioactive material throughput, effluent monitoring, and sampling of releases.

You are required to keep track of how much radioactive material is released to the environment as a result of your study. Depending on the isotope, form, and quantity of radioactive material used and released into the environment, one or more survey methods may be appropriate.

Specify the survey method(s) to be used to evaluate the amount and concentration of radioactive material released to the environment (i.e., mass balance, monitoring, sampling), and submit a copy of the survey procedures to be used.

4. Dose Limits to Members of the Public

Subpart 380-5 establishes radiation dose limits for individual members of the public. It requires that you conduct surveys of radiation levels in unrestricted areas in the environment and of radioactive materials released to unrestricted areas in the environment. The results of these surveys are used as the basis for demonstrating that your operations are conducted in such a way that the 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; one of the two methods must be used to demonstrate compliance with the dose limits.

The simplest method is outlined in Section 380-5.2(b)(2). Under this method, if the radionuclide concentration released to the environment (as a result of your study) is less than the effluent concentration value listed in 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 should be used when radioactive material is released directly to the air or to surface or groundwater (Method 1 below).

For those studies where it is not appropriate to use that method, or whose releases exceed the effluent concentration values in Table II of section 380-11.7, the method outlined in paragraph 380-5.2(b)(1) must be used to demonstrate compliance with the dose limits (Method 2 below).

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

a. Method 1 Demonstrating that--

(i) the annual average concentrations of licensed material released to the air or surface or groundwater do not exceed the values specified in the Part 380 regulations in 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, the sum of the ratios between the concentration of each radionuclide released and the concentration for that radionuclide listed in Table II of Subpart 380-11 must not exceed unity, as determined by the "sum-of-ratios" method described in Subpart 380-11.

b. Method 2

Demonstrating by measurement, calculation, or pathway analysis that the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose does not exceed the annual 100 millirem dose limit.

Submit a demonstration that your releases will be in compliance with the public dose limits. Describe how survey results will be used to confirm this demonstration.

5. Release Minimization Program

Section 380-5.1 requires that releases of licensed material to the environment be limited so that, in addition to meeting dose limits, doses to individual members of the public are as low as reasonably achievable (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.

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 licensees are required to develop and implement a radiation protection program (ALARA program). Your release minimization program

could be a part of your overall radiation protection program, or it may be maintained as a separate program. In either case, the release minimization program should specifically address environmental releases.

Your release minimization program should contain the following program elements:

- a. Management's formal policy commitment to maintaining public radiation doses due to environmental releases ALARA
- b. Analysis of trends in radionuclide usage and their effect on actual release levels, to evaluate the adequacy and operation of process equipment, release 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 monitoring programs appropriate for the releases caused as a result of the environmental study
- e. Review of procedures, equipment, 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 are released to the environment
 - (ii) An evaluation of procedures used and equipment involved to identify what improvements could be made to reduce the release of radioactive material
- f. For studies of more than one year in duration, an annual review of the release minimization program content and implementation

6. Records

Subpart 380-8 requires records to be maintained of (a) all 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.

7. Reporting Requirements

- a. Subpart 380-9 contains reporting requirements. Confirm that you will submit an annual release report to the Department by the end of each March of the year following the study, as required by Section 380-9.1. Also confirm that you will comply with the incident notification requirements of Section 380-9.2.
- b. When issued, the permit will require that a final report on the study be submitted to the Department, and approved, before any restricted area in the environment that was part of the study may be released for unrestricted use. This report must include survey results indicating the residual contamination levels of all locations where radioactive materials have been used/applied in the environment. The report must demonstrate that any residual contamination in soils complies with TAGM-4003.

8. State Environmental Quality Review Act (SEQR) Requirements

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 or increase in radionuclide releases to the environment, Part I of the enclosed Short Environmental Assessment Form (SEAF) must be completed and submitted with the application.

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

9. Signature

The letter of application should be dated and signed by the facility's radiation safety 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 signer's knowledge and belief. Unsigned applications will not be reviewed and 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 you have been issued a permit, you must conduct your study in accordance with the statements, representations, and procedures contained in the permit application

and supporting documents. Therefore, before you make any changes in your use of radioactive material in the environment (e.g., approved location/study area, equipment, procedures, radiation safety officer, or radioactive materials to be released to the environment), you must first obtain a permit modification.

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.

The requirements of SEQR must be met as described in item 9 of Section D of this guide. Permit modification applications must be signed as described in item 8 of Section D and dated. You should retain one copy of the application, since the statements made in the application will be made part of the modified permit. File your application as directed in Section C of this guide.

F. PERMIT RENEWALS

Your permit will be issued for a time period adequate to complete the study described in the application (usually one or two years). If your studies are ongoing, or for studies that need additional time to complete, the permit must be renewed in order to obtain authorization to continue using radioactive materials in the environment.

In this case, your permit will remain in effect after the expiration date only if the application for permit renewal has been submitted to the Department and determined to be complete at least 30 days prior to the expiration date. Therefore, the letter of application for permit renewal should be filed at least 60 days prior to the expiration date. If the Department finds your application is incomplete, this will allow you sufficient time to prepare and submit the required information and have the application declared complete 30 days before the expiration date.

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 study since the last renewal of the permit, a detailed description of these changes must be submitted with the renewal application. The Department will evaluate the nature of those changes and determine if a new permit application will be required for permit renewal. If the Department determines that a new application is needed, a permit application must be prepared in accordance with Section D of this guide.

The permit renewal application must meet the requirements of SEQR as described in item 8 of Section D. Applications must be signed as described in item 9 and dated.

You should retain one copy of the 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 this guide.

G. PERMIT DISCONTINUANCE

At the conclusion of the study, you should request that the permit be formally discontinued. Note that an expired permit will not be discontinued until the Department takes action to discontinue the permit, which requires the permittee to demonstrate that all potential sources of radionuclide releases to the environment have been eliminated.

Your letter of request for permit discontinuance must be signed as described in item 9 of Section D and dated. The request should include a final study report (as described in item 7b. of Section D of this guide). 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.

Be aware that if any planned decontamination activities have the potential to release radioactive materials to the environment, the permit may need to be modified prior to the final permit termination, to address potential environmental releases during these operations. In such instances, a letter of application for permit modification must be submitted, deemed complete, and the permit issued prior to initiating decontamination procedures. File your request as directed in Section C of this guide.

DEC Regions and Counties

Region 1

Nassau and Suffolk

Region 2

New York City

Region 3

Dutchess, Orange, Putnam, Rockland,
Sullivan, Ulster, Westchester

Region 4

Albany, Columbia, Delaware, Green,
Montgomery, Otsego, Rensselaer,
Schenectady, Schoharie

Region 5

Clinton, Essex, Franklin, Fulton, Hamilton,
Saratoga, Warren, Washington

Region 6

Herkimer, Jefferson, Lewis, Oneida, St.
Lawrence

Region 7

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

Region 8

Chemung, Genesee, Livingston, Monroe,
Ontario, Orleans, Schuyler, Seneca,
Steuben, Wayne, Yates

Region 9

Allegany, Cattaraugus, Chautauqua, Erie,
Niagara, Wyoming

Regional Permit Administrator

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SUNY Campus
Stony Brook, NY 11790
(631) 444-0360

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