Approved by OMB<sup>1</sup> Control No. 3150-0183 Expires: 02/28/2027

#### INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM QUESTIONNAIRE

#### New York Agreement State Program

#### Reporting Period: July 30, 2022-September 26, 2024

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

#### A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

Currently there are no open recommendations for New York City.

#### B. COMMON PERFORMANCE INDICATORS

#### I. <u>Technical Staffing and Training</u>

- 2. Please provide the following organization charts, including names and positions:
  - (a) A chart showing positions from the Governor down to the Radiation Control Program Director;
  - (b) A chart showing positions of the radiation control program, including management; and
  - (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.
  - (a)
- 1. Mayor: Eric Adams
- 2. Commissioner of Health: Dr. Ashwin Vasan
- 3. Deputy Commissioner for Environmental Health: Corinne Schiff
- 4. Assistant Commissioner for Environmental Sciences and Engineering (acting): Dianne Fung
- 5. Radiation Control Program Director: Christanna Kendrot
- (b) Organization chart will be provided separately
- (c) N/A
- 3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing and compliance, emergency response, low-level radioactive waste, uranium recovery, and other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program.

If consultants were used to carry out the program's radioactive materials responsibilities,

#### include their efforts. The table heading should be:

<u>Name</u>	Position <u>Area of Effort</u>	FTE%	
Name	Position	Area of Effort	FTE%(d)
Dianne Fung	Asst. Commissioner (acting)	Administration	5
Stanley Chin	Director, Administration	Administration	10
Christanna Kendrot	Director, ORH / Unit Chief, x-ray equipment	Administration	20
Erik Finkelstein	Unit Chief,	Administration	40
(a)	radioactive materials	Materials Licensing & Compliance Emergency Response	40 5
Hailu Tedla (a)	Health Physicist	Materials Licensing & Compliance Emergency Response	20 5
Jose Lorenzo (b)	Chief Inspector	Administration (supervision) Materials Licensing & Compliance	20 65
Olga Aminev (b)	Inspector	Materials Licensing & Compliance	50
Mark Rayman (b)	Inspector	Materials Licensing & Compliance	40
Roshell Wiggan	Radiation Emergency	Materials Licensing & Compliance	40
(C)	Response Specialist	Emergency Response	20
Shanaz Ghandhi	Radiation Safety Scientist	Emergency Response	10

a: Fully qualified License Reviewer

b: Fully qualified Inspector

c: License Reviewer in training

d: No individual FTE is 100% for the radioactive materials program since all staff have some involvement with radiation producing equipment regulation.

4. Please provide a listing of all new professional personnel hired into your radioactive materials program since the last review, and if possible, who they are replacing if a recently vacated position is being filled (please indicate how long the position remained vacant). Please indicate the date of hire; the degree(s) they received, if applicable; additional training; and years of experience in health physics or other disciplines, as appropriate.

#### > Personnel taking new positions:

Dianne Fung, acting Assistant Commissioner, Bureau of Environmental Sciences and Engineering, replacing Lily Huang, as of 8/1/24.

Erik Finkelstein, acting Director, Office of Radiological Health, replacing Mark Horberg, from 4/1/24 to 9/8/24.

Christanna Kendrot, Director, Office of Radiological Health, replacing Erik Finkelstein, as of 9/9/24

#### > Newly hired personnel:

Roshell Wiggan, M.S., replacing Sarah Bajwa. Hired 4/10/23 (position was vacant for about 10.5 months). 7 years experience with regulatory compliance, 2 years experience in life science research.

Shanaz Ghandhi, Ph.D., replacing Dixitkumar Patel. Hired 7/1/24 (position was vacant for about 13 months). 20 years experience in radiation safety.

5. Please list all professional staff who have not yet met the qualification requirements for a radioactive materials license reviewer or inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

Roshell Wiggan, license reviewer, has completed internal requirements for license review, will be considered fully qualified after taking NRC training course G-109, planned for March 2025 (if accepted to the course).

6. Please provide copies of the Program's training procedures.

To be provided separately

7. Identify any changes to your qualification and training procedure that occurred during the review period.

N/A

8. Please identify the technical staff that left your radioactive materials program during the review period and indicate the date they left.

Dixitkumar Patel, 6/3/23 Mark Horberg, 4/1/24

9. List any vacant positions in your radioactive materials program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

N/A

10. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

N/A

#### II. Status of Materials Inspection Program

11. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: license category or licensee name and license number, your inspection interval, and rationale for the difference.

N/A

12. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period.

	2022	2023	2024
	(7/30/22 - 12/31/22)		(as of 8/21/24)
Initial	4	18	10
Routine - priority 1	n/a	n/a	n/a
Routine - priority 2	5	19	10
Routine - priority 3	8	24	20
Routine - priority 5	27	94	56

(Initial inspections are not included in the count of routine inspections)

13. Please submit a table, or a spreadsheet, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue.

N/A

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Program Codes
- (4) Priority (IMC 2800)
- (5) Last inspection date or license issuance date, if initial inspection
- (6) Date Due
- (7) Date Performed
- (8) Amount of Time Overdue
- (9) Date inspection findings issued
- 14. Please submit a table or spreadsheet that identifies any Priority 1, 2, and 3 licensees and initial inspections that are currently overdue, per IMC 2800. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.

N/A

15. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.

N/A

16. Please provide copies of the Program's reciprocity procedure.

N/A (Since NYC only regulates medical and non-commercial use of radioactive materials, we are currently not performing reciprocity inspections, any reciprocity goes through New York State Health.)

#### III. <u>Technical Quality of Inspections</u>

Olga Aminev

17. Please provide copies of the Program's inspection procedure(s), or a confirmation that Program is using the NRC's inspection procedures.

To be provided separately.

Jose Lorenzo

18. What, if any, changes were made to your written inspection procedures during the reporting period?

The procedure has not been updated during the period.

19. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Inspector	Supervisor Lic	ense Category Date	
Inspector	Supervisor	License Category	Date
Jose Lorenzo	Erik Finkelstein	Medical (NRC Priority 3)	5/4/23
Mark Rayman	Jose Lorenzo	Medical (NRC Priority 5)	8/2/23

Olga Aminev	Jose Lorenzo	Medical (NRC Priority 5)	5/28/24
Jose Lorenzo	Erik Finkelstein	Medical (NRC Priority 5)	6/4/24
Mark Rayman	Jose Lorenzo	Medical (NRC Priority 5)	7/8/24

Medical (NRC Priority 5)

8/3/23

# 20. Describe or provide an update on your instrumentation, methods of calibration, and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

There are no changes since the previous review. Inspectors currently carry Ludlum model 2241 survey meters with NaI gamma probe and G-M pancake probe and/or Thermo RadEye G electronic ratemeters. All instruments are sent out to qualified outside vendors for annual calibration. There were sufficient calibrated instruments throughout the review period.

#### IV. Technical Quality of Licensing Actions

21. How many specific radioactive material licenses does your program regulate at this time?

265 (as of 8/21/24)

22. Please provide a list of licensing actions completed during the review period, including program code, license reviewer, and license type (e.g., medical, academic, commercial, R&D, industrial radiography, gauges, etc).

To be provided separately

23. Please indicate whether the licensing records are stored electronically, or in paper files, or in a combination of both.

Current licensing records are stored electronically. Records for licensing actions completed prior to March 2020 are stored as paper files.

- 24. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.
  - 93-2878-05, Columbia Presbyterian Medical Center, gamma knife renewal, 12/1/22
  - 52-2960-06, Weill Medical College, new PET production cyclotron, 2/8/23
  - 74-2960-12, New York Presbyterian, non-human use broad scope renewal, 4/3/23
  - 75-2909-04, Mount Sinai Hospital, medical broad scope renewal, 5/1/23
  - 74-3508-05, Icahn School of Medicine, non-human use broad scope renewal, 1/2/24
  - 91-2898-02, Mount Sinai West, medical limited use renewal, 2/1/24
  - 75-2885-01, Montefiore Medical Center, medical broad scope renewal, 2/15/24
  - 52-2968-06, Memorial Sloan Kettering, PET production cyclotron renewal, 3/1/24
  - 74-2919-02, Albert Einstein College of Medicine, non-human use broad scope renewal, 7/26/24
- 25. Please provide copy of the Program's licensing procedure(s) or a confirmation that the Program is using NRC's NUREG-1556.

We are using the relevant volumes of NUREG-1556 as our licensing procedures.

26. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

N/A

27. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

N/A

28. Please indicate which revision(s) of the Risk-Significant Radioactive Materials Checklist and Pre-Licensing Guidance were used by the Program during this review period.

Checklist to Provide a Basis for Confidence that Radioactive Materials Will be Used as Specified on the Application (Revised 01/29/19) 29. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

Mark Nolan M.D., license # 91-3187-01 Louis Glodowski, M.D., license # 91-3716-01

These two applications have been reviewed, but are held up due to not receiving an applicant response to questions from our office (regarding deficiencies in the application). These facilities are presumably not currently in operation. We hope to resolve by following up (either by phone or onsite inspection) to encourage the licensee to either complete the renewal or cancel the license.

#### V. <u>Technical Quality of Incident and Allegation Activities</u>

30. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

Licensee Name License # Date of Incident/Report Type of Incident

All reportable incidents have been submitted to NRC.

31. Provide a list of allegations that were closed during the review period and any allegations that remain open.

Currently we have no open allegations. List of closed allegations to be provided separately.

32. Provide copies of the Program's Incident and Allegation procedures.

To be provided separately.

33. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

N/A

#### • NON-COMMON PERFORMANCE INDICATORS

#### I. Legislation, Regulations, and Other Program Elements

34. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

NYC Health Code Article 175 (there have been no changes during the review period).

35. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

N/A

36. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct and provide a status of any outstanding comments. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.

An update on compatibility status was sent to NRC on 8/13/24. NYC regulations should be fully compatible with NRC, except for two issues that were noted by NRC in a letter dated 8/30/22. We intend to address those two NRC comments in the next regulatory update, currently planned for calendar year 2025.

37. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

N/A

#### OTHER

38. Is there anything else the IMPEP team should be made aware of while preparing for the IMPEP review?

N/A

#### Ш. Sealed Source and Device (SS&D) Evaluation Program

N/A for New York City

39. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

SS&D	Manufacturer,			
Registry	Distributor or	Product Type	Date	Type of
<u>Number</u>	<u>Custom User</u>	<u>or Use</u>	lssued	<u>Action</u>

40. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9 Technical Quality of Licensing Actions - Questions 18-22 Technical Quality of Incident and Allegation Activities - Questions 23-24

#### 111. Low-level Radioactive Waste Disposal Program

N/A for New York City

41. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9

Status of Materials Inspection Program - Questions 10-14 Technical Quality of Inspections - Questions 15-17 Technical Quality of Licensing Actions - Questions 18-22 Technical Quality of Incident and Allegation Activities - Questions 23-24

#### IV. Uranium Recovery Program

N/A for New York City

42. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9 Status of Materials Inspection Program - Questions 10-14 Technical Quality of Inspections - Questions 15-17 Technical Quality of Licensing Actions - Questions 18-22 Technical Quality of Incident and Allegation Activities - Questions 23-24

#### **Introduction and Purpose**

This policy describes the requirements for staff to be qualified as license reviewers or inspectors in the radioactive materials unit of the Office of Radiological Health (ORH), New York City DOHMH.

This policy is consistent with and based in part on the US Nuclear Regulatory Commission Inspection Manual, chapter 1248 (IMC 1248).

Part I of this document provides an overview of the policy and how it is implemented. Part II lists specific training requirements and describes the criteria for assessing if staff have met each requirement.

#### Part I: Implementation

#### 1. Training coordinator and training records

The Training Coordinator for the radioactive materials unit will be designated by the Chief of the Radioactive Materials Unit or by the Director of ORH. If undesignated, the Chief of the Radioactive Materials Unit will perform the role. The Training Coordinator is responsible for maintaining a current table or summary of completed and outstanding training for each license reviewer, inspector, and trainee. The summary will be maintained on the ORH share drive, along with relevant documentation such as training certificates. These records should include required training for qualification purposes as well as any other relevant training taken. The Training Coordinator is responsible for ensuring that staff are meeting the requirement for refresher training (see section 4 below), and for informing staff and their supervisor of any pending or potential gap in training requirements. Staff who complete relevant training must inform the Training Coordinator and provide records of completion.

#### 2. Qualification requirements

The required training, skills, and competencies needed to independently perform license review and/or inspections are listed on "training requirement" tables included at the end of this policy. There are two versions of the table, one for license review and one for inspection. When one of the requirements listed on the tables is completed, the trainee or their supervisor should inform the training coordinator, who should update their records with the task completed and date. (The trainee is also encouraged to track their own progress using a copy of the table.) When all the requirements listed on the table are completed, the supervisor should send a formal message (email or memo) to the trainee indicating that the individual is considered fully qualified.

#### 3. Equivalent training and experience

Some of the training requirements may be met by alternative, equivalent training or experience, such as previous on-the-job experience or other coursework that covers the same areas as some of the required NRC courses. The supervisor should approve credit for equivalent training if they believe that training has covered the relevant topics and prepared the trainee to work as an ORH license reviewer or inspector as well as the listed training would have. In that case the training record should be updated to indicate that the requirement was met through "equivalent experience" and the basis for approving the equivalent training should be documented and saved along with the training records.

#### 4. Refresher training

Qualified license reviewers and inspectors must maintain their qualification by taking 24 hours of refresher training every 2 years. The 24 hours may be from a single training course or a combination of multiple shorter courses. This training should be in subject areas relevant for the ORH program, such as health physics, radiation safety, security of radioactive materials, or courses focused on specific practices or procedures relevant to ORH regulation. The training may consist of taking additional NRC training beyond the required courses, or (with prior supervisor approval) retaking NRC training that was taken before, or (with prior supervisor approval) other formal training. Employees who fail to take refresher training as described are not allowed to sign licenses or conduct independent inspections until they meet this requirement, unless they are given a written waiver or extension by their supervisor.

#### 5. Restrictions on independent work prior to full qualification

<u>Not-yet-qualified trainee</u>: A trainee who is not yet qualified as a license reviewer may work on license actions for the purpose of supervised on-the-job training, but may not sign the finished license or act as peer reviewer for the work of other license reviewers. A trainee who is not yet qualified as an inspector may accompany a qualified inspector and participate in an inspection for training purposes but may not conduct an inspection by themselves.

<u>Partially qualified trainee</u>: A trainee who has not completed all of the requirements may be considered "partially qualified", which means they can act as an independent inspector or license reviewer *only for the types of licenses or facilities for which they have finished all of the relevant training topics and supervised work*. The trainee's supervisor should provide a written memo or email to the trainee listing which types of licenses and/or facilities the trainee is considered qualified to independently review and/or inspect.

#### 6. Grandfathering

ORH inspectors or license reviewers who were considered fully qualified before this policy went into effect are still considered fully qualified even if they have not completed all of the listed items, however they should continue to take refresher training and remedy any identified gaps in training as quickly as possible.

#### Part II: Description of the training requirements

This section describes the criteria for each of the items listed under "in-house training and study topics" on the training forms. Supervisors should sign off on items only after verifying that the trainee has fully met the criteria listed here.

For each topic there are "tasks" (items to study) and "evaluation criteria" (to be used by the supervisor in assessing if the trainee has completed the topic.) Most of the "tasks" are intended to be independent study assignments. (Naturally the supervisor should provide guidance / clarification as needed.) Some of the tasks are specifically listed as "supervisor led" which means it is intended to be presented as in-person instruction from experienced staff (although it is described as "supervisor led" the trainer does not always have to be the direct supervisor of the trainee).

#### 1. The Role of Agreement States in Radioactive Materials Regulation.

Purpose: To understand the jurisdiction of ORH in the context of the general scheme for radioactive materials regulation in the United States.

Tasks:

- Supervisor led: Understand the role of DOHMH-ORH within the NRC agreement state program and within the New York State program.
- Look over information on the NRC website re: the agreement state program (general info: <u>https://www.nrc.gov/about-nrc/state-tribal/agreement-states.html</u>; specific state-by-state info: <u>https://scp.nrc.gov/</u>).
- For license reviewer trainee: Browse the CRCPD directory and become familiar with how to look up contact people from other state programs.

Evaluation Criteria:

• The trainee understands the basic idea of the Agreement State program and the scope of NYC radioactive materials regulation.

#### 2. Article 175 / 10CFR regulations

Purpose: To ensure that ORH staff have sufficient familiarity with the structure and content of the regulations and can use these documents as needed to find required information.

Tasks:

- Read Article 175, focusing on the regulations for radioactive materials.
- Read the incorporated NRC regulations in 10CFR Parts 19, 20, 30, 35, 37, and 71, focusing on Part 20 (standards for protection against radiation) and Part 35 (medical use of byproduct materials).

Evaluation Criteria:

- The trainee should be asked to find, in the NYC and/or CFR code, regulations covering some specific topics, for example public dose limits, training for a radiation safety officer, etc., and provide the correct code citation.
- The trainee should know the meaning of the 10CFR "types of use" for radioactive material (35.100, 35.200, 35.300 etc.)

#### 3. NUREG-1556 (selected volumes) and other NRC guidance

Purpose: To ensure that ORH license review staff are competent to use NUREG 1556 to guide license review and to advise applicants in using NUREG 1556 to prepare applications, and to keep ORH procedure and regulatory interpretation consistent with NRC practice.

Tasks:

• Become familiar with the content of the NRC Medical Use Licensee Toolbox webpage (<u>https://www.nrc.gov/materials/miau/med-use-toolkit.html</u>) and the page for "emerging

medical technologies" (<u>https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html</u>).

- Look over and become familiar with the NRC NUREG 1556 webpage (<u>https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/</u>).
- Read NUREG 1556 volume 9 (latest revision), especially focusing on the table of contents, licensee responses required (in section 8), license checklists, and model licenses.
- Browse some other NUREG 1556 volumes that may be relevant to ORH licensing actions. Compare the required licensee response for RSO, authorized user, etc. for applicants for non-human licenses (volume 7) to the requirements for medical licenses (volume 9)

Evaluation Criteria:

- The trainee should be able to use the resources on the NRC "emerging medical technologies" webpage to find licensing guidance for a specific material.
- The trainee should be able to describe the basic structure of the NUREG documents and what types of information is included.
- The trainee should be asked to find, in the appropriate NUREG volume, the guidance for the applicant response for a specific question or topic.

#### 4. License types, files, and format of printed license

Purpose: To ensure that ORH staff have necessary familiarity with the license documents issued by ORH.

Tasks:

- Supervisor led: Review the different types of licenses issued by ORH (e.g. limited vs broad scope, medical vs non-human use, LINAC)
- Supervisor led: Review the ORH filing system and organization of the license file folders and electronic documentation
- Review the basic structure of the ORH license document, understand the purpose of license conditions including the tie-down condition
- Look over several types of licensees (e.g. type 91, 52, broad scope)

Evaluation Criteria:

- The trainee can explain the meaning of the items on a license including the materials, authorized users, and tie-down condition
- The trainee understands the major differences between limited scope and broad scope licenses, and between materials licenses and LINAC registrations

#### 5. License actions

Purpose: To ensure that ORH license review staff are qualified to provide initial review of applications for license actions.

Tasks:

- Become familiar with ORH radioactive materials and LINAC application forms, NRC 313(A) forms, and ORH checklist for review of medical use licenses
- Supervisor led: understand differences in what is required from licensee for various types of license actions (e.g. renewal vs. new license vs. amendment, medical vs. non-human vs. LINAC)

Evaluation Criteria:

- Trainee reviews some incoming amendment and renewal applications and is able to determine deficiencies if any
- Trainee can describe authorized user qualification requirements for different types of licenses (including for LINAC)

#### 6. License review process / communications with licensees

Purpose: To ensure that ORH license review staff understand the in-office procedures and steps for license actions.

Tasks:

- Review ORH licensing procedure
- Supervisor led: Review the formal process of ORH license review including the use of log • sheet and billing form

**Evaluation Criteria**:

- Trainee can properly produce billing form and document license actions in progress
- Trainee understands the security-related information requirements (i.e. keeping license folders and applications secured when not in use)

#### 7. RAM database

Purpose: To ensure that ORH license review staff are able to retrieve needed information from the database and to update information in the database as required.

Tasks:

Supervisor led: Review the use of the database including license search, entering license • actions, reviewing license history, creating new license, etc.

Evaluation Criteria:

- Trainee is able to use the database to find information about a specific license, or a list of • licenses meeting specific criteria, and to update or correct license information
- Trainee is able to properly update the database to show license actions performed

#### 8. Financial Assurance

Purpose: To ensure that ORH license review staff understand the financial assurance and decommissioning plan requirements in the health code, and how and when to apply them. Tasks:

- Review the relevant section of the regulations (i.e 10CFR 30.35). •
- Review the use of the financial assurance calculator (excel form) or equivalent tool. •

Evaluation Criteria:

Trainee is able to determine if a license requires financial assurance based on materials listed • on license and understands how to handle the issue during license review.

#### 9. Allegations / complaints

Purpose: To ensure that ORH inspection staff follow up appropriately on allegations and complaints. Tasks:

- Supervisor led: Review ORH procedure for documenting and responding to allegations and • complaints
- Review section on "reactive inspections" in ORH inspection manual •
- Accompany an inspector on a reactive inspection in response to a medical event notification or other incident or complaint

**Evaluation** Criteria:

- Trainee knows the difference between an "allegation" and a "complaint" •
- Trainee understands the basic process for receiving, responding to, and documenting allegations and complaints.

#### 10. General inspection procedures / inspection letters

Purpose: To ensure that ORH inspection staff understand the general protocol for performing and documenting inspections and preparing inspection letters.

Tasks:

- Review the ORH inspection manual
- Obtain and review copies of the current inspection forms for RAM and LINAC inspections.
- Accompany at least two different inspectors to inspections, including at least one inspection at a hospital, small medical office, and non-human use licensee
- Draft inspection letters based on the filled out inspection forms for accompanied inspections. (Look through license folders or shared drive for model letters to use as templates.)

Evaluation Criteria:

- Trainee understands content of ORH inspection manual, and can use the manual to find proper procedures for specific types of inspections Trainee understands use of inspection forms including which form(s) to use depending on type of facility / type of materials used at facility
- Trainee is able to draft inspection letter in proper format depending on result of inspection

#### 11. New licensee assurance requirements and pre-licensing visit

Purpose: To ensure that ORH licensing staff understand the protocol for evaluating new license applications to ensure that radioactive material will be used as intended, including performing prelicense visit.

Tasks:

- Obtain and review the NRC forms for ensuring that radioactive material is used as intended (new license checklist). Discuss with supervisor/experienced staff as needed to understand the use of these forms
- Review the ORH inspection manual section on pre-licensing visits
- Accompany an experienced license review staff on a pre-licensing visit

Evaluation Criteria:

- Trainee performs supervised review of a new license application, including appropriately filling out the new license checklist
- Trainee effectively conducts a supervised pre-licensing visit

#### 12. Use of GroveWare software and forms

Purpose: To ensure that ORH inspection staff are familiar and competent with the use of the tabletbased "GroveWare" software for inspection assignment and performance.

Tasks:

• Supervisor led: Receive training from qualified ORH inspector on the use of GroveWare software to review inspection assignments and record inspection results.

Evaluation Criteria:

- The trainee should be able to review their assignments on the GroveWare website and tablet.
- The trainee should be able to record and submit their inspection results using either the site visit form or the full inspection forms as appropriate.
- The trainee should be able to use GroveWare to create and submit a summons for violations.

#### 13. Citations / OATH / Hearings

Purpose: To ensure that ORH inspection staff properly write and issue citations and are prepared to appear at OATH hearings if/when necessary.

Tasks:

- Supervisor led: Receive training from gualified ORH inspector on the format and procedure • for issuing a citation during an inspection.
- Review "OATH Hearings Overview" (PowerPoint slides) and browse OATH rules at • website: http://www1.nyc.gov/site/oath/hearings/hearings-division-rules-of-practice.page
- Accompany ORH inspector to an OATH hearing

**Evaluation Criteria**:

• The trainee should be able to write a properly formatted and documented citation.

#### 14. Medical Events

Purpose: To ensure that ORH staff follow up appropriately on notification of a medical event. Tasks:

- Review the relevant section of the regulations (i.e.; 10CFR 30.3045) and ORH inspection • manual.
- Look over and understand the use of the medical event / incident log form •
- Supervisor led: Understand the reporting requirements (licensee to ORH and ORH to NRC) upon discovery/notification of a medical event and the relevant staff responsibilities
- Inspection trainees only: Accompany an inspector on a reactive inspection in response to a • medical event notification or other incident or complaint

Evaluation Criteria:

- Trainee is able to determine, based on a description of an incident, if it fits the definition of a ٠ medical event.
- Trainee is able to participate in medical event follow-up as appropriate for their job/role at ٠ ORH

#### 15. Site Access / Gathering Information / Effective Communication with the Public

Purpose: To ensure that ORH inspection staff are able to obtain necessary information while maintaining professional and friendly interactions with the public and licensee staff.

Tasks:

Accompany at least two different inspectors during inspection and observe the way the • inspectors present themselves and conduct interactions with licensee staff

Evaluation Criteria:

• Trainee is effective and respectful when dealing with public and licensee staff Employee name:

	Date of	Equivalent training or experience
Requirement	completion	(Describe and give date)
NRC agreement state training courses		
Licensing Practices and Procedures (G-109)		
Diagnostic and Therapeutic Nuclear Medicine (H- 304)		
Brachytherapy, Gamma Knife, and Emerging Technologies (H-313)		
Materials Control & Security Systems & Principles (S-201)		
Root Cause/Incident Investigation Workshop (G-		
Introductory Health Physics (H-117S)		
Fundamental Health Physics (H-122S)		
In-house training and study topics		
The Role of Agreement States in RAM Regulation.		
Article 175 / 10CFR		
NUREG-1556 (selected volumes)		
License types, files, and format of printed license		
License actions		
License review process / communications with		
licensees		
RAM database		
New licensee assurance requirements and pre-		
licensing visit		
Supervised license review		
Amendment: new authorized user		
Amenument: new materials		
Renewal: Hospital		
Renewal: Broad scope		
New license		
Cancel		
Unsealed material / written directive not required		
Unsealed material / written directive required		
Manual brachytherapy		
HDB		
Gamma knife		
Irradiator		
Academic laboratory		
Mobile medical		
LINAC		

Employee name:

	Date of	Equivalent training or experience
Requirement	completion	(Describe and give date)
NRC agreement state training courses		(
Inspection Procedures (G-108)		
Diagnostic and Therapeutic Nuclear Medicine		
(H-304)		
Brachytherapy, Gamma Knife, and Emerging		
Technologies Course (H-313)		
NRC Materials Control & Security Systems &		
Principles (S-201)		
Transportation of Radioactive Materials (H-308)		
Introductory Health Physics (H-117)		
Fundamental Health Physics I (H-122)		
In-house training and study topics		
The Role of Agreement States in RAM		
Regulation.		
Licence types files and format of printed		
license		
Allegations / complaints		
General inspection procedures / inspection		
letters		
Use of GroveWare software and forms		
Citations / OATH / Hearings		
Medical Events		
Site Access / Gathering Information / Effective		
Communication with the Public		
Supervised inspections		
Medical Office		
Hospital		
Research Facility (non-human use)		
Mobile Medical Service		
Reinspection		
Cancel / Close-out		
Unsealed material / written directive not		
required (cardiology)		
PET		
Generators		
Unsealed material / written directive required		
Y-90 Microspheres		
Manual brachytherapy / eye applicators		
HDR		
Gamma knife		
Irradiator		
LINAC		

# RADIOACTIVE MATERIALS PROGRAM INSPECTION MANUAL

#### **OFFICE OF RADIOLOGICAL HEALTH**



**Health** This manual is an adaptation of the US NRC Inspection Manual Chapter 2800 tailored for the Radioactive Material Program of the New York City Department of Health

JANUARY 2018

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#### 1. PURPOSE

To establish general guidance for conducting inspection of licensed facilities authorized to possess, use, transfer, and dispose of radioactive material under the New York City Health Code Article 175 for Radiation Control.

#### 2. OBJECTIVES

- To establish a general policy for inspection of licensed facilities under the NYC radioactive materials program.
- To describe a performance-based inspection approach and to identify specific conditions of poor performance that requires more frequent inspection of the licensee.
- To place the major emphasis of the materials inspection program on timely and thorough follow-up of incidents, events, and allegations.
- To enhance risk-informed relative priorities for routine inspections of all licensees and a program of special inspection activities as specified by relevant ORH guidelines.
- To aid in the achievement of a consistent process of inspection for materials licensees to ensure the health and safety of workers and the public and protect the environment.

#### **3. DEFINITIONS**

3.1 Pre-licensing Visit.

A site visit and face-to-face meeting with an entity for providing a basis for confidence that radioactive material will be used as specified. Staff should use the Pre-licensing checklist to determine which applicants require visits.

#### 3.2 Initial Inspection.

An inspection conducted within 6 months after a new license is issued, or after an amended license has been significantly expanded or changed ownership with significant changes to the license or program.

#### 3.3 Initial Security Inspection.

An inspection to verify that an applicant has implemented security requirements before the licensing action is issued allowing the application to take possession of risk significant radioactive material. Staff should use the checklist for Risk Significant Radioactive Materials to determine which applicants require inspections.

#### 3.4 Inspection.

The act of assessing licensee performance to determine whether the licensee is using radioactive material safely and whether an individual or organization is in compliance with established standards, such as Orders, regulations, license conditions, and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions). Inspections involve a visit to a licensee's facility, observations of licensed activities, interaction with licensee personnel, independent radiological measurements, and transmission of the inspection findings. Pre-licensing visits are not considered inspections.

#### 3.5 Inspection Plan.

An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

3.6 Inspection Priorities.

An inspection priority code is assigned to each radioactive material license. The priority code (i.e., 1, 2, or 3) is the interval between routine inspections, expressed in years. The same priority code is assigned to all licenses that authorize that particular type of use. Enclosure 1 lists the program codes (types of use) along with the assigned priority codes. The priority represents the relative risk of radiation hazard. Priority Code 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority Code 3 represents the lowest risk.

3.7 Reactive Inspection.

A reactive inspection is a special inspection in response to an incident, allegation, or information obtained by ORH (e.g., report of a medical event, report by a member of the public or an employee of a licensee). Reactive inspections may focus on one or several issues, and need not examine the rest of a licensee's program. If the reactive inspection does not cover the activities normally reviewed during a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

3.8 Routine Inspection.

Periodic, comprehensive inspections performed at a specified interval, as defined in Enclosure 1.

3.9 Risk Significant Radioactive Material (RSRM).

RSRM refers to the values in Enclosure 4: Table 1 - "Category 1 quantities," and "Category 2 quantities" as described under Appendix A of 10 CFR 37.

3.10 Security Requirements.

Requirements mandated by regulation, Order, license condition, or other legally binding requirements for certain licensees possessing or shipping RSRM.

3.11 Special Inspection Activities.

Those inspection activities specified in Section 7 of this manual where special guidance is needed. Those activities cover: 1) inspections of expired licenses, terminated licenses, and licensees undergoing decommissioning; 2) inspections of significantly expanded licensee programs; 3) reciprocity inspections; 4) team inspections; 5) inspections of revoked or abandoned licenses; 5) reactive inspections and follow-up to escalated enforcement.

#### 4. BASIC REQUIREMENTS

The Materials Inspection Program designates reactive inspections [See Section 5.4] as the highest priority, followed by initial inspections [See Section 5.5] and routine inspections [See Section 5.6] for the Priority Codes (in ascending numeric order) listed in Enclosure 1.

All routine materials inspections should be performed on an unannounced basis. However, since coordination with pertinent licensee personnel is required as part of an initial security inspection, these security inspections may be announced to ensure that the appropriate personnel will be in attendance. Coordination with the local law enforcement agency is encouraged, but is not required as part of an initial security inspection.

The license reviewer(s) shall assign priority, with the most restrictive program code setting the inspection priority for each new or amended license. In other words, some licenses authorize activities that can be classified under more than one program code. If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority

Sources requiring security inspections are inspected at the same frequency as the program code that corresponds to the RSRM.

All licensees possessing Category 1 and Category 2 quantities of radioactive materials will be assigned Priority 1 or Priority 2 inspections corresponding to the priority assigned under their program code (refer RAD 37 enclosure 3)

For example, a gamma knife user (Program Code 93) has routine and security inspections every 1 year.

Inspection plans should be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections, as decided by Chief of Radioactive Materials. As an example, an inspection plan may reflect areas in which there is the highest level of safety concerns, the set of documents or inspection history that need to be examined, the staff that would be interviewed, the specific survey procedure to be applied or the step by step process that may be followed to investigate the causes of an incident.

## **5. GENERAL INSPECTION PROCESS**

The purpose of this manual is to describe the types of materials inspections program. For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. Inspection procedures listed in Enclosure 2 provide more specific guidance for onsite inspection activities. Section 8 provides guidance for documenting inspection results.

The inspector charges the appropriate inspection fee in accordance with the fee schedules for each program code indicated in the billing statement form (Refer enclosure 3 form RAD-12) and submits the completed form for processing by DOHMH finance.

5.1 Pre-inspection activities.

Pre-inspection activities include preparation to ensure that the inspector is sufficiently familiar with the types of uses and the generic requirements applicable to the licensed program. The effort expended on inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector. The extent to which an inspector prepares for routine inspections should be based on discussions with the supervisor.

To adequately prepare, an inspector shall review:

- The license to determine if it has any unusual license conditions that would affect the approach to the inspection, e.g., significant changes in licensed operations, or implementation of security requirements for RSRM.
- The licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items and determining whether any events have been reported by the licensee during the current inspection cycle.
- Any commitments made by the licensee or restrictions imposed by the ORH as a result of inspection finding letter or an Order issued since the last inspection.
- Any notes in the file regarding special inspection emphasis, i.e.,

license reviewer's note to request a near term inspection regarding a significant licensing action.

- Any security requirements, guidance, questions and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief, and final determinations by the Office).
- Any allegations trends and a follow-up of the licensee's evaluation and response to allegations in consultation with the Field Supervisor [See Section 8.2]
- If the licensee is authorized to possess RSRM, request the licensee to provide National Source Tracking System (NSTS) inventory record at least two days in advance.

Prior to the inspection, the inspector should review all the current licensing documents and procedures from the corresponding folder. For problems identified during the course of the routine inspection, the inspector should ask the licensee for pertinent procedures and backup licensing documents maintained onsite by the licensee. If the documents are not available from the licensee, the inspector should contact the ORH for assistance. This practice would apply to routine inspections only.

To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and his or her supervisor on a case-by-case basis [See Section 5.4].

Inspectors should anticipate whether or not they will encounter sensitive information during inspection of a licensee. Inspectors should be aware of minimum handling requirements for sensitive unclassified information, such as Official Use Only or Proprietary Information. For further information the inspector should contact the Field Supervisor or the Office.

Finally, the inspector should select appropriate and calibrated radiation detection instrumentation for the inspection and obtain the necessary inspection forms pertaining to the program area to be inspected (Enclosure 3).

5.2 Onsite Inspection Activities.

Based on the pre-inspection activities, the inspector should be prepared to evaluate a licensee's performance radiation safety and/or security programs. The inspector should make himself/herself familiar about the scope of the

licensees program including possession of RSRM subject to enhanced security requirements. Inspection activities described below include: focus areas, performance-based approach, necessary review and retention of copies of a licensee's records, communication of findings during an inspection, awareness of a licensee's safety culture, and common elements to every inspection.

The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus areas:

- Security and control of licensed material.
- Shielding of licensed material.
- Comprehensive safety measures.
- Radiation dosimetry program.
- Radiation instrumentation and surveys.
- Radiation safety training and practices.
- Management oversight.
- Licensed activities performed by contracted personnel.

These focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material.

If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus area, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes. The inspector should use a performance-based approach to evaluate the focus areas. A determination regarding safety and compliance with the NYC

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requirements should be based on direct observation of work activities, interviews with licensee workers and contracted personnel performing licensed activities, demonstrations by appropriate workers performing tasks regulated by NYC, independent measurements of radiological conditions at the licensee's facility, and where appropriate, a review of selected records. Direct examination of these licensed activities and discussions with cognizant workers should provide an inspector with reasonable assurance of a licensee's ability to safely use byproduct material and is preferable to a review of selected records alone.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, high radiation exposures, or allegations.

The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Observations of licensee operations, interviews with staff, review of licensee documents to complement and support inspector observations, and obtain independent and confirmatory measurements should then be conducted. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, review of licensed work done by contracted personnel, overall management of the licensed program, and integration of safety.

The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation that could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. For example, an inspector should not insist on interviews when:

- A worker is delayed in performing scheduled work activities.
- A worker is preparing or administering dosages or doses.
- A worker is providing patient care.
- A licensee is dealing with customers or members of the public.

Review of licensee records and other documents should be directed toward verifying that current operations are in compliance with Article 175 as well as any applicable requirements and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary.

In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.

The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensees understanding and agreement that a violation occurred, preferably before leaving the site.

The inspector should keep the ORH management informed of significant safety and security findings (i.e., safety hazards, personnel overexposures, failure or inability to control access, failure or inability to monitor, detect, and respond to unauthorized access, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate guidance under such circumstances.

To have a positive impact on maintaining safety, security, and effectiveness, the inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a questioning attitude and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns) and that the licensee is reviewing work done by contracted personnel in licensed activities. The inspector's conclusions about safety culture may be useful when violations are identified and linked to significant risk (i.e., there are an unacceptable number of occurrences with unacceptable health and safety consequences).

#### 5.3 Common Inspection Elements

5.3.1 Entrance Meeting.

After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observations of licensed activities currently in progress.

The purpose of the entrance briefing is to inform licensee management that an inspection is being conducted and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of the presence of the ORH inspectors on site, and apprize management that an exit meeting will be conducted at the end of the inspection to detail the inspection findings.

This is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

The inspector should ask the licensee representative to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (e.g., excessive personnel exposures, unexpected releases to the environment, quality assurance problems, loss of material). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

When an inspection is likely to involve proprietary information, given the technical area or other considerations of inspection scope, the inspector should discuss with licensee management during the entrance meeting how the information will be handled during the inspection. 5.3.2 Follow up on Previous Items.

Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took the corrective actions as described in its response to the Summons and followed-up on safety concerns and unresolved issues identified during the previous inspection, including allegations.

#### 5.3.3 General Overview.

The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.

#### 5.3.3.1 Organization.

Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management, the Radiation Safety Officer (RSO), and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).

## 5.3.3.2 Scope of Program.

Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc., and anticipated changes in the range of the radiation use program.

#### 5.3.3.3 Observation of Actual Facilities and Licensed Activities.

Ideally, the inspector should observe work in progress that involves regulated activities by ORH. If there is no opportunity, then the inspector should ask the workers to demonstrate and explain selected licensed activities. Note that workers should be asked to perform demonstrations that do not unnecessarily expose themselves to radiation. Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. In addition:

- Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.
- Perform routine inspections, when applicable, during first run operations.
- Make direct observations of radiation safety systems and practices in use.
- The walk-through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.
- Make direct observations of physical security systems and storage locations, if possessing RSRM.
- 5.3.4 Independent and Confirmatory Measurements.

Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.

The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (e.g., the inspector's detection equipment malfunctions during an inspection trip). Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible surfaces.

Examples of measurements that may be performed include area radiation surveys, scans for contamination, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, and other locations.

The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation, to observe survey procedures and the appropriateness of instrumentation for the types of material used. However, the inspector must use ORH's instruments for independent verification of the licensee's measurements. The inspector's instruments must be in current calibration and source checked before travelling for inspection.

#### 5.3.5 Special License Conditions.

If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions.

#### 5.3.6 Exit Meeting.

At the conclusion of the inspection the inspector should conduct an exit meeting with the most senior licensee representative present at the facility. As appropriate, the inspector should complete the relevant section of the inspection form before the exit meeting so that the findings can be properly communicated during the exit meeting. The purpose of the exit meeting is to discuss preliminary inspection results. The inspector should inform the licensee that inspection results, including the characterization of proposed enforcement actions, could change based on ORH management review. [See Section 8.4]

If a senior management representative is unavailable for the exit meeting, the inspector should hold a preliminary exit meeting with appropriate staff onsite. As soon as practical after the inspection, the inspector shall hold an exit meeting directly with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting). This meeting involving the licensee's management and RSO can take place by telephone or conference call.

For initial and routine inspections, the inspector should request the meeting and control the meeting for purposes of the inspection. During the meeting, the inspector shall explain any cited violation of the regulatory requirements and the inspector's understanding of the Page | 18
licensee's corrective action plan for each violation [See the last three paragraphs of Section 5.2 about keeping the licensee informed of apparent violations during the inspection].

To avoid the formal disputed violation process the inspector should confirm the licensee's agreement and mutual understanding of cited violations and associated corrective action plans. If the licensee disagrees with a violation, the inspector should contact his or her supervisor before leaving the site to obtain further instructions. It may be necessary to continue the inspection or modify the cited violation. Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, the inspector should inform the licensee about the next steps in the enforcement process.

The inspector should explain safety/security-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

Prompt corrective actions must be initiated by the licensee for violations of regulatory requirements that affect safe and secure operations of a licensed facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree on the magnitude of the concern regarding public health and safety and/or security of the facility, ORH management should be notified immediately.

Although deficiencies identified in some areas (i.e., workers' knowledge of standards for protection against radiation under the NYC Health Code Article 175.03) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Summons.

At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature. If so, the inspector should ensure proper handling of the information.

For a reactive inspection, the inspector should refer to relevant guidelines (e.g.; NRC IP 87103 available at the NRC website) for specific instructions about the exit meeting. Depending on the complexity of the situation and when it's warranted, the inspector

should keep the ORH management informed of the inspection details and explain the exit meeting strategy with his or her supervisor before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to the ORH management. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the ORH management. The licensee's next opportunity to discuss the findings will be after the ORH management has reviewed these matters.

After returning from inspection, the inspector shall discuss the results of the inspection with his or her supervisor. This discussion should be sufficient to alert management to significant enforcement, safety, security, or regulatory issues. This meeting need not be documented, but it should be held in all cases. To complete the inspection, the inspector shall document the inspection results in accordance with guidance [See Section 8] and other documents, as appropriate. An inspection report will be issued in discussion with the field supervisor.

#### 5.4 Reactive Inspections

Inspections performed to follow up on incidents (e.g., medical event, overexposure, or loss or release of radioactive materials) take precedence over the routine inspection program. ORH management shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. The ORH management shall also determine if the event warrants a recommendation for an enhanced inspection comprising a team of inspectors, rather than a reactive inspection. The reactive inspection will emphasize the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. Generally, issues of compliance will be addressed after all safety issues and program weaknesses are identified and clearly understood.

Inspections resulting from allegations will be documented in accordance with

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internal ORH procedures.

Reactive involving a medical event or incidents will be performed using an appropriate ORH guidance or an NRC equivalent (such as Management Directive 8.10, "NRC Medical Event Assessment Program" or Inspection Procedure (IP) 87103, Inspection of Material Licensees Involved in an Incident or Bankruptcy, which can be downloaded from the NRC web page).

A narrative inspection report will be written for all reactive inspections by the inspector. The narrative report will include a discussion of inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The Field Supervisor shall annotate inspection reports with the Nuclear Material Events Database (NMED) Event No. and/or the ORH event notification (EN) number if the reactive inspection was initiated by a reportable event.

5.5 Initial Inspections.

Initial inspections of a new licensee or an amendment for an existing licensee that has a significant expansion of its program shall be announced and completed within approximately 6 months of the date the new license or amendment was issued. To schedule the initial inspection, the date in the next inspection date field in the Rad DataBase shall be 6 months from the date the new license or amendment was issued.

5.5.1 Initial inspections of all licensees.

Once on site, the inspector should interview licensee staff (management and technical) to determine if licensed material has been possessed or licensed operations have been performed. Methods for determining if licensed activities have been performed include, but are not limited to the following: performing a site tour, performing confirmatory measurements, and/or contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed licensed operations, then the inspector should conduct an inspection in accordance with Section 6 and other applicable guidance.

If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

- Determine the licensee's plans for future possession of licensed material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.
- Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss unique license conditions.
- Request that the licensee notify ORH before the receipt of licensed material or initiation of licensed operations.
- Document the onsite inspection by completing the appropriate inspection form corresponding to the program (refer to Enclosure 3). The program scope description in the form used should include the licensee's plans for future possession of material or plans to perform licensed operations.
- Ensure that the date in the next inspection date field in the Rad DataBase is entered according the cycles indicated in enclosure 1.
- 5.5.2 New licenses exempted from an initial inspection.

There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.

- New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
  - The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);
  - The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
  - The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a Page | 22

diagnostic nuclear medicine license);

- The licensee significantly increases the number of authorized users; or
- The new license authorizes one or more new facilities.

If none of these conditions applies, then the last Inspection date and next inspection date fields in the Rad Database should remain the same as for the previous license.

New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The last inspection date and next inspection date data elements in the Rad DataBase should remain the same as for the licensee's initial license.

5.6 Routine Inspections.

Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority listed in Enclosure 1.

Security inspections for licensees possessing RSRM are to be conducted at the same frequency corresponding to the routine inspection priority listed in Enclosure 1. The security inspection may be conducted at the same time as the routine inspection. If the licensee has possessed material or performed licensed operations since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program- specific inspection procedure. If the licensee has not possessed material or performed licensed operations since the last inspector, the inspector should perform a routine inspection of the facility as defined in the program- specific inspection procedure. If the licensee has not possessed material or performed licensed operations since the last inspection, the inspector should follow the bulleted instructions in Section 5.5((1).

5.7 Pre-licensing Visit.

Generally, Pre-licensing visits shall be conducted for new entities that do not have an existing Agreement State or NRC license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license. Reviewers should use the Prelicensing Checklists to determine if pre-licensing visits are needed. The purpose of the pre- licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow- up, per the guidance in the Pre-licensing Checklist (refer RAD 110 enclosure 3). At a minimum, all storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license.

The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated.

5.8 Health and Safety Considerations.

One of the major purpose of inspection is to ensure radioactive materials are used in a manner that doesn't cause undue risk to the workers of the licensed facilities, the patients and the public at large. As a result, inspectors are required to adhere to the highest safety standards so that they can keep themselves safe in the course of their inspection and set a good example for the licensee they are inspecting. The types of safety measures the inspector should take include but not limited to the following:

- Wear his or her radiation monitoring badge at the appropriate part of the body (usually at the torso) when entering into the premise of a licensed facility
- Have a radiation survey meter or a Personal Radiation Detector (PRD) as appropriate with current calibration appropriate to the radiation field in the licensed facility. The survey instrument should be turned on and background measurement taken before entering a radiation area or premises where radioactive materials are used or stored
- Never ignore alarms triggered during survey and never proceed further into a radiation area unless the cause of the alarm is accounted for and appropriate safety measures are taken
- As far as practicable apply the basic measures to keep doses received to the minimum possible by observing the distance, time and shielding rule when conducting inspections in radiation controlled areas
- Take every precaution to avoid contamination of hands or any part of the body (including their survey instrument) during inspection that involves unsealed radioactive materials. Wear gloves as necessary during the inspection survey and conduct a quick self-scan before leaving the licensee facility

- Prior to setting off to the site, be familiar with the nature and quantity of radiation sources at the licensee facility and establish a basic understanding of the radiation field and the degree of hazard under typical operating conditions
- Keep in mind general health and safety issues including physical, chemical, electrical and other such hazards beyond radiation safety issues

#### 6. INSPECTION INTERVALS

6.1 Scheduling Inspections.

To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled within a window around their inspection due dates. Inspection of licensees in Priority Codes 1, 2, and 3 may vary around their due date by 25 percent. Inspections will not be considered "overdue" until they exceed the scheduling window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

#### 6.2 Combining Inspections.

If a licensee holds several licenses with different Program Codes that are assigned different Priority Codes in Enclosure 1, a single inspection may be scheduled whenever practicable to more effectively use the inspector's travel time. Inspections for determining compliance with security requirements may be conducted at the same time as the health and safety inspections. In determining whether to combine inspections on a continuing basis, consideration should be given to not "over-inspect" a lower-priority license versus the need and desirability to inspect a licensee's total activities for a more complete assessment of its safety and compliance performance. The priority designations of the lower-priority licenses shall not be changed in these cases; the more frequent inspections of lower-priority licenses shall be handled only in the scheduling process.

#### 6.3 Inspections after Escalated Enforcement.

If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on Severity Level III or above violation(s) shall be scheduled and conducted within 6 months of the issuance of the escalated enforcement action (Severity Level III or above). This inspection

should be in accordance with the guidance in Section 7.4 for reducing the inspection interval, after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous violations. The Office may perform this follow-up inspection as a part of a routine inspection. If the final escalated enforcement dispositions the violations with enforcement discretion to not cite and results in no Summons, a special inspection is not required

6.4 Reduction of Inspection Interval.

The inspection interval shall not be extended beyond that specified by the priority system indicated in Enclosure 1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation safety program. Poor compliance history is one indicator of such problems. Lack of management involvement or control over the radiation safety program is another indicator. Specifically, licensees that meet one or more of the following conditions shall be considered for reduction in inspection interval if:

- A Severity Level I, II, or III violation results from the most recent inspection; or
- Issuance of an Order as a result of the most recent inspection; or
- A "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (i.e., a paragraph that requires the licensee to address adequate management control over the licensed program); or
- An event requires a reactive inspection; or
- Repetitive violations occur.

The above list is not exhaustive; the inspection interval can and should be reduced for any other reason deemed pertinent by the Office.

A licensee that meets the above criteria may have its inspection interval reduced by any length. For example, a priority 2 licensee with a Severity Level III or above violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the Severity Level III or above violation may have already been completed within 6 months. [See Section 6.3] The reduction shall be valid only until the next inspection, but the Office shall consider the results of the next inspection when determining whether the reduced interval should be continued, changed, or returned to normal.

The designated inspection priority for these licensees should not be changed in the Rad DataBase. However, the "next inspection date" field in the Rad DataBase should be changed to contain the reduced date for the next inspection. The reduced inspection date should be noted in the Rad DataBase.

To document the reduction in the interval between inspections, a brief note (i.e., in the inspection records) should be written by the inspector describing the condition for reducing the interval and be approved and signed by the Field Supervisor, and placed in the corresponding Folders at the office.

6.5 Other Changes in Inspection Interval.

At the discretion of the Office, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees.

#### 7. SPECIAL INSPECTION ACTIVITIES

7.1 Expired and Terminated Licenses and Decommissioning Activities.

Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by reviewing the licensee's transfer, disposal, and closeout survey data; confirming that an authorized recipient has received the material; and/or by performance of an inspection that may include independent or confirmatory measurements. The inspector should also review records of disposals, and public dose that may be required to be submitted to the ORH on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule. Specific guidance for decommissioning requirements and performing closeout inspections is outlined in the NRC guides NUREG-1757 and IP 83890, respectively, and are available for download form the NRC website.

If during the initial or routine inspections the inspector notices that the licensee moves or is out of business, the inspector should communicate immediately with the ORH management and license reviewers. The inspector should make every effort to contact the licensee to effect the submittal of a formal license termination request. The inspector should ensure that licensee submits proof of the transfer or disposal of radioactive material, closeout surveys and relevant letters of communications to finalize the termination of the license. The inspector provides the necessary documentations to license reviewers along with a memorandum to recommend the license termination.

#### 7.2 Significantly Expanded Programs.

During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspectors and the reviewers should make their supervisors aware of the following changes in a licensee's scope of use.

Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

- The licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of RSRM;
- The license authorizes a physical move of a facility
- The license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;
- The licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;
- The number of authorized users has significantly increased or decreased; and
- The licensee has ceased activities at the entire site or in any building or area as defined in NYC Health Code 175.101(h)

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the Field Supervisor.

A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded or reduced. [See the six points in the preceding paragraph] In that case, the license reviewer, in consultation with management shall ensure that the next inspection date data element in the Rad DataBase is changed and shall include a note in the office files for the inspector.

If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with the Field Supervisor should notify management for categorizing the licensee as a facility requiring enhanced physical security measures. An onsite inspection

must be performed to verify that the applicant has implemented the security requirements or enhanced physical security controls before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.

#### 7.3 Reciprocity Inspections.

NYC Health Code under Article 175.101(m) may permit any person with a specific license from an Agreement State or the US NRC to bring, possess or use radioactive material within the NYC DOHMH jurisdiction. The licensee must submit the request 3 days before engaging in the licensed activity.

- The request for reciprocity arrangement usually comes to NYC DOHMH through the Bureau of Environmental Radiation Protection (BERP) of the NYS Department of Health or directly from the vendor.
- The Field Supervisor in consultation with director determines the requests that warrant reciprocity inspection by ORH.
- The Field supervisor determines enforcement action and other follow-up actions as appropriate for the inspection.
- Completed reciprocity inspections will be documented according to the prescribed formats or as narratives as determined by the field supervisor.

7.4 Team Inspections.

Team inspections are not commonly conducted by ORH but circumstances may occur to convene such inspections under some conditions. Examples where team inspections may be appropriate are:

- Routine inspections of major licensees (i.e., broad-scope academic and broad- scope medical licensees). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.
- Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).
- Routine inspections of major licensees within the year before license

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renewal. Team inspections are appropriate methods to assess licensees' strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, pre-licensing visits are not considered inspections, and team inspections should not take the place of pre-licensing visits.

At the discretion of the Office, inspection plans may be developed for all team inspections. Inspection plans should be considered for team inspections of major, broad-scope academic or medical licensees, or under special circumstances determined by the ORH management.

7.5 Abandonment of Licensed Activities.

Returned, undeliverable mail to licensees should trigger an immediate follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The decision of the office when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

#### 8. DOCUMENTATION OF INSPECTION RESULTS

8.1 What Constitutes an Inspection.

The following guidance is provided to assist in determining when activities constitute an inspection.

An inspection will be considered to have been performed if:

- The inspection involves a licensee that possesses or has possessed licensed material since the last inspection, including material possessed under "storage license" or that is performing or has performed licensed activities since the last inspection; or
- The inspection is an initial inspection that has been performed in accordance with Section 5.5.

If it is possible to inspect records or other items according to license conditions or the relevant regulations from the NYC Health Code, such activities should be inspected and be recorded as an inspection, whether the radiation safety officer (RSO) is present or not, including those licenses that have expired or are being processed for termination.

If the RSO is not onsite, the inspector shall make a telephone call to contact the RSO about the inspection. At the conclusion of the inspection, the inspector shall re-contact the RSO to explain the inspection results. If the inspector is unsuccessful in announcing the inspection to the RSO, the inspector shall make a follow-up telephone call to the RSO as soon as possible after the onsite inspection.

An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector will document the on-site activities by placing a note in the Office files, signed by the inspector that briefly summarizes the attempted inspection. Together, the inspector and his or her supervisor should determine when another attempt will be made to inspect the licensee and the "next inspection date" field in the Rad DataBase should be changed to reflect the new date.

A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

#### 8.2 Allegations.

Allegations will be followed up and the results documented and transmitted in accordance with the general guidance described in the NRC Management Directive 8.8, "Management of Allegations" taking into account variations applicable to local NYC jurisdiction. Allegations may be made by email, telephone, through a third party, 311, in person either in the field to an inspector, or in the Office. The Office takes every allegations and every alleger seriously out of concern for the health and safety of the public. No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, or other documents that will be documented in the office files. The following is further guidance about "chilling" effect.

In conducting interviews or other activities with licensee personnel, inspectors should be sensitive to areas where employees may be reluctant to raise concerns about the licensee's program. Even if the licensee addresses an employee's concern regarding safety issues, there could be underlying factors that could produce a "chilling" effect or reluctance for employees to report such issues. For example, the following questions will help an inspector determine if problems exist in the licensee's safety program:

- Has there been an unexplained change in the number or nature of valid concerns that employees have raised with the licensee or the Office?
- Have there been interactions with ORH staff that suggest that some employees may be hesitant to raise concerns or present information to ORH?
- Are employee concerns addressed by licensee management in a timely manner?
- Is the licensee's corrective action successful in addressing employees' concerns?

If any indication of a "chilling" effect is found, the inspector shall inform ORH management for further review and follow-up.

Upon receipt of an allegation, the Office evaluates the validity and makes a determination of the significance of the health and safety implications. Allegations with potential important health and safety ramifications will be given high priority for investigation. Following a written summary presented to the Office, an inspector with the appropriate experience will be assigned

without delay to investigate the allegations. The Office will address the allegations in any one of the following ways:

- Inspection of the licensed facility on which allegation is made where the inspector conducts a follow up inspection and focuses on the area, records, licensee staff that may have information about the allegations on the events, conditions or failure to act. The inspector may hold an exit meeting with licensee management at the end of the investigation.
- Depending on the nature of the situation, the allegation may be amenable to resolution through technical review in the Office, in which case the investigation of allegation may be tasked to staff with the appropriate experience for review.
- The Office may direct the investigation to be conducted by the licensee and request a written report upon the completion of the investigation. The Office reviews the licensee's report and determines whether the response is adequate or if further investigation is warranted.

Upon the conclusion of each investigation, the findings and resolutions are reviewed by the Field Supervisor and is approved in discussion with the Office management in order to determine the next course of action (including issuing Summons or other actions as may be warranted). The parties that made the allegations will be informed of the findings and the resolution actions by any appropriate means of communications.

The Office maintains the information generated for each allegation from its receipt to its resolution in a manner consistent with record of the keeping requirements of the Department.

8.3 Documenting Inspection Results.

Types of documentation. The inspector shall use the applicable ORH prescribed inspection forms (see Enclosure 3) and a narrative inspection record, as necessary, to document inspection results and violations. An inspector may document non- escalated violations in the prescribed forms.

The inspector must ensure that each violations cited include a brief statement of the circumstances, including the date(s) of the violation or NCA (No Cause for Action) and the facts necessary to demonstrate that a requirement was not met; reference to the regulation or license condition that was violated; and a description of the licensee's corrective actions. The licensee will be issued a report with a cover letter or as in many cases the report could be only in the form of a letter. The letter may be issued with or without a Summons and should not contain any security-related information. If security-related or sensitive information has to be conveyed to the licensee, the inspector will prepare a separate enclosure with the proper markings authorized by the Office.

8.3.1 Narrative Inspection Report.

A narrative inspection report is required for all team inspections and actions involving an enforcement conference and/or escalated enforcement. For cases of escalated enforcement, the narrative report should address only the areas of concern and any violations that were identified. A cover letter with a narrative inspection report, and the applicable enforcement action of ORH, will be sent to the licensee. The cover letter should not contain any security-related or sensitive information. If security-related or sensitive information is conveyed to the licensee, the inspector should prepare a separate enclosure with the proper markings. The narrative report should also contain the information described in the next section.

8.3.2 Required Information to Document Inspections.

All documented inspection results or narrative inspection report must contain the following minimum information:

- The procedure(s) used.
- The focus areas examined.
- The status of follow-up items involving prior enforcement or reported licensee events.
- Sufficient information to support cited violations and closed violations identified during a previous inspection.
- Description of completed and anticipated corrective actions for any identified violations.
- A succinct description of the scope of the licensee's program.

• For security inspection with no violations, the inspector should add a statement in the inspection record that the licensee's implementation of security requirements was reviewed and deemed to be adequate.

The inspector must document findings with enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement (use titles only, names should be avoided, if possible), and when it was violated (including dates, or period of time of non-compliance, if known). If the licensee provides immediate or long term corrective action for the violation, this information should also be included as part of the inspection record.

Any subsequent inspector should be able to refer to the inspection record to prepare for an inspection to easily determine what corrective actions were taken, and why a violation was not cited.

All inspection documentation shall be filed in the licensee's file at the Office. For medical events, the narrative report must follow the guidance issued by the Office or an NRC guidelines (such as in Management Directive 8.10, which can be downloaded from NRC website). Narrative inspection reports may be used to document other types of inspections at the discretion of the ORH management.

Each type of report must be signed following Supervisory review and documented in the office files.

8.4 Methods of Transmitting Inspection Results.

Results of inspections may be reported to the licensee with a letter either with or without Summons.

8.4.1 Verbal.

The inspector will verbally present the inspection findings to the licensee at the conclusion of the exit interview.

8.4.2 Letter to licensee, with or without Summons.

When findings are documented in an Inspection Record or in a narrative inspection report, a letter shall be used to inform the licensee of the results of the inspection.

8.4.3 Marking of Inspection Documentation.

Information relative to the licensee's physical protection measures (security-related information) is sensitive information and needs to

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be protected. The inspector should ensure that the Summons, documentation of findings, Inspection Records, or narrative inspection reports, and any other separate enclosure are appropriately protected in accordance with proper office procedures.

#### 9. INPUT INTO TRACKING SYSTEMS

9.1 Input into the Rad DataBase.

Enclosure 1 provides a listing of license program codes with the associated inspection priorities. License reviewers or Field Supervisor should enter data promptly into the Rad DataBase at the time a new license is issued or an inspection has been performed, including the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are made to the next inspection date (reductions in the inspection intervals), license reviewers or Field Supervisor should enter the data for the revised next inspection date into the Rad Database.

9.2 Input into the Nuclear Material Events Database (NMED).

Nuclear Material Events occurring the within the jurisdiction of NYC DOHMH are reported to ORH according the relevant provisions of the NYC Health Code Article 175.

Events that warrant reporting to the Office may include:

- Stolen, lost or missing licensed radioactive sources
- Loss of control of licensed radioactive material
- Exposures, radiation levels, and concentration of radioactive material exceeding applicable limits
- Leaking sealed radioactive sources
- Medical events including dose to an embryo/fetus or nursing child

The Field Supervisor duly arranges the investigation of these events and ensures that they are reported in the NMED database according to prescribed formats (refer to Reporting Nuclear Material Events SA-300 available at the NRC webpage for download). The target for ensuring that NMED records are complete is 60 days from the date the event is reported unless investigation is still ongoing. Records of medical events should also be maintained in the office files corresponding the licensee's folder.

## **10. LIST OF ENCLOSURES**

# 10.1 Inspection Priority Codes by Program Codes

Program Code	Priority Code	Category Title	Remark
52	3	Limited scope non-human use license for academic, research and development	
74	2	Broadscope non-human use license for academic, research and development	Licensee maybe subjected to enhanced physical security requirements as applicable
75	1	Broadscope license for medical and human use research	Licensee maybe subjected to enhanced physical security requirements as applicable
91	2	Limited scope medical use license – nuclear cardiology/manual brachytherapy	Licensee maybe subjected to enhanced physical security requirements as applicable
	2	Limited scope medical use license – HDR	
92	1	Limited scope medical use license - teletherapy	Obsolete – currently non- existent in NYC
93	1	Limited scope medical use license – gamma stereotactic radiosurgery	

#### 10.2 Selected Inspection Procedures<sup>+</sup>

NRC Inspection Procedure No.	Inspection procedure	Remark/program code
IP 87130	Nuclear medicine programs – written directive not required	91, 75
IP 87131	Nuclear medicine programs – written directive required	91, 75
IP 87132	Brachytherapy programs	91, 75
IP 87133	Medical gamma stereotactic radiosurgery and teletharapy programs	93
IP 87134	Medical broadscope programs	75
IP 83890	Closeout inspection and survey	Applicable to any program code as needed
IP 83822	Radiation protection	Applicable to any program code as needed

+ Inspection team need to refer these manuals and be familiar with the respective document ahead of conducting the inspection scheduled. These procedures are available in the ORH "shared computer hard drive" or can be downloaded from the NRC website.

10.3	ORH	prescribed	inspection	forms for	r the	various	program	areas+

Inspection Form #	Form description/applicable areas	Remark/program code
RAD 5200	Laboratory inspection form – non-human use license for academic and research	52, 74
RAD 135	Nuclear medicine inspection form – human use license	91
		Use RAD 5500 attachment if facility has afterloader or brachytherapy
RAD 5500	AFTERLOADER / MANUAL BRACHYTHERAPY "SUB-FORM"	91, 75
		Accompanies nuclear medicine form (RAD 135) as applicable
RAD 192	Irradiator Inspection "Sub-Form"*	74, 75, 91
		Accompanies these inspections if facility has irradiator(s)
RAD 750	Broadscope human use license inspection from	75
		Use RAD 5500 attachment if facility has afterloader or brachytherapy
RAD 740	Broadscope non-human use license inspection from	74
		RAD 192 to be accompanied if facility has irradiator(s)
RAD 37	Physical security inspection form**	91, 93, 74, 75
		To be used specifically for facilities requiring enhanced physical
		security per 10 CFR 37
RAD 111	Re-inspection field form	All license types
RAD 110	Pre-licensing inspection field form	All license types
RAD 16	Medical events inspection forms	91, 93, 75
RAD 12	Statement for requesting inspection fee	All license types

+ The inspection forms for the respective program areas are available in the ORH "shared computer hard drive"

\* The irradiator sub-form addresses only radiation protection aspects but not security issues

\*\*The physical security inspection form addresses only the physical protection of Category I and II radioactive materials. Physical security information collected with this form has to be protected and maintained in a separate locked filing cabinet \*\*The physical security inspection form addresses only the physical protection of Category I and II radioactive materials. Physical security information collected with this form has to be protected and maintained in a separate locked filing cabinet and maintained in a separate locked filing cabinet.

### 10.4 Category I and Category II Threshold Quantities

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)			
Americium-241	60	1,620	0.6	16.2			
Americium-241/Be	60	1,620	0.6	16.2			
Californium-252	20	540	0.2	5.40			
Cobalt-60	30	810	0.3	8.10			
Curium-244	50	1,350	0.5	13.5			
Cesium-137	100	2,700	1	27.0			
Gadolinium-153	1,000	27,000	10	270			
Iridium-192	80	2,160	0.8	21.6			
Plutonium-238	60	1,620	0.6	16.2			
Plutonium-239/Be	60	1,620	0.6	16.2			
Promethium-147	40,000	1,080,000	400	10,800			
Radium-226	40	1,080	0.4	10.8			
Selenium-75	200	5,400	2	54.0			
Strontium-90	1,000	27,000	10	270			
Thulium-170	20,000	540,000	200	5,400			
Ytterbium-169	300	8,100	3	81.0			
The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are provided for practical usefulness only and rounded after conversion.							

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#### Enclosure 4 – Category I and Category II Threshold Quantities

#### **Calculations Concerning Multiple Sources or Multiple Radionuclides**

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation.

Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

 $R_1$  = total activity for radionuclide 1  $R_2$  = total activity for radionuclide 2  $R_N$  = total activity for radionuclide n  $AR_1$  = activity threshold for radionuclide 1  $AR_2$  = activity threshold for radionuclide 2  $AR_N$  = activity threshold for radionuclide n



#### 11.0 References

- 1. NRC INSPECTION MANUAL, FSME/MSSA, MANUAL CHAPTER 2800, Materials Inspection Program, U.S. Nuclear Regulatory Commission, 2010.
- 2. New York City Health Code, Article 175, Radiation Control.
- 3. NRC Regulations Title 10, Code of Federal Regulations

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-2844-01	Maimonides Medical Center	EF	amendment	Erik Finkelstein	8/1/2022
91-3228-01	Joshua Kerstein, M.D.	EF	amendment	Erik Finkelstein	8/1/2022
91-3579-01	Joshua Kerstein, M.D.	EF	amendment	Erik Finkelstein	8/1/2022
91-3504-01	Joseph Wiesel, MD dba NYU Langone Care	EF	amendment	Erik Finkelstein	8/2/2022
74-3042-01	CUNY-City College	EF	renewal	Erik Finkelstein	8/4/2022
91-3733-01	Aasha Gopal, M.D.	EF	termination	Erik Finkelstein	8/10/2022
91-2651-01	St. John's Episcopal Hospital	EF	renewal	Erik Finkelstein	8/16/2022
91-3081-01	Orlandino Almeida, M.D.	EF	amendment	Erik Finkelstein	8/16/2022
91-3104-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	8/16/2022
91-3364-01	Jiong-Ming Hu, M.D.	EF	renewal	Erik Finkelstein	8/16/2022
91-3617-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	8/16/2022
91-3682-01	Ijaz Ahmad, M.D.	EF	renewal	Erik Finkelstein	8/16/2022
91-3725-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	8/16/2022
91-3767-01	Pramod Sanghi M.D.	EF	new license	Erik Finkelstein	8/16/2022
52-3015-01	NYC Housing Preservation and Developme	EF	amendment	Erik Finkelstein	8/18/2022
75-2909-04	Mount Sinai Hospital	EF	amendment	Erik Finkelstein	8/18/2022
52-2911-01	CUNY- Brooklyn College	EF	amendment	Erik Finkelstein	8/19/2022
91-3490-01	Leslie Botnick, M.D.	EF	termination	Erik Finkelstein	8/19/2022
91-3683-01	Elena Bezoff, M.D.	EF	renewal	Erik Finkelstein	8/19/2022
91-3753-01	Talha Shaikh, M.D.	EF	amendment	Erik Finkelstein	8/25/2022
91-3759-01	Paul Gliedman M.D.	EF	amendment	Erik Finkelstein	8/25/2022
75-2955-01	NYU Langone Hospitals	HT	amendment	Hailu Tedla	8/26/2022
91-3476-01	Vincent Mustaciolo, M.D.	EF	renewal	Erik Finkelstein	8/31/2022
91-3703-01	Marc Adams, M.D.	EF	amendment	Erik Finkelstein	8/31/2022
91-3770-01	Talha Shaikh M.D.	EF	new license	Erik Finkelstein	8/31/2022
91-2842-01	New York-Presbyterian Brooklyn Methodi	EF	amendment	Erik Finkelstein	9/1/2022
91-2842-01	New York-Presbyterian Brooklyn Methodi	EF	amendment	Erik Finkelstein	9/1/2022
91-2897-01	Mount Sinai/Beth Israel Medical Center	EF	amendment	Erik Finkelstein	9/2/2022
91-3768-01	Luis Glodowski M.D.	EF	new license	Erik Finkelstein	9/6/2022
91-2894-01	New York Presbyterian/Queens	EF	amendment	Erik Finkelstein	9/7/2022
52-2967-01	NYS Institute for Basic Research	HT	renewal	Hailu Tedla	9/14/2022
91-3686-01	Sameet Palkhiwala, M.D.	EF	renewal	Erik Finkelstein	9/15/2022
91-3765-01	Marios Gagos, M.D.	EF	new license	Erik Finkelstein	9/20/2022
91-2902-01	NYCHHC - Coney Island Hospital	EF	amendment	Erik Finkelstein	9/22/2022
91-2936-01	New York Eye & Ear Infirmary	EF	amendment	Erik Finkelstein	9/26/2022
74-2960-12	NY Presbyterian Hospital/Weill Med Coll	EF	amendment	Erik Finkelstein	10/3/2022
91-3352-01	Humayun Rashid, M.D.	EF	renewal	Erik Finkelstein	10/4/2022
91-3362-01	Marian David, M.D.	HT	renewal	Hailu Tedla	10/4/2022
91-3684-01	Marc Rybstein, M.D.	EF	renewal	Erik Finkelstein	10/4/2022
91-2649-01	NYCHHC - Woodhull Med Mntl Hlth Ctr	EF	renewal	Erik Finkelstein	10/5/2022
91-2901-01	NYCHHC - Queens Hospital Center	EF	amendment	Erik Finkelstein	10/11/2022
75-2986-01	Long Island Jewish Medical Center	EF	amendment	Erik Finkelstein	10/13/2022
91-2897-01	Mount Sinai/Beth Israel Medical Center	EF	amendment	Erik Finkelstein	10/17/2022
91-3771-01	Brian Galler, DO	HT	new license	Hailu Tedla	10/20/2022
91-2926-01	Lenox Hill Hospital	EF	amendment	Erik Finkelstein	10/28/2022
52-3687-01	New York Proton Center	EF	renewal	Erik Finkelstein	11/2/2022
91-2842-01	New York-Presbyterian Brooklyn Methodi	EF	amendment	Erik Finkelstein	11/2/2022
91-2844-01	Maimonides Medical Center	EF	amendment	Erik Finkelstein	11/2/2022
91-3559-01	Reuven Grossman, M.D.	EF	renewal	Erik Finkelstein	11/2/2022

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-3570-01	Ayman Farid, M.D.	EF	amendment	Erik Finkelstein	11/2/2022
91-3697-01	Pramod Sanghi, M.D.	EF	renewal	Erik Finkelstein	11/2/2022
91-3710-01	Weill Cornell Imaging at New York Presby	EF	amendment	Erik Finkelstein	11/2/2022
91-3758-01	Daniel Amen, M.D.	EF	amendment	Erik Finkelstein	11/2/2022
93-2960-05	New York Presbyterian Hospital	EF	amendment	Erik Finkelstein	11/2/2022
91-3689-01	Steven Shayani, M.D.	EF	renewal	Erik Finkelstein	11/3/2022
91-3159-01	Karolyn Kerr, M.D.	EF	termination	Erik Finkelstein	11/15/2022
91-3769-01	George C Liu M.D.	EF	new license	Erik Finkelstein	11/16/2022
52-3120-02	CUNY-Hunter College	EF	amendment	Erik Finkelstein	11/17/2022
91-3104-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
91-3104-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
91-3617-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
91-3617-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
91-3725-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
91-3725-01	Benjamin Abiri, M.D.	HT	amendment	Hailu Tedla	11/17/2022
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	11/28/2022
91-2898-02	Mount Sinai West	EF	amendment	Erik Finkelstein	11/29/2022
91-3726-01	Mount Sinai St. Lukes	EF	amendment	Erik Finkelstein	11/29/2022
91-2924-01	Brooklyn Hospital Center	EF	amendment	Erik Finkelstein	11/30/2022
91-3427-01	John Melnick, M.D.	EF	amendment	Erik Finkelstein	12/1/2022
91-3680-01	Jac Scheiner, M.D.	EF	amendment	Erik Finkelstein	12/1/2022
91-3698-01	Marc Brown, M.D.	EF	renewal	Erik Finkelstein	12/1/2022
91-3775-01	Ahmed Aslam, M.D.	EF	new license	Erik Finkelstein	12/1/2022
93-2878-05	Columbia Presbyterian Medical Center	EF	renewal	Erik Finkelstein	12/1/2022
91-3192-01	K. Peter Rentrop, M.D.	EF	termination	Erik Finkelstein	12/12/2022
52-3120-02	CUNY-Hunter College	EF	amendment	Erik Finkelstein	12/13/2022
91-3749-01	Karolyn Kerr M.D.	EF	termination	Erik Finkelstein	12/19/2022
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	12/27/2022
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	12/27/2022
91-3206-01	Michael Abiri, M.D.	EF	termination	Erik Finkelstein	12/27/2022
75-2986-01	Long Island Jewish Medical Center	EF	amendment	Erik Finkelstein	12/28/2022
91-3079-01	NYCHHC Jacobi Medical Center	EF	amendment	Erik Finkelstein	12/28/2022
91-3772-01	Joseph Cirrone M.D.	EF	new license	Erik Finkelstein	12/29/2022
91-2897-01	Mount Sinai/Beth Israel Medical Center	EF	amendment	Erik Finkelstein	12/30/2022
74-2878-03	Columbia Presbyterian Medical Center	EF	amendment	Erik Finkelstein	1/3/2023
91-3774-01	Inderpal Chhabra M.D.	EF	new license	Erik Finkelstein	1/3/2023
91-3777-01	Qian Zhao, M.D.	EF	new license	Erik Finkelstein	1/3/2023
91-3021-01	Peter Rentrop, M.D.	EF	termination	Erik Finkelstein	1/11/2023
52-3630-01	CUNY Advanced Science Research Center	EF	amendment	Erik Finkelstein	1/12/2023
75-2968-01	Memorial Sloan-Kettering Cancer Center	EF	amendment	Erik Finkelstein	1/14/2023
91-3470-01	David H. Thierman, M.D.	EF	renewal	Erik Finkelstein	1/26/2023
91-2894-01	New York Presbyterian/Queens	EF	amendment	Erik Finkelstein	1/27/2023
91-3373-01	Rakesh Gupta, M.D.	EF	renewal	Erik Finkelstein	1/31/2023
52-3492-01	Alliance Imaging	EF	renewal	Erik Finkelstein	2/1/2023
91-2941-01	Khalid Hassan, M.D.	EF	renewal	Erik Finkelstein	2/1/2023
91-3077-01	Joseph H. Ma, M.D.	EF	renewal	Erik Finkelstein	2/1/2023
91-3197-01	Weill Medical College of Cornell Universit	EF	renewal	Erik Finkelstein	2/1/2023
91-3199-01	Don B. Bandari, M.D.	EF	renewal	Erik Finkelstein	2/1/2023
91-3484-01	Ijaz Ahmad, M.D.	EF	renewal	Erik Finkelstein	2/1/2023

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-3561-01	Joseph L. Musso, M.D.	EF	renewal	Erik Finkelstein	2/1/2023
93-2960-05	New York Presbyterian Hospital	EF	amendment	Erik Finkelstein	2/1/2023
91-3310-01	Kings County Hospital Center	EF	amendment	Erik Finkelstein	2/2/2023
52-2960-06	Weill Medical College of Cornell Universit	EF	new license	Erik Finkelstein	2/8/2023
52-2968-04	Memorial Sloan-Kettering Cancer Center	EF	termination	Erik Finkelstein	2/8/2023
91-3726-01	Mount Sinai St. Lukes	EF	amendment	Erik Finkelstein	2/8/2023
91-3703-01	Marc Adams, M.D.	EF	renewal	Erik Finkelstein	2/14/2023
91-3710-01	Weill Cornell Imaging at New York Presby	EF	renewal	Erik Finkelstein	2/15/2023
91-3709-01	Manuel Morlote, M.D.	EF	renewal	Erik Finkelstein	2/17/2023
91-3500-01	K. Peter Rentrop, M.D.	EF	amendment	Erik Finkelstein	2/23/2023
91-3776-01	Syed Husain M.D.	EF	new license	Erik Finkelstein	2/24/2023
91-3779-01	Sonal Jani M.D.	EF	new license	Erik Finkelstein	2/24/2023
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	3/1/2023
91-2898-02	Mount Sinai West	EF	amendment	Erik Finkelstein	3/1/2023
91-3428-01	James Bowers, M.D.	EF	amendment	Erik Finkelstein	3/1/2023
91-3477-01	Ira Blaufarb, M.D.	EF	renewal	Erik Finkelstein	3/1/2023
91-3563-01	Timothy Jayasundera, M.D.	EF	renewal	Erik Finkelstein	3/1/2023
91-3634-01	Wissam Hoyek, M.D.	EF	amendment	Erik Finkelstein	3/1/2023
91-3707-01	Back Kim, M.D.	EF	renewal	Erik Finkelstein	3/1/2023
91-3730-01	Syed Arman Husain M.D.	EF	termination	Erik Finkelstein	3/1/2023
93-2878-05	Columbia Presbyterian Medical Center	EF	amendment	Erik Finkelstein	3/1/2023
91-3781-01	Johnathan Khodadadian M.D.	EF	new license	Erik Finkelstein	3/2/2023
91-3211-01	North Central Bronx Hospital	EF	amendment	Erik Finkelstein	3/10/2023
91-3696-01	Ozgen Dogan, M.D.	EF	termination	Erik Finkelstein	3/10/2023
91-3484-01	Ijaz Ahmad, M.D.	EF	amendment	Erik Finkelstein	3/15/2023
52-3114-01	NYC Department of Sanitation Environme	EF	amendment	Erik Finkelstein	3/20/2023
91-2840-01	Staten Island University Hospital	EF	amendment	Erik Finkelstein	3/20/2023
91-3079-01	NYCHHC Jacobi Medical Center	EF	renewal	Erik Finkelstein	3/20/2023
91-3710-01	Weill Cornell Imaging at New York Presby	EF	amendment	Erik Finkelstein	3/20/2023
52-3015-01	NYC Housing Preservation and Developme	EF	termination	Erik Finkelstein	3/22/2023
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	3/22/2023
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	3/22/2023
91-3247-01	Marc Sherman, M.D.	EF	amendment	Erik Finkelstein	3/30/2023
74-2960-12	NY Presbyterian Hospital/Weill Med Coll	EF	renewal	Erik Finkelstein	4/3/2023
74-2968-02	Memorial Sloan-Kettering Cancer Center	EF	amendment	Erik Finkelstein	4/3/2023
91-3559-01	Reuven Grossman, M.D.	EF	amendment	Erik Finkelstein	4/3/2023
91-3718-01	George Fernaine, M.D.	EF	amendment	Erik Finkelstein	4/3/2023
91-3753-01	Talha Shaikh, M.D.	EF	amendment	Erik Finkelstein	4/3/2023
91-3771-01	Brian Galler, DO	EF	amendment	Erik Finkelstein	4/3/2023
91-3708-01	Samir Garyali M.D.	EF	renewal	Erik Finkelstein	4/6/2023
91-3783-01	Omer Aras M.D.	EF	new license	Erik Finkelstein	4/6/2023
52-3214-01	NYPD Counterterrorism Division	EF	amendment	Erik Finkelstein	4/10/2023
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	4/11/2023
91-3347-01	Richmond University Medical Center	EF	amendment	Erik Finkelstein	4/11/2023
91-3381-01	Kent Friedman, M.D.	EF	renewal	Erik Finkelstein	4/18/2023
91-3776-01	Syed Husain M.D.	EF	termination	Erik Finkelstein	4/21/2023
52-3630-01	CUNY Advanced Science Research Center	EF	amendment	Erik Finkelstein	4/25/2023
/5-2878-01	Columbia Presbyterian Medical Center	LF	amendment	Erik Finkelstein	4/25/2023
52-1557-07	CUNY - College Of Staten Island	HT	renewal	Hailu Tedla	4/28/2023

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-2897-01	Mount Sinai/Beth Israel Medical Center	EF	amendment	Erik Finkelstein	4/28/2023
75-2909-04	Mount Sinai Hospital	EF	renewal	Erik Finkelstein	5/1/2023
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	5/1/2023
75-2968-01	Memorial Sloan-Kettering Cancer Center	EF	amendment	Erik Finkelstein	5/1/2023
91-3380-01	Adam Deutsch, M.D.	EF	renewal	Erik Finkelstein	5/1/2023
91-3784-01	Francesco Rotatori, M.D.	EF	new license	Erik Finkelstein	5/1/2023
91-2842-01	New York-Presbyterian Brooklyn Methodi	EF	amendment	Erik Finkelstein	5/2/2023
91-2919-01	Albert Einstein College of Medicine	EF	termination	Erik Finkelstein	5/8/2023
91-3491-01	Timothy Jayasundera, M.D.	EF	renewal	Erik Finkelstein	5/8/2023
91-3782-01	Nai-Lun Chang, M.D.	EF	new license	Erik Finkelstein	5/9/2023
91-3500-01	K. Peter Rentrop, M.D.	EF	termination	Erik Finkelstein	5/12/2023
91-3720-01	Ellen Wang, D.O.	EF	termination	Erik Finkelstein	5/12/2023
91-3786-01	Farzad Haghighi M.D.	EF	new license	Erik Finkelstein	5/12/2023
93-2960-05	New York Presbyterian Hospital	EF	amendment	Erik Finkelstein	5/15/2023
91-1515-02	North Shore University Hospital	EF	amendment	Erik Finkelstein	5/16/2023
91-3202-01	Thomas Chen, M.D.	EF	renewal	Erik Finkelstein	5/18/2023
91-2904-01	Harlem Hospital Center	EF	amendment	Erik Finkelstein	5/25/2023
91-3197-01	Weill Medical College of Cornell Universit	EF	amendment	Erik Finkelstein	5/25/2023
91-3211-01	North Central Bronx Hospital	EF	renewal	Erik Finkelstein	5/26/2023
91-3773-01	Samir Garyali M.D.	EF	new license	Erik Finkelstein	5/26/2023
91-2936-01	New York Eye & Ear Infirmary	EF	amendment	Erik Finkelstein	5/30/2023
91-3079-01	NYCHHC Jacobi Medical Center	EF	amendment	Erik Finkelstein	5/31/2023
75-2909-04	Mount Sinai Hospital	EF	amendment	Erik Finkelstein	6/1/2023
91-2924-01	Brooklyn Hospital Center	EF	renewal	Erik Finkelstein	6/1/2023
91-3442-01	Nan-Ning Chang, M.D.	EF	amendment	Erik Finkelstein	6/1/2023
91-3778-01	Guillaume Bassil M.D.	EF	new license	Erik Finkelstein	6/1/2023
91-3715-01	Daniel Shifteh, M.D.	EF	termination	Erik Finkelstein	6/13/2023
91-2901-01	NYCHHC - Queens Hospital Center	EF	amendment	Erik Finkelstein	6/14/2023
75-2878-01	Columbia Presbyterian Medical Center	EF	amendment	Erik Finkelstein	6/20/2023
91-2894-01	New York Presbyterian/Queens	HT	renewal	Hailu Tedla	6/22/2023
91-3085-01	Alfred Rosenbaum, M.D.	EF	amendment	Erik Finkelstein	6/23/2023
91-3577-01	Ariel Lederman, M.D.	EF	renewal	Erik Finkelstein	6/23/2023
52-3214-01	NYPD Counterterrorism Division	EF	renewal	Erik Finkelstein	6/27/2023
91-3081-01	Orlandino Almeida, M.D.	EF	renewal	Erik Finkelstein	7/3/2023
91-3719-01	Francesco Rotatori, M.D.	EF	termination	Erik Finkelstein	7/6/2023
91-3726-01	Mount Sinai St. Lukes	RW (w EF)	amendment	Roshell Wiggan	7/13/2023
91-2904-01	Harlem Hospital Center	RW (w EF)	amendment	Roshell Wiggan	7/19/2023
91-2840-01	Staten Island University Hospital	EF	amendment	Erik Finkelstein	7/24/2023
91-2842-01	New York-Presbyterian Brooklyn Methodi	EF	amendment	Erik Finkelstein	7/26/2023
91-3215-01	Mikhail Kapchits, M.D.	RW (w EF)	renewal	Roshell Wiggan	7/27/2023
91-2846-01	Wyckoff Heights Medical Center	RW	amendment	Roshell Wiggan	7/31/2023
75-2885-01	Montefiore Medical Center	RW	amendment	Roshell Wiggan	8/1/2023
91-2926-01	Lenox Hill Hospital	EF	amendment	Erik Finkelstein	8/9/2023
52-3114-01	NYC Department of Sanitation Environme	RW	amendment	Roshell Wiggan	8/24/2023
91-3310-01	Kings County Hospital Center	RW	amendment	Roshell Wiggan	8/29/2023
91-3085-01	Alfred Rosenbaum, M.D.	RW	renewal	Roshell Wiggan	9/19/2023
52-3120-02	CUNY-Hunter College	HT	amendment	Hailu Tedla	10/4/2023
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	10/4/2023
75-2909-04	Mount Sinai Hospital	EF	amendment	Erik Finkelstein	10/4/2023

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91-2840-01	Staten Island University Hospital	EF	amendment	Erik Finkelstein	10/4/2023
91-2849-01	St. Barnabas Hospital	EF	renewal	Erik Finkelstein	10/4/2023
91-3760-01	Ossama Samuel, M.D.	EF	amendment	Erik Finkelstein	10/4/2023
91-3785-01	Ananth Adurthy Shankar M.D.	EF	new license	Erik Finkelstein	10/4/2023
52-3630-01	CUNY Advanced Science Research Center	EF	amendment	Erik Finkelstein	10/12/2023
52-3732-01	Cardiac Imaging Inc.	EF	amendment	Erik Finkelstein	11/1/2023
91-2926-01	Lenox Hill Hospital	EF	amendment	Erik Finkelstein	11/1/2023
91-3351-01	Olakunle Akinboboye, M.D.	EF	amendment	Erik Finkelstein	11/1/2023
91-3385-01	Joshua Halpern, M.D.	EF	renewal	Erik Finkelstein	11/1/2023
91-3502-01	Tariq Jamil, M.D.	EF	renewal	Erik Finkelstein	11/1/2023
91-3506-01	New York Presbyterian / Lower Manhatta	EF	renewal	Erik Finkelstein	11/1/2023
91-3698-01	Marc Brown, M.D.	EF	amendment	Erik Finkelstein	11/1/2023
91-3718-01	George Fernaine, M.D.	EF	renewal	Erik Finkelstein	11/1/2023
91-3787-01	Ross Wank M.D.	EF	new license	Erik Finkelstein	11/1/2023
91-3788-01	Jan Eubig, M.D.	EF	new license	Erik Finkelstein	11/1/2023
93-2960-05	New York Presbyterian Hospital	EF	amendment	Erik Finkelstein	11/2/2023
74-2989-02	Rockefeller University	EF	amendment	Erik Finkelstein	11/3/2023
52-2903-01	NYU Tandon School of Engineering	EF	termination	Erik Finkelstein	11/15/2023
74-2955-04	New York University	EF	amendment	Erik Finkelstein	11/15/2023
91-3104-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	11/28/2023
91-3617-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	11/28/2023
91-3725-01	Benjamin Abiri, M.D.	EF	amendment	Erik Finkelstein	11/28/2023
75-2968-01	Memorial Sloan-Kettering Cancer Center	RW	amendment	Roshell Wiggan	11/29/2023
91-2907-01	NYCHHC Elmhurst Hospital	RW	renewal	Roshell Wiggan	11/29/2023
91-3396-01	Michael Avaricio, M.D.	RW	renewal	Roshell Wiggan	11/29/2023
91-3504-01	Joseph Wiesel, MD dba NYU Langone Car	RW	renewal	Roshell Wiggan	11/29/2023
91-3504-01	Joseph Wiesel, MD dba NYU Langone Car	RW	amendment	Roshell Wiggan	11/29/2023
91-3505-01	Joseph Wiesel MD dba NYU Langone Carc	RW	renewal	Roshell Wiggan	11/29/2023
91-3770-01	Talha Shaikh M.D.	RW	amendment	Roshell Wiggan	11/29/2023
91-3790-01	Brian Galler, D.O.	RW	new license	Roshell Wiggan	11/29/2023
91-3559-01	Reuven Grossman, M.D.	HT	amendment	Hailu Tedla	12/1/2023
91-3760-01	Ossama Samuel, M.D.	HT	amendment	Hailu Tedla	12/1/2023
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	12/4/2023
91-2926-01	Lenox Hill Hospital	EF	amendment	Erik Finkelstein	12/4/2023
75-2960-04	NY Presbyterian Hospital	RW	amendment	Roshell Wiggan	12/6/2023
91-3000-01	Samala Swamy, M.D.	RW	termination	Roshell Wiggan	12/6/2023
91-2897-01	Mount Sinai/Beth Israel Medical Center	EF	renewal	Erik Finkelstein	12/12/2023
91-2924-01	Brooklyn Hospital Center	EF	amendment	Erik Finkelstein	12/12/2023
74-2955-02	NYU Medical Center	RW	amendment	Roshell Wiggan	12/18/2023
74-3508-05	Icahn School of Medicine at Mount Sinai	EF	renewal	Erik Finkelstein	1/2/2024
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	1/2/2024
91-2651-01	St. John's Episcopal Hospital	EF	amendment	Erik Finkelstein	1/2/2024
91-3639-01	K. Peter Rentrop, M.D.	EF	termination	Erik Finkelstein	1/2/2024
91-3723-01	Vinod Patel M.D.	RW	renewal	Roshell Wiggan	1/2/2024
91-3792-01	Farzad Haghighi, M.D.	EF	new license	Erik Finkelstein	1/2/2024
91-3793-01	Charles Iraube M.D.	EF	new license	Erik Finkelstein	1/2/2024
91-3722-01	Qian Zhao M.D.	KW	termination	Roshell Wiggan	1/3/2024
91-3783-01	Omer Aras M.D.	EF	amendment	Erik Finkelstein	1/11/2024
91-3714-01	Tony Abraham, D.O.	EF	renewal	Erik Finkelstein	1/17/2024

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-3356-01	Michael Manolios, M.D.	RW	termination	Roshell Wiggan	1/23/2024
74-2955-04	New York University	EF	amendment	Erik Finkelstein	1/24/2024
91-2904-01	Harlem Hospital Center	EF	renewal	Erik Finkelstein	1/24/2024
91-2924-01	Brooklyn Hospital Center	RW	amendment	Roshell Wiggan	1/25/2024
91-3506-01	New York Presbyterian / Lower Manhatta	RW	amendment	Roshell Wiggan	1/25/2024
91-3726-01	Mount Sinai St. Lukes	RW	renewal	Roshell Wiggan	1/25/2024
75-2986-01	Long Island Jewish Medical Center	EF	amendment	Erik Finkelstein	2/1/2024
91-2898-02	Mount Sinai West	EF	renewal	Erik Finkelstein	2/1/2024
91-3228-01	Joshua Kerstein, M.D.	EF	renewal	Erik Finkelstein	2/1/2024
91-3579-01	Joshua Kerstein, M.D.	EF	renewal	Erik Finkelstein	2/1/2024
91-3602-01	Sumir Sahgal, M.D.	EF	renewal	Erik Finkelstein	2/1/2024
91-3725-01	Benjamin Abiri, M.D.	EF	renewal	Erik Finkelstein	2/1/2024
91-3786-01	Farzad Haghighi M.D.	EF	amendment	Erik Finkelstein	2/1/2024
91-3790-01	Brian Galler, D.O.	EF	amendment	Erik Finkelstein	2/1/2024
91-3683-01	Elena Bezoff, M.D.	EF	amendment	Erik Finkelstein	2/2/2024
74-3030-01	Columbia University / Barnard College	RW	amendment	Roshell Wiggan	2/14/2024
91-2894-01	New York Presbyterian/Queens	RW	amendment	Roshell Wiggan	2/14/2024
91-3347-01	Richmond University Medical Center	RW	amendment	Roshell Wiggan	2/14/2024
91-3664-01	Howard Eisenstein, M.D.	EF	renewal	Erik Finkelstein	2/14/2024
91-3710-01	Weill Cornell Imaging at New York Presby	RW	amendment	Roshell Wiggan	2/14/2024
75-2885-01	Montefiore Medical Center	EF	renewal	Erik Finkelstein	2/15/2024
91-3237-01	Harold Klestzick, D.O.	EF	renewal	Erik Finkelstein	2/27/2024
75-2986-01	Long Island Jewish Medical Center	RW	amendment	Roshell Wiggan	2/28/2024
91-2902-01	NYCHHC - Coney Island Hospital	RW	amendment	Roshell Wiggan	2/28/2024
91-3687-02	New York Proton Center	RW	renewal	Roshell Wiggan	2/28/2024
91-3753-01	Talha Shaikh, M.D.	RW	amendment	Roshell Wiggan	2/28/2024
91-3770-01	Talha Shaikh M.D.	RW	amendment	Roshell Wiggan	2/28/2024
91-3772-01	Joseph Cirrone M.D.	RW	amendment	Roshell Wiggan	2/28/2024
52-2968-06	Memorial Sloan-Kettering Cancer Center	EF	renewal	Erik Finkelstein	3/1/2024
91-3493-01	Richard Lucariello, M.D.	EF	renewal	Erik Finkelstein	3/1/2024
91-2923-01	Jamaica Hospital	EF	amendment	Erik Finkelstein	3/7/2024
91-2902-01	NYCHHC - Coney Island Hospital	RW	renewal	Roshell Wiggan	3/14/2024
91-3661-01	Newsha Ghodsi, M.D.	RW	amendment	Roshell Wiggan	3/18/2024
91-1619-02	Mount Sinai Hospital of Queens	EF	amendment	Erik Finkelstein	3/22/2024
91-2901-01	NYCHHC - Queens Hospital Center	RW	amendment	Roshell Wiggan	3/22/2024
91-2840-01	Staten Island University Hospital	RW	amendment	Roshell Wiggan	3/27/2024
91-2904-01	Harlem Hospital Center	RW	amendment	Roshell Wiggan	3/27/2024
91-2923-01	Jamaica Hospital	RW	renewal	Roshell Wiggan	3/2//2024
91-3104-01	Benjamin Abiri, M.D.	RW	renewal	Roshell Wiggan	3/2//2024
91-3617-01	Benjamin Abiri, M.D.	RW	amendment	Roshell Wiggan	3/2//2024
93-2960-05	New York Presbyterian Hospital	RW	amendment	Roshell Wiggan	3/2//2024
91-2841-01	Brookdale Hospital Medical Center		renewal	Erik Finkelstein	4/1/2024
91-2844-01	Iviaimonides Medical Center	KW	amendment	Koshell Wiggan	4/1/2024
91-2926-01	Lenox Hill Hospital		amendment		4/1/2024
91-2950-01	BronxCare Health System	EF FF	renewal	Erik Finkelstein	4/1/2024
91-3/29-01	Congrong Lin, M.D.	th cc	renewal	Erik Finkelstein	4/1/2024
91-3/21-01	Daniel Riegel, M.D.		renewal	Erik Finkelstein	4/2/2024
91-2907-01	NYCHHC EIMNUrst Hospital	KW	amendment	Koshell Wiggan	4/5/2024
91-3609-01	Peter E. Zambito, M.D.	КW	renewal	Koshell Wiggan	4/10/2024

License #	Licensee	Reviewer	Action	PrimaryReviewer	Date Complete
91-3018-01	Kingsbrook Jewish Medical Center	RW	termination	Roshell Wiggan	4/22/2024
91-3793-01	Charles Traube M.D.	EF	amendment	Erik Finkelstein	4/30/2024
75-2960-04	NY Presbyterian Hospital	EF	amendment	Erik Finkelstein	5/2/2024
93-2955-05	NYU Langone Hospitals	RW	amendment	Roshell Wiggan	5/3/2024
52-3662-01	Blue Pearl Veterinary Partners	RW	termination	Roshell Wiggan	5/9/2024
52-3789-01	Hospital for Veterinary Surgery	EF	new license	Erik Finkelstein	5/9/2024
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	5/17/2024
75-2955-01	NYU Langone Hospitals	EF	amendment	Erik Finkelstein	5/17/2024
91-3570-01	Ayman Farid, M.D.	RW	renewal	Roshell Wiggan	5/21/2024
75-2878-01	Columbia Presbyterian Medical Center	EF	amendment	Erik Finkelstein	5/24/2024
91-3794-01	Karthik Gujja M.D.	EF	new license	Erik Finkelstein	5/24/2024
93-2878-05	Columbia Presbyterian Medical Center	EF	amendment	Erik Finkelstein	5/24/2024
91-3037-01	Charles Traube, M.D.	EF	termination	Erik Finkelstein	5/28/2024
75-2885-01	Montefiore Medical Center	EF	amendment	Erik Finkelstein	6/3/2024
75-2968-01	Memorial Sloan-Kettering Cancer Center	RW	amendment	Roshell Wiggan	6/3/2024
75-2986-01	Long Island Jewish Medical Center	RW	amendment	Roshell Wiggan	6/3/2024
91-2945-01	Interfaith Medical Center	RW	amendment	Roshell Wiggan	6/3/2024
91-3231-01	Fredrick J. Feuerbach III, M.D.	RW	renewal	Roshell Wiggan	6/3/2024
91-3085-01	Alfred Rosenbaum, M.D.	RW	termination	Roshell Wiggan	6/5/2024
91-2926-01	Lenox Hill Hospital	RW	amendment	Roshell Wiggan	6/6/2024
91-3385-01	Joshua Halpern, M.D.	RW	termination	Roshell Wiggan	6/6/2024
91-3608-01	Sarath Reddy, M.D.	RW	renewal	Roshell Wiggan	6/11/2024
91-3759-01	Paul Gliedman M.D.	RW	termination	Roshell Wiggan	6/20/2024
91-3796-01	Ahmed Aslam M.D.	HT	new license	Hailu Tedla	6/20/2024
52-3114-01	NYC Department of Sanitation Environme	EF	amendment	Erik Finkelstein	6/21/2024
91-3298-01	Niranjan Mittal, M.D.	RW	termination	Roshell Wiggan	6/24/2024
91-3797-01	John Lee M.D.	RW	new license	Roshell Wiggan	6/24/2024
52-2967-01	NYS Institute for Basic Research	RW	amendment	Roshell Wiggan	7/2/2024
91-3300-01	Eliscer Guzman, M.D.	RW	termination	Roshell Wiggan	7/2/2024
91-3795-01	Jennifer Betourney M.D.	RW	new license	Roshell Wiggan	7/3/2024
91-2896-01	Douglas Decorato, MD	RW	amendment	Roshell Wiggan	7/8/2024
91-3605-01	Marco Gentilucci, M.D.	RW	renewal	Roshell Wiggan	7/8/2024
74-2919-02	Albert Einstein College of Medicine	HT	renewal	Hailu Tedla	7/26/2024
74-2878-03	Columbia Presbyterian Medical Center	RW	amendment	Roshell Wiggan	8/1/2024
91-2894-01	New York Presbyterian/Queens	RW	amendment	Roshell Wiggan	8/1/2024
91-2901-01	NYCHHC - Queens Hospital Center	RW	amendment	Roshell Wiggan	8/1/2024
91-2945-01	Interfaith Medical Center	EF	renewal	Erik Finkelstein	8/1/2024
91-3238-01	Paul Romanello, M.D.	RW	renewal	Roshell Wiggan	8/1/2024
91-3790-01	Brian Galler, D.O.	RW	amendment	Roshell Wiggan	8/1/2024
91-3756-01	Ajay Bhatnagar, M.D.	RW	amendment	Roshell Wiggan	8/2/2024
91-2991-01	New York Community Hospital	RW	renewal	Roshell Wiggan	8/6/2024
91-3683-01	Elena Bezoff, M.D.	RW	termination	Roshell Wiggan	8/7/2024
91-3617-01	Benjamin Abiri, M.D.	RW	renewal	Roshell Wiggan	8/8/2024
91-3250-01	Yi-Ming Yang, M.D.	RW	termination	Roshell Wiggan	8/14/2024
91-3247-01	Marc Sherman, M.D.	RW	renewal	Roshell Wiggan	8/19/2024
52-3408-01	Mark E. Peterson, DVM	EF	renewal	Erik Finkelstein	8/21/2024

# ORH Radioactive Materials Unit – Incident/Event Response Policy

## 1. Introduction

The NYC Health Code requires radioactive materials licensees to report certain events and incidents to the Department of Health. This policy describes the actions and responsibilities at Office of Radiological Health (ORH) after receiving such a report.

## 2. Reportable events

The following table describes the types of reportable events covered in this policy:

Type	Reporting requirement (report from licensee to DOH) <sup>1</sup>	Code reference
Medical event	Notification next calendar day after discovery	• 10 CFR 35.3045
	Written report within 15 days	
Lost, stolen, or	• Telephone notification immediately or within 30 days,	• 10CFR 20.2201
missing material	depending on quantity of radioactive material	
	Written report within 30 days after telephone report	
Incidents (i.e.	• Telephone notification immediately or within 24 hours	• 10CFR 20.2202 -
large releases or	depending on severity	2203
exposures)	Written report within 30 days	
Overexposures	Written report within 30 days	• 10CFR 20.2203
Leaking sealed	Report within 5 days	• 10 CFR 35.3067
source		
Events (fires,	• Telephone report within 4 hours or 24 hours (depending on	<ul> <li>10CFR 30.50</li> </ul>
explosions etc)	nature of event)	
	Written report within 30 days of initial report	
Dose to an	<ul> <li>Notification next calendar day after discovery</li> </ul>	• 10CFR 35.3047
embryo/fetus or	Written report within 15 days after discovery	
nursing child		

<sup>1</sup>Not every occurrence is reportable – the regulation lists specific criteria to determine what is a reportable event or incident.

## 3. ORH responsibilities and actions

Notifications regarding possible radioactive materials incidents, should be directed to the Chief of the Radioactive Materials Unit, or to any staff of the radioactive materials unit. At that point, the staff member receiving the communication is responsible for the following actions:

- Immediately: Obtain preliminary information including:
  - o name, title, and contact information of the person calling (for a telephone notification),
  - o name, address, and license number of facility where incident took place,
  - o basic description of incident,
  - $\circ$  nature of ongoing risk (if any) and involvement of first response agencies (if relevant).
- Within 1 hour: Ensure that the Director of ORH and/or the Chief of Radioactive Materials is notified.

The Chief of Radioactive Materials is responsible for the following:

- Within 1 day: In consultation with the Director of ORH, determine if a reactive inspection is required.
- Within 1 day: Ensure that incident is properly reported to NRC, if warranted. See section 4 below.
- Within 2 days: Enter known information about the event/incident on the events tracking database (Microsoft Access database, currently in the ORH shared drive at <u>\\NASPRGSHARE220\Share\ehs\ehs-ese\Radiat\Incidents\incidents.accdb</u>). This record should be updated when further information or reports about the incident are received.
- If a written report from the licensee is required, keep track to make sure that the report is received by ORH.
- Within 30 days of receiving final report from licensee: Determine if the event warrants any further action from ORH, (such as changes to a license condition or monitoring of corrective action) and if so, ensure the appropriate action is taken.

The Supervisor of Inspectors is responsible for the following actions:

- Within 3 days (may need to be sooner, depending on event severity): If warranted, arrange for an inspection as soon as possible.
  - The reactive inspection should include documentation of corrective actions being taken or planned by the facility, and should include the issuance of a Notice of Violation if it is determined that the event/incident was due to significant violations of the Health Code. (See the ORH Radioactive Materials Inspection Manual for more on reactive inspections.)
- Within 14 days: For Medical Events, ensure that the event is documented in the NMED database.

## 4. NRC reporting requirements

- NRC procedure SA-300 describes the reporting requirements for reports from the agreement state to the NRC. Generally the report to NRC needs to be made within the same time frame as the report from the licensee to the Department of Health (see the reportable event table above).
- The reporting methods and contact information are described in SA-300. See attachment 1 below for a summary of NRC contact information.

## 5. Reference / benchmark documents

- New York City Health Code Article 175
- ORH radioactive materials section Inspection Manual (dated 1/24/2018), especially section 5.4 on reactive inspections.
- NRC revised interim procedure SA-300: Handbook on Nuclear Material Event Reporting for the Agreement States (issued 11/28/2022)

(Contact information copied from NRC procedure SA-300, table B.1)

Report	Contact Information	
	NRC Headquarters Operations Center	
Report to the NRC Headquarters	Email: HOO.HOC@nrc.gov	
the following methods.	Telephone: (301)-816-5100	
	Fax: (301) -816-5151	
	Upload to NMED	
	Email: <u>NMED@inl.gov</u>	
	By mail:	
Submit a written report by using one of the following methods.	Director Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission 11545 Rockville Pike Rockville, MD 20852-2738 Attention: Chief, Medical Safety & Events Assessment Branch, Mail Stop T5B60	

(Sample fax sheet taken from SA-300, table B.4)

FAX TO: NRC OPERATIONS CENTER		
Agreement State Agency:	[State] Dept. of Health, Division of Radiation Protection	
Event Report ID No.:	State ID, YY, No., e.g. TN-06-0001	
License No.:	CL-Z00X-1	
Licensee:	County Inspection Inc.	
Event date and time:	Month XX, YYYY, between 4:00 and 5:00 am	
Event location:	City, State	
Event type:	Stolen Radiography Device	
Notifications:	[State] Dept. of Health has notified local police, and the	
	FBI due to possibility of unlawful criminal activity. Press	
	release has not been issued at this time.	
Event description:	[State] Dept. of Health was notified on [date], by a	
	representative from [licensee], of the theft of a radiography	
	exposure device [camera] from a locked equipment trailer	
	on Thursday morning, April 6, 2006. The locked camera	
	and the keys to the camera were stolen. The radiography	
	camera is identified as XYZ Company, Model 160B, serial	
	No. B-3333, containing [radionuclide] [activity, when	
	<b>known</b> ] 88.3 curies of Iridium-192. The device cables were	
	not stolen. The State has an inspector on site and will	
	continue to keep NRC informed of the status of our	
	Investigation.	
Transport vehicle description:	N/A	
Point of contact:	Minnie C. Gauges, 301-415-0001	
## NYC Radioactive Materials Complaints / Allegations since 6/30/22

- A complaint was forwarded to NYC 311 from a person working for U.S. EPA, who also followed up with our office on 12/28/22. They had received an anonymous tip about "radioactive lead levels" in elementary schools. After contacting the EPA staffer who had forwarded the report, we concluded there was not enough specific information to investigate further. Considered closed.
- Complaint received 1/17/23 via NYC 311 system. An anonymous person referred to "uranium mining" at an address in Brooklyn. We followed up with the New York State radiation control program, and by searching for business in that area and didn't find anything to substantiate the complaint. Considered closed.
- Complaint received 12/3/23 from NYC 311 system. An anonymous caller claimed that radioactive materials were improperly stored at a location that probably referred to NYC license # 91-3753-01. We followed up with an inspection at this location on 12/8/23, and found no evidence of improper storage. The incident is closed.
- Complaint received 1/18/24 from NYC 311 system. A resident expressed concern about radiation from a medical office in their building (NYC license # 91-3662-01). We followed up with an inspection at this site on 1/24/24, visiting the office and taking readings in the building. There was no violation found, and no elevated radiation readings detected, the incident is closed.
- An allegation was forwarded to our office on 3/11/24 from New York State radiation program, regarding New York Presbyterian Hospital (gamma knife, NYC license # 93-2960-05). On 3/12/24 we spoke on the phone to the person making the allegation, who was the spouse of a neurosurgeon listed on that license. They referred to an incident occurring on 11/6/23, which had previously been reported to our office by the hospital as a medical event, and some other issues, generally they felt that management was not appropriately responsive to concerns. The complaint was communicated to our inspector, who was scheduled to conduct a regular cycle inspection at the site (for the broad scope medical license). After completing the inspection on 4/19/24 the inspector stated they had not identified any problems with supervision or safety culture. Considered closed.
- Allegation received by phone call and email on 5/2/24 from an employee at Memorial Sloan Kettering PET production facility (NYC license # 52-2968-06). They said they had reported a problem with equipment, and this had led to various problems with supervisors and other staff. After reviewing and discussing the situation we decided there were no allegations of health code violations and the personnel issues described were outside of our jurisdiction.