State of Connecticut Department of Energy and Environmental Protection

Radioactive Materials Program

RCP-901.3

Performance-Based Inspections

Prepared By: Daren Strickland **Date:** 09/25/2024

Reviewed By: [signature] **Date:** October 2, 2024

Approved By: [signature] **Date:** 10/2/2024

Revision	Date	Description of Changes

TABLE OF CONTENTS

SECTION	TITLE	PAGE
	TABLE OF CONTENTS	
1.0	PURPOSE……	4
	1.1 Applicability……...	
2.0	SCOPE……	4
3.0	REFERENCES……...	4
4.0	DEFINITIONS AND ABBREVIATIONS…….	5
5.0	GENERAL……..	6
	5.1 EQUIPMENT	
	5.2 PRECAUTIONS AND LIMITATIONS	
	5.3 RESPONSIBILITIES	
	5.3.1 Inspector	
	5.3.2 Supervising Radiation Control Physicist (SRCP)	
	5.3.3 Radiation Control Program Director (RCPD)	
	5.4 PREREQUISITES	
	5.5 RECORDS	
	5.6 FILES	
6.0	PROCEDURE…….	8

ATTACHMENTS

Attachment 1 NRC Safety Culture Policy Statement…… 32

1.0 PURPOSE

1.1 Applicability

1.1.1 Inspections conducted by the Radioactive Materials Program (RMP) are to be performance-based, meaning the inspector evaluates the licensee performing activities for which they are licensed.

1.1.2 The procedure describes how the Inspector is to conduct performance-based inspections. The NRC Inspection Procedures and Inspection Manual 2800 are to be used along with guidance found in:

RCP-901.1 *Scheduling Inspections*
RCP-901.2 *Inspection Preparation*
RCP-901.4 *Documentation of Inspection Results*
RCP-901.5 *Assuring the Technical Quality of Inspections*
RCP-901.6 *Tracking Inspections*

1.1.3 A review of the licensee's program documentation or a walk-down (tour) of a facility is **not** a performance-based inspection.

1.1.4 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.

1.1.5 This procedure helps the inspector identify and prioritize those activities that impact on a licensee's performance.

2.0 SCOPE

2.1 Applicability

2.1.1 This procedure applies to the performance of radioactive materials inspections by qualified inspectors.

2.1.2 This procedure provides guidance on resources for conducting routine and non-routine inspections.

3.0 REFERENCES

3.1 Sections 22a-153-1 to 22a-153-150, inclusive, of the Regulations of Connecticut State Agencies

3.2 Sections 22a-148 through 22a-165(h) of Chapter 446a – Radiation and

Radioactive Materials of the Connecticut General Statutes

3.3 Sections 1-200 through 259, inclusive of the Freedom of Information Act of the Connecticut General Statutes

3.4 Sections 1-21j-1 through 57, inclusive of the Freedom of Information Commission Regulations of Connecticut State Agencies

3.5 NUREG-1556 Volume 19, Revision 1, "Guidance for Agreement State Licensees About NRC Form 241 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement States Jurisdiction (Reciprocity)."

3.6 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."

3.7 NRC Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."

3.8 NRC Inspection Procedure 8700 series

3.9 NRC Inspection Manual Chapter, 2800, "Materials Inspection Program."

3.10 NRC Management Directive 8.10, "NRC Assessment Program for Medical Event or an Incident Occurring at a Medical Facility."

4.0 DEFINITIONS & ABBREVIATIONS

4.1 DOT-Department of Transportation

4.2 NMED-Nuclear Materials Events Database

4.3 NOV-Notice of Violation

4.4 NOW – Notice of Warning

4.5 NSTS-National Source Tracking System

4.6 NRC – Nuclear Regulatory Commission

4.7 PII-Personally Identifiable Information

4.8 RCPD-Radiation Control Program Director

4.9 RSC- Radiation Safety Committee

4.10 RSO-Radiation Safety Officer

4.11 RSRM-Risk Significant Radioactive Material - a Category 1 or Category 2 quantity of radioactive material as defined in Appendix A to 10 CFR Part 37

4.12 SRCP-Supervising Radiation Control Physicist

4.13 WBL-Web-Based Licensing

5.0 GENERAL

5.1 EQUIPMENT

5.2 PRECAUTIONS AND LIMITATIONS

5.3 RESPONSIBILITIES

5.3.1 Inspector

5.3.1.1 For each initial, routine, and non-core (limited scope) inspection:

5.3.1.1.1 Reviews as appropriate, application, license, and inspection reports and Departmental, NRC Information Notices.

5.3.1.1.2 Determines instruments needed to conduct independent measurements.

5.3.1.1.3 Conducts performance-based inspections by observing licensed activities in progress.

5.3.1.1.4 Reviews the inspection findings with the SCRP and/ or the RCPD, as necessary.

5.3.1.2 For each reactive, reduced, or special inspection:

5.3.1.2.1 Reviews relevant information based upon the required scope of the inspection.

5.3.1.2.2 Conducts an inspection with a focus on the required

scope by observing licensed activities in progress.

5.3.1.2.3 Reviews the inspection findings with the SRCP and/or RCPD, as necessary.

5.3.1.2.4 Informs the licensee of pending initial inspections and reactive inspections, if necessary.

5.3.2 Supervising Radiation Control Physicist (SRCP)

5.3.2.1 Within two weeks of submission, reviews the inspection findings with the assigned inspector(s), as necessary. Confer with the RCPD for review, if needed.

5.3.2.2 Determines if a reactive or special inspection is warranted if it should be performed promptly, or if can be included in the next routine inspection. Assigns an inspector or team of inspectors to perform the inspection.

5.3.2.3 Provides inspection statistics to the RCPD periodically. These may be generated using WBL.

5.3.3 Radiation Control Program Director (RCPD)

5.3.3.1 RCPD or designee performs an annual accompaniment inspection with each RMP Inspector and documents results. See Appendix B in SA-102 for template.

5.3.3.2 May perform duties of Inspector or SRCP in their absence.

5.4 PREREQUISITES

5.5 RECORDS

5.5.1 Letter with NOV or Department Letter or clear inspection form.

5.5.2 Inspection Report maintained in file with WBL.

5.5.3 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 Department network files.

5.6 FILES

5.7 ATTACHMENTS

5.7.1 Attachment 1 – NRC Safety Culture Policy Statement

6.0 PROCEDURE

6.1 General

6.1.1 An inspection will be considered to have been performed if:

6.1.1.1 The inspection involves a licensee that possessed licensed material since the last inspection, or that is performing or has performed licensed activities since the last inspection; or

6.1.1.2 The inspection is an initial inspection that has been performed in accordance with this procedure; or

6.1.1.3 Inspections of temporary job site where activities were not available to the inspector at the time of the inspection should be recorded as an inspection of the main office and the inspection documentation should make note of this or

6.1.1.4 An inspection for licenses that have expired or are being processed for termination.

6.1.2 The inspection will be considered performed by the inspector when:

6.1.2.1 The inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a risk-module or focus element or the licensee did not meet the performance expectation for a given risk-module or focus element; and

6.1.2.2 The inspector has communicated the results of the inspection to the licensee in accordance with RCP-901.4, Section 6.1.1 “Methods of Documenting Inspection Results”.

6.1.3 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, as a result, the inspector is unable to perform inspection activities. The inspector should determine when another attempt will be made to inspect the licensee, document attempted inspection in accordance with RCP-901.4 *Documentation of Inspection Results*.

6.1.4 Performing inspections should be completed in accordance with this procedure. The procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection that may be found in other Department or NRC guidance documents. All routine inspections are unannounced unless specific instructions are received from the SRCP or other factors (i.e., initial inspections and mobile unit at different locations) require that an inspection is to be announced.

6.1.5 Risk Modules (RM), Focus Elements (FE), specific guidance, or focus areas from the NRC inspection procedures are selected 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. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the focus elements or focus areas for the specific modality.

6.1.6 If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a RM or FE, the inspection effort expended in reviewing that particular for RM or FE will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given RM or FE, 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 appropriateness of the licensee's procedures, and a review of the selected records maintained by the licensee documenting activities and outcomes.

6.1.7 The inspector should use a performance-based approach to evaluate the RM and FE. A determination regarding safety and compliance with Department requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing task regulated by the Department, independent measurements of radiological conditions at the licensee's facility, and, where appropriate, a review of selected records. Emphasis should be placed on observing licensee performance as it relates to staff training,

equipment operation and adequacy, overall management of the licensed program, and integration of safety and security.

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

6.1.9 The inspector must be prepared to meet all entry requirements established by the licensee (i.e.; view the licensee's safety video(s), use of personal protective equipment, security protocols, or meet any special requirements for entering sterile environments prior to beginning the performance-based inspection.

6.1.10 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 the licensed activities. The inspector shall not under any circumstances knowingly allow unsafe work practice which could lead to an unsafe situation to occur or continue in the inspector's presence in order to provide a basis for enforcement action.

6.1.11 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance 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 be aware whether or not the information reviewed or gathered has been declared proprietary information by the licensee.

6.1.12 Proprietary and/or patient information should not be taken from the licensee unless confidential, security-related, or personally identifiable information has been removed. In the case of a medical incident only the information relevant to the incident should be included. Personally identifiable information such as name, medical record, and social security numbers are examples of Personally Identifiable Information (PII).

6.1.13 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 files more complete. Inspectors shall ensure that the licensee understands that the retained record will become publicly available consistent with the State's Freedom of Information statutes, regulations and determinations and shall give the licensee the opportunity to provide redacted copies or to request withholding the information.

6.1.14 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 the licensee of findings or concerns. The inspector should allow ample time during the inspection for the 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 licensee's understanding that an apparent violation occurred, preferably before leaving the site. The inspector shall also take time to discuss any recommendations.

6.1.15 The inspector shall keep the SRCP informed of significant findings (i.e.; safety hazards, willfulness, and other potential escalated enforcement issues) identified during the course of the inspection this will ensure that the inspector is following appropriate Department guidance under such circumstances.

6.1.16 The inspector should develop a general sense of the licensee's safety culture for licensed activities (See Attachment 1 – NRC Safety Culture Policy).

6.2 Inspection Preparation

Preparation for inspections is defined in RCP-901.2 *Inspection Preparations*, Attachment 1 to RCP 901.2 is an example of an inspection planning checklist.

6.3 Performance-Based Inspections

6.3.1 Entrance Meeting: The inspection begins with a meeting with appropriate licensee personnel. Request to meet with the individual in charge of the facility the day of the inspection. Inform the individual of the intent to perform an inspection and request permission to access the facilities. Document the name of the individual who authorized access. The RSO should have authority to grant access to the facility. If denied access, document the denial, leave the premises, and notify the SRCP. The inspector shall assure that licensee management will be made aware of the inspection.

6.3.1.1 The inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This is often an opportunity for the inspector to identify personnel to be interviewed. Inform the licensee that radiation detection meters will be utilized to perform confirmatory and independent surveys during the inspection.

6.3.1.2 The licensee representative should be asked to identify any recent problems related to the licensed program.

6.3.1.3 When an inspection is likely to involve proprietary information, PII, and patient information, the inspector should discuss how the information will be handled during the inspection.

6.3.1.4 If appropriate, the exit meeting should be scheduled during the entrance meeting.

6.3.1.5 The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary, PII, or patient related. 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 files more complete.

6.3.1.6 In all cases where licensee documents are retained beyond inspection, inspectors should follow requirements of IMC 0620 "Inspection Documents and Records". Inspectors shall ensure that the licensee understands that the retained record will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding the information.

6.3.2 Follow-up on Previous Items: Determine whether the licensee followed up on no-cited or cited violations identified during previous inspection. Determine whether the licensee took corrective actions as described in the licensee's response to the Notice of Violation (NOV) or Notice of Warning (NOW) (refer to RCP-901.5, "Assuring the Technical Quality of Inspections," and RCP-902.1, "Enforcement, Escalated Enforcement and

Administrative Actions" for additional discussion on Notice of Warnings) and followed up on safety concerns and unresolved issues identified during the previous inspection. Inspectors should ensure that corrective actions implemented from previous inspections are being followed to prevent recurrence of the violation by:

6.3.2.1 Review of the original NOV/NOW in the original inspection report and verify the licensee instituted sufficient corrective actions to prevent recurrence and are in accordance with the disposition of the NOV/NOW.

6.3.2.2 Determine whether the violation will be closed during the current inspection and obtain information necessary to close the unresolved item.

6.3.2.3 Document the results of the follow-up inspection activity in an inspection report.

6.3.3 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.

6.3.3.1 Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection.

6.3.3.2 Identify the reporting relationship and management structure between the licensee's executive management, the RSO, and, if applicable, the chairperson and other members of the Radiation Safety Committee (RSC).

6.3.3.3 Interview cognizant personnel to determine the types, quantities, and use of radioactive materials, frequency of use, staff size, etc., and anticipated changes in the radiation program.

6.3.3.4 Determine if the licensee possesses material in accordance with a general license.

6.3.4 The Inspection: The inspector should observe licensee operations, interview staff, and conduct document review to compliment and support observations. Perform radiation surveys to obtain independent and confirmatory measurements.

6.3.4.1 Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, handling of licensed material, overall management of the licensed program, and integration of safety. In performance-based inspections, a problem with licensee performance leads an inspector to identify programs or procedures for evaluation. If there is no opportunity to observe work in progress that involves Department regulated activities, the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites.

6.3.4.2 If an activity results in significant problems, licensee management should be informed as soon as possible. This will allow the licensee sufficient time to begin root cause analysis and possibly determine corrective action prior to the exit meeting.

6.3.4.3 Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. The walk-through may be performed at any time during the inspection. The inspector may need to return to some portion(s) of the facility at a later time to observe specific activities.

6.3.4.4 Conduct inspections of principal activities that are potentially significant contributor(s) to dose, regardless of shift.

6.3.4.5 Perform routine inspections, when applicable, at times of high use of licensed material.

6.3.4.6 Make direct observations of radiation safety systems and practices in use.

6.3.4.7 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of records should occur only if current records are out of compliance and it is necessary to determine the presence of

a prevalent or persistent problem.

6.3.5 Independent and Confirmatory Measurements: Measurements performed by the inspector can be independent or confirmatory. Independent measurements are performed by the inspector without comparison to the licensee's measurements. With confirmatory measurements, inspector conducted measurements are compared to licensee measurements. The inspector should always ensure that the survey meter is appropriate for the type of radiation encountered and that the meter is within the calibration window.

6.3.5.1 The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility.

6.3.5.2 Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e.; inspector's detection equipment malfunctions during the inspection trip).

6.3.5.3 Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.

6.3.5.4 Examples of measurements that may be performed include area radiation surveys, wipe samples, environmental samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.

6.3.5.5 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. However, the inspector must use Department issued radiological equipment for independent verification of the licensee's measurements.

6.3.6 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 special license conditions.

6.3.7 Exit Meeting: The inspection concludes with an exit meeting with licensee management or the licensee's designee. If a senior management representative is unavailable for the exit meeting, the inspector should hold an exit meeting with the appropriate staff onsite. Depending on the results of the inspection, the inspector may hold another exit meeting directly with senior a management representative and the licensee's RSO. This meeting involving the licensee's management and RSO can be held virtually or by telephone.

6.3.7.1 When appropriate, the inspector should prepare (Department Form 591M Safety Inspection Report and Compliance Inspection) before the exit meeting so that the form can be properly executed during the exit meeting. The form may be issued in the field for:

6.3.7.1.1 An inspection that results in no findings

6.3.7.1.2 To document an inspection resulting in a minor violation with a notice of warning (NOW); or

6.3.7.1.3 To document a violation of that is not subject to civil penalty per RCSA 22a-6b, that does not require an amendment to the license to correct and is not willful or repetitive in nature. The violation being documented in this manner must be corrected while the inspector is present or can easily be corrected within 30 days of the date of the inspection. Any corrective actions must be listed on (591M form).

6.3.7.2 When (591M form) is used to document the results of an inspection, 591M form part 3 or narrative inspection report must also be completed. The inspector must ensure that each cited and non-cited violation on the form include: a brief statement of the circumstances, including the date(s) of the violation and the facts necessary to demonstrate that a requirement was not met; reference to a regulation, license condition, or other legally binding requirement that violated; and a description of the licensee's corrective action.

6.3.7.3 The results of an inspection and any unresolved items will be discussed with the licensee. During the meeting, the inspector shall explain the violation of the Department requirements and the inspector's understanding of the licensee's corrective action plan for each item (if corrective actions have been determined). The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations. Additionally, inspector should clearly indicate that all violations discussed are preliminary pending management review and approval.

6.3.7.4 Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of the licensed site or facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated, or the licensee has made a commitment to initiate corrective actions. If the inspector and licensee disagree on the magnitude of the concern regarding safe operation of the facility, the SRCP should be notified immediately.

6.3.7.5 Although observations identified in some areas may not be considered violations (e.g., a worker's knowledge of radiation protection regulations), the inspector should bring such observations to the attention of licensee management at the exit meeting. Observations may also in the cover letter transmitting the inspection report or Notice of Violation (NOV) at the discretion of the SRCP.

6.3.7.6 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, including PII and patient information. If so, the inspector should assure proper handling of the information.

6.3.8 Evaluating Inspection Results: After returning from an inspection, the inspector shall discuss, either through verbal or written manner, the results of the inspection with the SRCP. The inspector should make an accurate determination of the actual condition of the activities inspected. The technical basis or root causes of identified problems must be emphasized,

not just in the symptoms or administrative indications. The reliability of both equipment and workers should be evaluated with respect to safety. Inspection findings should be evaluated for generic health and safety problems. Performance conditions for inspections is discussed in RCP-901.4 *Documentation of Inspection Results*.

6.4 Initial Inspections

6.4.1 Initial inspections of a new licensee shall be announced and completed within 12 months of the date the new license or amendment was issued by the Department; however, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months or license issuance. Scheduling initial inspections are determined in RCP 902.1 Scheduling Inspections. If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

6.4.1.1 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, personnel, and equipment are in place to safely handle licensed material, as described in the license application.

6.4.1.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions and give the licensee an opportunity to ask regulatory questions.

6.4.1.3 Remind the licensee to notify the Department within 30 days after receipt of licensed material or initiation of licensed operations, as required by license condition. Document the contact and enter the record into the WBL. The conversation record should include the licensee's plans possession of material or plans to perform principal activities.

6.4.1.4 Ensure that the due date is set for 18 months from license issuance.

6.4.2 Performing initial inspections.

During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received

or if principal activities have been performed.

Methods for determining if principal activities have been performed include but are not limited to the following: performing a site tour, performing independent measurements, and/or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.

If the licensee has possessed licensed material or performed principal activities, then the inspector should conduct an inspection in accordance with this procedure and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

6.4.2.1 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, personnel, and equipment are in place to safely handle licensed material, as described in the license application.

6.4.2.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions and give the licensee an opportunity to ask regulatory questions.

6.4.2.3 Remind the licensee to notify the Department within 30 days after receipt of licensed material or initiation of licensed operations, as required by license condition.

6.4.2.4 Remind the licensee of the requirement in 10 CFR 30.36(d) to provide written notification to the Department within 60 days if no principal activities under the license have been conducted for a period of 24 months.

6.4.2.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.

6.4.2.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost savings and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by ± 6 months.

6.4.3 Document the onsite inspection by completing a (591M form) for the exit interview or complete other inspection reports as described in RCP-901.4 *Documentation of Inspection Results.* The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.

6.4.4

New licenses excepted 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.

6.4.5 New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and the "next inspection date "for the licensee's previous license still apply to the new license.

6.4.6 New licenses that are issued as a result of change of ownership or transfer of control are not required to receive an initial inspection unless:

6.4.6.1 The organization controlling the licensed activities, changes substantially (i.e.; changes in key personnel, authorities, or resources associated with the radiation safety program);

6.4.6.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;

6.4.6.3 The licensee significantly increases the different uses authorized on the license (i.e.; adds brachytherapy to a diagnostic nuclear medicine license);

6.4.6.4 The licensee significantly increases the number of authorized users; or

6.4.6.5 The new license authorizes one or more new facilities.

6.4.7 If none of these conditions applies, the "last inspection date" and the "next inspection date "for the licensee's previous license still apply to the new license.

6.4.8 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 the "next inspection date "for the licensee's previous license still apply to the new license.

6.5 Routine Inspections

6.5.1 Routine Inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority defined in RCP-901.1 *Scheduling of Inspections*.

6.5.2 If the licensee has possessed licensed material or performed principal activities since the last inspection, the inspector should conduct a routine inspection of the facility as defined in the program-specific inspection procedure using a performance-based inspection as discussed in Section 6.3.

6.5.3 If the licensee has not possessed licensed material or performed principal activities since the last inspection, the inspector should follow instructions in Section 6.4.

6.5.4 Inspectors should plan to conduct routine inspections close to the due date. However, to achieve the goals of cost savings and efficient use of staff time, and travel, routine inspections may be scheduled within a window around their inspection due dates. Inspection of licensees in Priority Codes 1 and 2 may vary around their due date by ± 50 percent. Routine inspections of Priority Codes 3 and 5 licensees may vary around their due dates by ± 1calendar year.

6.5.5 Inspections will not be considered "overdue" until they exceed the scheduling window. In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, inspections may be scheduled before their window if the department receives information that warrants earlier inspection. The basis for scheduling the inspection before the window should be documented in the inspection records and sign by the SRCP and placed in the licensee file and in WBL.

6.6 Reactive Inspections

6.6.1 Reactive inspections focus on limited issues that are not within the scope of a routine inspection. Inspections performed to follow up on incidents (i.e.; medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. The RCPD shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary.

6.6.2 Preparation for these inspections shall be under the directions of the RCPD. Narrative reports shall be prepared, if required, by the RCPD. The inspection frequencies for reactive inspections are defined in RCP 602.1 *Scheduling Inspections*. Performing reactive inspections should be completed in accordance with RCP-904.1 *Management of Allegations* and/or RCP-904.2 *Incident Response*.

6.6.3 The emphasis during the reactive inspection will be on 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.

6.6.4 Issues of compliance will generally be addressed after all safety issues and program weaknesses are identified and understood.

6.6.5 It is particularly important that the inspector keep the RCPD informed of the inspection details and to explain the exit meeting strategy before beginning the meeting. During the exit meeting, the inspector should explain preliminary inspection findings including apparent violations of

regulatory requirements. The inspector should ask the licensee to confirm the licensee's and inspector's understanding of the finding. 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 RCPD. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the RCPD. The licensee's next opportunity to discuss the findings will be after the RCPD has reviewed these matters.

6.6.6 If a narrative inspection report is required, the report will include a discussion of the inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing factors 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 inspector shall annotate inspection reports with the Nuclear Material Events Database (NMED) Event No. if the reactive inspection was initiated by a reportable event.

6.6.6.1 Incidents: Inspections of reportable incidents (e.g., medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. All reactive inspections will be performed using guidance in RCP-904.2 *Incident Response*. Reactive inspections of incidents will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

6.6.6.2 Medical Events: Inspections of medical events shall be conducted in accordance with the guidance in RCP-904.2 *Incident Response*. Reactive inspections involving a medical event will be performed using guidance in Management Directive 8.10, "NRC Medical Event Assessment Program."

6.6.6.3 Allegations: Allegations shall be processed in accordance with RCP-904.1 *Management of Allegations.*

6.7 Special Inspections

6.7.1 Special inspections (i.e., reciprocity, temporary job site, team, etc.) focus

on the limited issues that are not within the scope of a routine inspection. Preparation for these inspections shall be under the direction of the SRCP. Narrative reports shall be prepared, if required by the SRCP, for special inspections. Inspection frequencies for special inspections are defined in RCP 602.1 *Scheduling of Inspections.*

6.7.2 For a licensee authorized to work at a temporary job site, the inspector shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

6.7.2.1 Reciprocity Inspections: Performing reciprocity inspections should be completed in accordance with RCP-901.2 Inspection Preparations, IMC 2800 "Materials Inspection Program" and IMC 1220 "Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore waters," and Inspection of Agreement State Licenses under 10 CFR 150.20.

6.7.2.2 Temporary Job Site Inspections: For a license authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

6.7.2.2.1 During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of the licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).

6.7.2.2.2 The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.

6.7.2.2.3 If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).

6.7.2.2.4 If a temporary job site inspection is not performed, a

brief note will be written in the inspection records, explaining the missed temporary job site inspection. In certain cases, "the next inspection date" data element in WBL may indicate a reduced inspection interval.

6.7.2.3 Permanent Field Offices: If the license does not authorize licensed activities to be performed at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities. If an inspection identifies significant program weaknesses (indicative of poor program management/oversight), the SRCP should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

6.7.2.3.1 If the license authorizes licensed activities to be conducted at 1-5 locations, at least 40% of the locations should be inspected.

6.7.2.3.2 If the license authorizes licensed activities to be conducted at 6-20 locations, at least 30% of the locations should be inspected.

6.7.2.3.3 If the license authorizes licensed activities to be conducted from more than 20 permanent facilities (main office plus 19 field offices), at least 20 % of the locations should be inspected.

6.7.2.3.4 The calculated number of locations to be inspected should be rounded to the nearest whole number greater than zero. Additional locations may be inspected, as needed.

6.7.2.3.5 Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

6.7.2.3.6 If the license does not authorize licensed activities to be

performed at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.

6.7.2.3.7 If an inspection identifies significant program weaknesses (indicative of poor program management/oversight), the SRCP should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

6.7.2.4 Expired and Terminated licenses and Decommissioning Activities: Notification that a license has expired or is being terminated (and an inspection is required in accordance with RCP-900.3, *License Termination/Revocation*), 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.

6.7.2.4.1 Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and close-out survey data; by confirmation that an authorized recipient has received the material, and/or by performing an inspection that may include confirmatory surveys, at the discretion of the RCPD or SCRP.

6.7.2.4.2 The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the Department on termination or retirement of license. Such actions would be conducted as soon as appropriate after notification is received.

6.7.2.4.3 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.

6.7.2.5 Abandonment of Licensed Activities: Returned or undeliverable mail to licensees should trigger a prompt 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, than an inspector should be sent to the licensee's site. The decision as to 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.

6.7.2.6 Inspections After Escalated Enforcement: If escalated enforcement action has taken place for a particular licensee, a special inspection follow-up shall be scheduled and conducted within 6 months of the last inspection or sooner after completion of the escalated enforcement action, to assess the licensee's follow-up actions and compliance with response to the previous Severity Level III or above violations. The Department may perform this follow-up inspection as part of a routine inspection. In determining when to conduct the follow-up inspection, the Department should consider the risk-significance, severity level, and number of violations.

6.7.2.7 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 inspector and the reviewer should make their supervisors aware of the following changes in a licensee's scope of work. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

6.7.2.7.1 The licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of risk significant radioactive material (RSRM);

6.7.2.7.2 The licensee authorizes a physical move of a facility or a new use at a temporary job site;

6.7.2.7.3 The licensee authorizes new (i.e., since the previous inspection) satellite facilities where licensed materials will be used or stored;

6.7.2.7.4 The licensee has recently increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;

6.7.2.7.5 The number of authorized users has significantly increased or decreased; and

6.7.2.7.6 The licensee has ceased activities at the entire site or in any building area as defined in 10 CFR 30.36(d).

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 inspection 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 if activities have ceased. See the six points in the preceding paragraph. If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff should add Program Code 01000. An onsite inspection must be performed to verify that applicant has implemented the security requirements before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.

6.8 Reduced Inspections

6.8.1 The inspection interval shall not be extended beyond that specified by the priority system indicated in RCP-901.1 *Scheduling of Inspections*. The interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system based on poor licensee performance. If there was a reduction in inspection frequency, ensure that the frequencies are reduced as discussed in RCP-901.1 *Scheduling of Inspections*. The inspection should be performed in accordance with this procedure, however, special attention should be focused on the areas of poor performance. Other aspects of the program should only be focused on as time and opportunity allows.

6.8.2 At the discretion of the SRCP, 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 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 burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that focus specifically on higher risk licensee activities. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent a timely inspection from being completed. The basis for altering the scheduling of inspections should be documented in the inspection records and signed by the SRCP and placed in the licensee file in WBL.

6.9 Team Inspections

6.9.1 The Department shall schedule and conduct team inspections of major licensees within Connecticut on an as-needed basis. The decision on whether to conduct a team inspection involving other agencies Outside DEEP shall be made by the SRCP and RCPD.

6.9.2 Examples of situations where team inspections may be appropriate are:

6.9.2.1 Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processor/manufacturers). 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.

6.9.2.2 Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).

6.9.2.3 Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess a licensee's strengths and weaknesses, and to provide feedback to the licensing process. Team inspections should include license reviewers on the team for routine inspections. Note that

pre-licensing visits are not considered inspections and teams should not be implemented for pre-licensing site visits.

6.9.2.4 Inspections of any type (routine or reactive) that include team members from outside the Department, including other state agency or federal agency representatives.

6.10 Coordination with Other Agencies

6.10.1 The Radiation Division does not conduct licensee compliance with requirements of other local, state, or federal agencies, except the U.S. Department of Transportation (DOT). However, an inspector may identify and refer items of concerns within another agency's regulatory authority to those agencies.

6.10.1.1 If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the SRCP should inform the appropriate liaisons within the other agency about the concerns.

6.10.1.2 Except for DOT regulations, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies.

6.10.1.3 Thus, in discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations but are to point out concerns to heighten the licensee awareness and to take prompt corrective action.

6.10.1.4 The inspector should also advise the licensee of the obligation to inform the SRCP who may coordinate the information with the other lead agency.

6.11 Security Inspections

6.11.1 The requirements of 10 CFR Part 37 apply only to licensees in possession of aggregated Category 1 and 2 quantities of radioactive materials, including sealed and unsealed sources.

6.11.2 Affected licensees may include manufacturers, distributors, self-shielded irradiators, open-air beam calibrators, pool-type irradiators, medical facilities with blood irradiators and/or gamma-ray stereotactic radiosurgery (gamma knife), radiopharmacies, industrial radiographers, and licensees transporting Category 1 and 2 quantities of radioactive material.

6.11.3 The focus of this inspection is the security of those licensed under 10 CFR Part 30, subject Part 37 requirements when possessing certain aggregated Category 1 and 2 quantities of radioactive material. (See NRC Inspection Procedure 87137 for additional details.)

6.12 Pre-licensing Site Visits

6.12.1 The purpose of 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 guidance in the NRC Pre-licensing Checklist.

6.12.2 At a minimum, all storage and proposed use locations for unknown entities must be visited.

6.12.3 By the end of the visit, the reviewer should have observed, collected, ad documented sufficient information to provide a basis of confidence that the applicant will use the radioactive material as specified in their license application.

6.12.4 Pre-licensing visits must be completed for unknown entities before the issuance of a license.

Attachment 1
NRC Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production, schedule, and the cost of the effort versus safety). It should be noted that although the term ''security'' is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both

safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

(1) Leadership Safety Values and Actions – Leaders demonstrate a commitment to safety in their decisions and behaviors;
(2) Problem Identification and Resolution – Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
(3) Personal Accountability – All individuals take personal responsibility for safety;
(4) Work Processes – The process of planning and controlling work activities is implemented so that safety is maintained;
(5) Continuous Learning – Opportunities to learn about ways to ensure safety are sought out and implemented;
(6) Environment for Raising Concerns – A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
(7) Effective Safety Communication – Communication maintains a focus on safety;
(8) Respectful Work Environment – Trust and respect permeate the organization; and
(9) Questioning Attitude – Individuals avoid complacency and continuously challenge existing conditions and activities, to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes. It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy