



**State of Connecticut Department of Energy and Environmental Protection
Radioactive Materials Program**

RCP-901.2

Inspection Preparations

Prepared By: _____ **Date:** _____

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1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to an inspector preparing for the performance of an inspection.
- 1.1.2 Preparation for conducting initial, routine, special, reactive, and reduced frequency are covered.

2.0 SCOPE

2.1 Applicability

- 2.1.1 This procedure applies to the actions performed by inspectors prior to an inspection including preparation guidance, resources, and definitions.
- 2.1.2 This procedure describes the types of inspections performed including scope and purpose of each type of inspection performed.

3.0 REFERENCES

3.1 References

- 3.1.1 Sections 22a-153-1 to 22a-153-150, inclusive, of the Regulations of Connecticut State Agencies
- 3.1.2 Sections 22a-148 through 22a-165(h) of Chapter 446a – Radiation and Radioactive Materials of the Connecticut General Statutes
- 3.1.3 NRC Inspection Manual, Manual Chapter 2800, “Materials Inspection Program”
- 3.1.4 NUREG-1556 Series
- 3.1.5 NRC Inspection Procedures (IP) 8700 series

4.0 DEFINITIONS & ABBREVIATIONS

- 4.1 NMED-Nuclear Materials Events Database
- 4.2 NSTS-National Source Tracking System

- 4.3 NRC – Nuclear Regulatory Commission
- 4.4 RCPD-Radiation Control Program Director
- 4.5 RSRM-Risk Significant Radioactive Material
- 4.6 SRCP-Supervising Radiation Control Physicist
- 4.7 WBL-Web-Based Licensing

5.0 GENERAL

5.1 EQUIPMENT

- 5.1.1 Computer for access to WBL

5.2 PRECAUTIONS AND LIMITATIONS

5.3 RESPONSIBILITIES

5.3.1 Inspector

- 5.3.1.1 Provides the Supervising Radiation Control Physicist (SRCP) on a monthly basis, utilizing WBL, a list of inspections due for the next 6 months. These are in accordance with their Priority Code and documented on the *Inspections Due for the Next 6 Months-By Priority Report*.

- 5.3.1.2 Maintains the files for WBL current with letters, forms, and reports.

- 5.3.1.3 Properly prepares for each inspection by following guidance from the proper procedure section in this document.

5.3.2 Supervising Radiation Control Physicist (SRCP)

- 5.3.2.1 As designated by the RCPD, assign inspections to qualified member of the inspection staff. Maintains the *Inspections Due for the Next 6 Months-By Priority Report*.

- 5.3.2.2 Discusses with inspection staff any items from previous inspections and their proposed plan, if required.

5.3.2.3 Approves inspection plans if required, before the inspection begins.

5.3.3 Radiation Control Program Director (RCPD)

5.3.3.1 RCPD or designee assigns inspections to a qualified member of the inspection staff in the absence of the SRCP.

5.3.3.2 RCPD or designee approves travel plans as necessary.

5.4 PREREQUISITES

5.5 RECORDS

5.5.1 Files

5.5.1.1 Records are primarily filed electronically and WBL is the primary residence of these records. An alternative/back-up means of filing must be available on the Connecticut network and may include State of Connecticut Department of Energy and Environmental Protection (Department) network files.

5.5.1.2 The completed inspection reports and any necessary correspondence mailed to and/or received from the licensee are placed in the licensee's electronic and/or paper files.

5.6 ATTACHMENTS

6.0 PROCEDURE

6.1 General Inspection Process

6.1.1 This procedure is designed to provide guidance that is applicable to all types of licensed programs.

6.1.1.1 General inspection preparation should be completed in accordance with this procedure and applicable RCP procedures.

6.1.1.2 It is expected that inspectors understand and use the unique individual guidance documents available for each inspection modality, such as use of an appropriate NRC Licensing Guide (NUREG-1556) Safety Audit, an appropriate Inspection Checklist, or Inspection Procedure (NRC IP 8700 series) for the inspection type.

- 6.1.1.3 Scheduling of Inspections is in accordance with RCP-901.1 *Scheduling of Inspections*.
- 6.1.1.4 Inspection of licensees shall be conducted per RCP-901.3 *Performance-Based Inspections*.
- 6.1.1.5 Checklists for the different inspections by licensee type may be derived from applicable NUREG 1556 series program audit checklist or NRC Inspection Procedure. Inspections may be conducted utilizing these checklists and procedures as guidance.
- 6.1.1.6 RCP-901.5 *Assuring the Technical Quality of Inspections* provides detailed guidance on inspections and their reports.
- 6.1.1.7 Any new Regulatory Issue Summaries or Informational Notices that may be applicable to the licensee since the last inspection.
- 6.1.2 It is not necessary for the inspector to review all the current licensing documents and procedures from the licensee file. However, to adequately prepare, an inspector shall review:
 - 6.1.2.1 The license to determine:
 - 6.1.2.1.1 If any unusual license conditions exist or tie-down commitments exist that would affect the approach to the inspection. i.e., authorization for non-routine maintenance, use of material at temporary job sites.
 - 6.1.2.1.2 If the licensee is authorized for activities at temporary job sites, prepare to make every reasonable attempt to include an unannounced inspection of licensed activities at any temporary job site(s).
 - 6.1.2.2 The licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items, and to determine whether any events have been reported by the licensee during the current inspection cycle. Older issues preceding the last inspection should be reviewed, if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.
 - 6.1.2.3 The Nuclear Materials Events Database (NMED) to determine if

any incidents have occurred since last inspection.

- 6.1.2.4 Any commitments made by the licensee or restrictions imposed by the Department because of an order or other enforcement action issued since last inspection.
- 6.1.2.5 Any information regarding special inspections, i.e., license reviewer's request for an inspection regarding a significant licensing action. For example, an amendment for new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of amendment.
- 6.1.2.6 Any allegation trends and a follow-up of the licensee's evaluations and response to the allegation.
- 6.1.2.7 Any changes to the Regulatory Requirements since the last inspection that affect the licensee's program.
- 6.1.2.8 A copy of the applicable Sealed Source and Device Registration Certificates.
- 6.1.3 For a reactive inspection, the inspector should review specific information as determined by the SRCP on a case-by-case basis.
- 6.1.4 Inspectors should anticipate whether or not they will encounter protected information during the inspection of a licensee and be prepared to provide the minimum handling requirements for confidential information.
- 6.1.5 Anticipate security requirements, guidance, questions and answers, and/or supplemental correspondence (e.g., licensee responses, requests for relief, and final Department determinations).
- 6.1.6 If the licensee is authorized to possess risk significant radioactive material (RSRM). Review the National Source Tracking System (NSTS) inventory online record prior to the inspection.
- 6.1.7 The inspector should identify the location of the licensee, make necessary travel arrangements, and discuss special aspects of the inspection with the SRCP, as necessary.
- 6.1.8 The inspector should prepare questions for interviews and consider the focus areas or focus elements listed in applicable NRC inspection procedure.

- 6.1.9 If necessary, methods for determining if licensed activities have been performed effectively may include contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee.
- 6.1.10 The inspector must be prepared to meet all the entry requirements established by the licensee (i.e., view the licensee's safety video, use of personal protective equipment, or meet any special requirements for entering sterile environments). Staff must also wear their assigned dosimetry and appropriate personal protective equipment (safety shoes, safety glasses, hearing protection, and hard hats). It is a best practice to have PPE available for every inspection, if needed.
- 6.1.11 The inspector should obtain the appropriate inspection reports, select appropriate and calibrated radiation detection equipment, and use the appropriate Inspection Procedure(s) and safety audits from the NUREG 1556 series as guidance for the inspection and obtain any other documentation that may be useful.
- 6.1.12 Radiation detection instruments are assigned to individuals, with additional equipment available at the Windsor laboratory, to ensure appropriate instrumentation for potential surveys as related to the licensed activities being inspected. There are various alpha, beta, and gamma survey instruments, contamination and exposure rate instruments, and radioisotope identification detectors available.

6.2 Initial Inspections

- 6.2.1 The licensee is informed to report the first receipt of licensed material to the CT-DEEP Radiation Division. Initial inspections are conducted within twelve months following receipt of the notice from the licensee that licensed material has been received or one year following issuance of the license whichever occurs first. All initial inspections of a new license, or any existing license which obtained an amendment for Program Code 02240 (medical Therapy-Other Emerging Technology) are to be announced. Preparation for routine inspections should be conducted in accordance with Section 6.1 and other applicable guides.

6.3 Routine Inspections

- 6.3.1 All routine inspections are unannounced unless specific instructions are received from the SRCP that an inspection is to be announced.

- 6.3.2 Preparation for routine inspections should be conducted in accordance with Section 6.1 and other applicable guidelines.
- 6.3.3 Routine inspection frequency is as determined by RCP-901.1 *Scheduling Inspections* and Attachment 6, **Program Codes for each License Type** in RCP-900.1
- 6.3.4 While encouraged for use, an inspection plan is not required.
- 6.4 Reactive Inspections
 - 6.4.1 Reactive inspections focus on limited issues, often related to specific incidents, that are not within the scope of preparation for a routine inspection. If the reactive inspection does not cover the activities normally reviewed during routine inspection, then the scheduling window still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.
 - 6.4.2 The SRCP shall promptly assess the preliminary information received concerning the incident to determine if a reactive inspection is necessary.
 - 6.4.3 The SRCP will notify the inspector of the incident and if an inspection is required.
 - 6.4.4 The inspector will review the appropriate specific information to prepare for a reactive inspection.
 - 6.4.5 The inspector should also prepare for issues of noncompliance, which will generally be addressed after all safety issues and program weaknesses are identified and clearly defined and understood.
 - 6.4.6 Reactive Inspections for Incidents. The emphasis while preparing for reactive inspection in response to incidents is 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.
 - 6.4.7 Reactive Inspections for Medical Events. Preparations for inspections of medical events shall be conducted in accordance with the guidance in RCP- 904.2 *Incident Response*.

6.4.8 Reactive Inspections for Allegations. Preparations for inspections of allegations shall be processed in accordance with RCP-904.1 *Management of Allegations*

6.5 Special Inspections

- 6.5.1 Special inspections (i.e., reciprocity, security, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections may be under the supervision of the SRCP. Preparing for reciprocity inspections should be completed in accordance with this procedure and all applicable RCPs. Narrative reports shall be prepared, if required by the SRCP, for special inspections. Inspection frequencies for special inspections are defined in RCP-901.1 Scheduling Inspections.
- 6.5.2 Reciprocity Inspections. The inspector should prepare for an unannounced inspection of actual field work and review appropriate information to use during inspection.
- 6.5.3 Temporary Job Site and Permanent Field Office Inspections. The inspector should prepare for an unannounced inspection of licensed activities at these location(s). Preparation for temporary job site and permanent field office inspections should be conducted in accordance with Section 6.1 and other applicable guides.
- 6.5.4 Abandoned, Expired, and Terminated License 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 releases for unrestricted use.
- 6.5.4.1 Emphasis should be placed on security and control of radioactive materials while preparing for an inspection at these types of facilities.
- 6.5.4.2 Prepare to review the licensee's transfer, disposal, and closeout survey data; and /or prepare to perform confirmatory surveys.
- 6.5.4.3 Prepare to review records of radioactive material disposals and public dose that may be required to be submitted to the Department.
- 6.5.4.4 Prepare to verify that the licensee is complying with regulations for timely decontamination and decommissioning and meeting

the required schedules for license action.

- 6.5.4.5 If licensed activity is suspected to have been abandoned by the licensee, the SRCP and RCPD will consult with Department leadership and legal counsel for investigation. Indicators of abandoned license activities include returned mail, unreturned phone calls / emails, disconnected telephone lines. If there is a suspicion of abandonment, the site visit for inspection should be prioritized by the inspectors.
- 6.5.5 Team Inspections. Team inspections will be conducted on an as-needed basis.
 - 6.5.5.1 At the SRCP's discretion inspection plans may be developed for all team inspections.
 - 6.5.5.2 Inspection plans should be considered for team inspections of major, broad scope academic, or medical licensees, large manufacturers, or in cases where team members from agencies outside the Department (other than NRC or other Agreement State radiation control agencies) are involved.
- 6.5.6 Reduced Inspections. Reduced inspections may be performed for a variety of reasons as determined by the SRCP or RCPD.
 - 6.5.6.1 The most common reason is due to poor license performance. All other reasons will be addresses with the inspector assigned to the inspection by the RCPD.
 - 6.5.6.2 Poor performance history, or if health and safety are of a concern, the focus should be on the areas of poor performance and only other areas of the RCP if time allows.
 - 6.5.6.3 The inspection should be unannounced unless specific individuals and/or activities need to be reviewed that are not available or performed on a routine basis by the licensee.
 - 6.5.6.4 All other preparation should be conducted in accordance with RCP-901.2 and other applicable guides.
- 6.5.7 Inspections After Escalated Enforcement. If escalated enforcement action has taken place for a licensee, a special inspection that focuses on the implementation of the licensee's corrective action plan in response to

escalated enforcement violations (Moderate, High, or Very High consequence). These inspections shall be scheduled and conducted within 12 months of the issuance of the escalated enforcement action.

6.6 Inspection Preparation Plan

See attachment 1 to this procedure for an inspection plan template. The Inspection Plan may be used for inspection preparation. The following should be reviewed:

- 6.6.1 License: Differences between the license and the application, if any; “tie-down” commitments and information submitted by the license that is not a “tie-down” condition in the license.
- 6.6.2 License File: Determine if the license has been amended since the last inspection. Note differences such as increased scope of operations, changes in principal staff, new/different facilities, new “tie-down” commitments or other special license conditions.
- 6.6.3 Regulatory Requirements: Determine changes to the regulatory requirement since the last inspection that affect the licensee’s program.
- 6.6.4 Results of Last Inspection: Review the result of the last inspection, if any enforcement action was taken, or if clear inspection form with minor noncompliance items was issued, note the items that the licensee committed to correct.
- 6.6.5 Guidance: Use appropriate documents to determine specific requirements that should be reviewed during the inspection. [NOTE: This should include the review of the appropriate Inspection Procedures.]
- 6.6.6 Notices: Review the Department’s and the NRC’s Information Notices and Regulatory Issue Summaries files and the NRC’s Office of Nuclear Materials Safety and Safeguards Letters to determine if there have been any recent issues concerning this type of licensee that should be reviewed during this inspection.
- 6.6.7 Nuclear Materials Events Database (NMED): Review NMED for licensee events.
- 6.6.8 Allegations: If there was an allegation, the next inspection should address the issue.
- 6.6.9 Sealed Source and Device Registration: Should be reviewed.

6.6.10 NRC and State RCP letters: Review the variety of STC, NMSS, RCPD, and other NRC or State RCP letters for issues of relevance to the licensee.

Attachment 1 – Inspection Plan



Inspection Plan Template

Licensee Name:		
License Type:	Date of Last Inspection:	
License Number:		
Previous Inspection Findings and Corrective Actions (if applicable):		
Inspection Planning Element	Reviewed	Comments / Notes
Review of license conditions and licensing actions since last inspection	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Review Regulatory Requirement changes since last inspection	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Review of available inspection modality guidance (i.e. NUREG-1556 and NRC Inspection Procedure)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Review of Department and the NRC Information Notices / Safeguard Notices for this specific type of license	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Review of NMED for reportable incidents for the licensee	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

Review any allegations since the last inspection.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Review Sealed Source Device Registry Certificates for licensee sources	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Review of other recent NRC or State RCP letters of issues of significance specific to the modality	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Other:		