

VIRGINIA RADIOACTIVE MATERIAL PROGRAM EQUIPMENT LIST

Staff Survey Instruments

1. Ludlum 2401-P
2. Ludlum 2241-3 w/stick probe and pancake probe
3. Exploranium Identifier

Field Lab Survey Instruments

1. GM Survey meters with stick probes and pancake probes
2. Alpha Scintillation survey meters and probes
3. micro-R meters
4. radionuclide identifiers with neutron detection capability
5. survey meters with extendable probes to reach rail cars
6. air samplers with tripods and external battery supply

Radiation Laboratory

1. Gamma Analysis- Two detectors- High Purity drifted Germanium (HpGe) detector in a one ton shield for low-level environmental analysis, and Sodium Iodide (NaI) detector in a shield.
2. Alpha/beta counting- low-level counting system with a sample changer for detection of alpha and beta radiation
3. Liquid Scintillation Counting System (LSC) for low-level beta counting

Calibrations

All instrument calibrations are performed by the vendor or a licensed service provider.

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July 1, 2007

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Virginia Department of Health

Radioactive Materials Program



Radioactive Materials Program Procedure Section 2.3

Performance Based Inspection

Prepared By: _____ Date _____

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Approved By: _____ Date _____

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1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to the implementation of performance based inspections.
- 1.1.2 This procedure does not preclude the review of a licensee's program documentation.
- 1.1.3 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.
- 1.1.4 This procedure helps the inspector to identify and prioritize those activities that impact on a licensee's performance.

1.2 References

- 1.2.1 NRC, "Inspecting for Performance -Materials", Student Manual.
- 1.2.2 NRC Inspection Manual, Chapter 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States,' and Inspection of Agreement State Licensees Operating Under 10 CFR Part 150.20".
- 1.2.3 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program".
- 1.2.4 NRC Management Directive 8.10, "NRC Medical Event Assessment Program".
- 1.2.5 12VAC5-481, 'Virginia Radiation Protection Regulations'.
- 1.2.6 Code of Virginia 32.1-227 through 238.

1.3 Computer Based Letters, Forms, and Reports

1.4 Hardcopy Files

- 1.4.1 Current NRC Information Notices
- 1.4.2 Reading File
- 1.4.3 NRC Inspection Manual

1.5 Definitions

- 1.5.1 Acute Performance Conditions means conditions that have an obvious adverse impact on safety and/or reliability.
- 1.5.2 Core Inspection means all initial inspections of priority 1, 2, 3, and 5 licensees and all routine inspections of priority 1, 2, or 3 licensees.

- 1.5.3 Initial Inspection means the first inspection after a license is issued.
- 1.5.4 Inspection means the act of assessing licensee performance to determine if radioactive materials are used safely; and, whether the licensee is in compliance with rules, regulations, statutes, license conditions, and the licensee commitments submitted in support of the application for license and incorporated in the license by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing visits or telephone communications are not inspections.
- 1.5.5 Latent Performance Conditions means conditions that are underlying and usually obscure. If unchanged, these may result in acute conditions at some future time if circumstances change.
- 1.5.6 Non-Core Inspections means routine inspections of priority 5 licensees, other than initial inspections.
- 1.5.7 Performance Based Inspection (PBI) means observation of a licensee's program activities to determine if regulatory and radiation safety objectives are being achieved. This type of inspection can be applied to any functional area of any license. The only variable is the technical nature of the activities of different licensees. The principal measures of successful performance are safety and reliability. A performance-based inspection focuses on the safety and reliability of program activities.
- 1.5.8 Precursor Performance Conditions means conditions that are changing with time and will likely result in acute conditions at some future time. Precursors are similar to latent conditions, but are more definite in their eventual outcome.
- 1.5.9 Reactive Inspection means a special inspection in response to an incident, allegation, or special information obtained by the agency (e.g., medical events). These inspections may focus on one or several issues and need not examine the rest of a licensee's program. A reactive inspection counts as a routine inspection only if the total licensed program is evaluated.
- 1.5.10 Reliability means the capability to perform as designed or intended when needed and for the duration required. A lack of reliability is generally only of concern when safety is adversely affected as a result. It is important for inspectors to recognize that reliability applies to both equipment and workers.
- 1.5.11 Risk means the relationship between consequence and probability. The highest probability coupled with the most severe consequence represents the highest risk.
- 1.5.12 Routine Inspection means a periodic, comprehensive inspection performed at a specified frequency.
- 1.5.13 Safety means relative freedom from harm or hazard to the public, workers, or the environment. Safety is a relative measure of the

hazard associated with a given activity. Inspectors need not be able to quantify levels of safety during an inspection. It is sufficient to identify whether or not an activity, condition, or trend is adverse to safety. Safety must not be dependent on any administrative classification system.

1.5.14 Special Inspection means those inspection activities where special guidance is needed. These activities include: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning; (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary job site or field site inspections; (5) team inspections; (6) inspections of abandoned licenses; and (7) general licensee's program inspections.

1.5.15 Team Inspections means inspections conducted by three or more inspectors or any inspection that includes an inspector from outside of Virginia (other than NRC or Agreement State Program representatives). A team inspection can be a routine inspection of a major licensee or a reactive inspection in response to a particular incident or event. Team inspections don't include those where a supervisor accompanies an inspector in order to evaluate the inspector's performance.

2.0 RESPONSIBILITIES

2.1 Program Assistant

Maintains the hardcopy file with current inspection field notes/reports and the computer-based letters, forms and reports files.

Updates files as necessary.

For initial inspections, report all the following information to the Director, Radioactive Materials Program (DRMP): the licensee, the license number and priority, the date the license was issued, the date the licensee received licensed material, the date licensed activity started, and when known, the date when the initial inspection must be conducted.

For routine inspections of priority 1, 2 or 3 licenses, the specified due dates shall be reported to the DRMP monthly.

2.2 Radiation Safety Specialists

For each assigned initial, routine core and non-core inspection:

- a) Reviews, as appropriate, application, license and inspection files, NRC Information Notices, and VAREGS.
- b) Determines instruments needed to conduct independent measurements.

- c) Conducts a performance-based inspection.
- d) Reviews the inspection findings with the DRMP at the conclusion of the inspection.

For each assigned reactive or special inspection:

- a) Reviews the required scope of the inspection with the DRMP, or designee, and prepares an inspection plan for review and approval.
- b) Conducts an inspection based on the approved inspection plan.
- c) Reviews the inspection findings with the DRMP at the conclusion of the inspection.
- d) Informs the DRMP as to changes/progress in accomplishing assigned inspections.

Inform the licensee of pending:

- a) Initial inspections,
- b) Special inspections with the exception of reciprocity and temporary jobsites, and
- c) Reactive inspections with the exception of allegations as determined by DRMP.

2.2 Director, Radioactive Materials Program Supervisor (DRMP)

Reviews and approves inspection plans.

Reviews the inspection findings with the assigned inspector(s) at the conclusion of the inspection.

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

Reports inspection statistics to the Director, Division of Radiological Health (DDRH) quarterly.

Perform annual accompaniments with each Radiation Safety Specialist and document the results.

3.0 PROCEDURE

3.1 General

Performing inspections should be completed in accordance with this procedure. This 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; For example, use of an appropriate VAREG, use of appropriate VDH Checklist for applicable inspection type, scheduling as

determined in RMPP 2.1 “Scheduling of Inspections”. All routine inspections are unannounced unless specific instructions are received from the DRMP that an inspection is to be announced.

3.1.1 Focus areas 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 following focus areas:

- a) security and control of licensed material;
- b) shielding of licensed material
- c) comprehensive safety measures;
- d) radiation dosimetry program;
- e) radiation instrumentation and surveys;
- f) radiation safety training and practices; and
- g) management oversight.

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.

3.1.2 The inspector should use a performance-based approach to evaluate the focus areas. A determination regarding safety and compliance with VDH requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by VDH, 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.

3.1.3 In reviewing the license 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, or high radiation exposures.

- 3.1.4 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) prior to beginning the performance based inspection.
- 3.1.5 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. The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.
- 3.1.6 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 as proprietary information by the licensee.

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. 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.

- 3.1.7 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 an apparent violation occurred, preferably before leaving the site.
- 3.1.8 The inspector should keep the DRMP informed of significant findings (i.e., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate VDH guidance under such circumstances.

3.1.9 To have a positive impact on maintaining safety 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). The inspector's conclusions about safety culture may only 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).

3.2 Inspection Preparation

Preparation for inspections is defined in RMPP Section 2.2, "Inspection Preparation".

Attachment 2.2-1 is an example of an inspection plan.

3.3 Performance Based Inspections

3.3.1 Entrance Meeting

The inspection begins with a meeting with appropriate licensee personnel. The inspector shall assure that licensee management (signer of the application for license or appropriate senior management) will be made aware of the inspection. 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 inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This is often an opportune time for the inspector to identify personnel to be interviewed. The licensee representative should be asked to identify any recent problems related to the licensed program. When an inspection is likely to involve proprietary information, the inspector should discuss how the information will be handled during the inspection. If appropriate, the exit meeting should be scheduled during the entrance meeting.

3.3.2 Follow-up on Previous Items.

Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took corrective actions as described in the licensee's response to the Notice of Violation (NOV) and followed-up on safety concerns and unresolved issues identified during the previous inspection.

3.3.3 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. 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 RSO, and, if applicable, the Chairperson and other members of the RSC. Interview cognizant personnel to determine the types, quantities, and use of radioactive material, frequency of use, staff size, etc., and anticipated changes in the radiation use program. Determine if the licensee possesses material in accordance with a general license.

3.3.4 The Inspection

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

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. In performance based inspections a problem with licensee performance leads the inspector to identify programs or procedures for evaluation. If there is no opportunity to observe work in progress that involves VDH 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.

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 a corrective action prior to the exit meeting.

3.3.4.1 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 portions of the facility at a later time to observe specific activities.

3.3.4.2 Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.

3.3.4.3 Perform routine inspections, when applicable, during first run operations.

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

3.3.4.5 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 the current records are out of compliance and it is necessary to determine the presence of a prevalent or persistent problem.

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

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 VDH's instruments for independent verification of the licensee's measurements.

3.3.6 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 the special license conditions.

3.3.7 Exit Meeting

The inspection concludes with an exit meeting with licensee management. 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 will usually be held by telephone conference call.

As appropriate, the inspector should prepare VDH Form 591 before the exit meeting so that the form can be properly executed during the exit meeting.

The results of the inspection and any unresolved items will be discussed with the licensee. During the meeting, the inspector shall explain any cited violation of VDH requirements and the inspector's understanding of the licensee's corrective action plan for each violation. The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee 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 safe operation of the facility, the DRMP should be notified immediately.

Although deficiencies identified in some areas (i.e., workers' knowledge of **12VAC5-481 Part IV, "Standards For Protection Against Radiation"**, requirements) 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 NOV.

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 assure proper handling of the information.

3.3.8 Evaluating Inspection Results

After returning from an inspection trip, the inspector shall discuss the results of the inspection(s) with the DRMP. 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 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 should also be evaluated to predict their impact on future operations. This meeting need not be documented. Documentation for inspections is discussed in RMPP 2.4 "Documentation of Inspection Results".

3.4 Initial Inspections

Initial inspections of a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy–Other Emerging Technology) shall be announced and completed within 12 months of the date the new license or amendment was issued by VDH. Scheduling initial inspections are determined in RMPP 2.1 “Scheduling of Inspections”.

3.4.1 Initial inspections of all licensees

Once onsite, 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.

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

3.4.1.1 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.

3.4.1.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions.

3.4.1.3 Request that the licensee notify VDH before receipt of licensed material or initiation of licensed operations.

3.4.1.4 Document the onsite inspection by completing a Form 591.

3.4.1.5 Ensure that the date in the “next inspection date” data element in the RAM database is 12 months from the date of the onsite visit.

3.5 Routine Inspections

Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority as defined in RMPP 2.1 "Scheduling of Inspections". 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 using a performance based inspection as discussed in Section 3.3. If the licensee has not possessed material or performed licensed operations since the last inspection, the inspector should follow the instructions in Section 3.4.1.1 through 3.4.1.4.

3.6 Reactive Inspections

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 DRMP shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary.

Preparation for these inspections shall be under the direct supervision of the DRMP. Narrative reports shall be prepared, if required by the DRMP. The inspection frequencies for reactive are defined in RMPP 2.1 "Scheduling of Inspections". Performing reactive inspections should be completed in accordance with RMPP 3.1 “Management of Allegations”.

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.

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

It is particularly important that the inspector keep the DRMP informed of the inspection details and explain the exit meeting strategy 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 DRMP. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the DRMP. The licensee's next opportunity to discuss the findings will be after the DRMP has reviewed these matters.

If a narrative inspection report is required, the report will include a discussion of 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 inspector shall annotate inspection reports with the Nuclear Materials Event Database (NMED) Event No. if the reactive inspection was initiated by an NMED reportable event.

3.6.1 Incidents

Inspections of reportable incidents (e.g., medical events, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program.

With the exception of medical events, all other reactive inspections will be performed using the guidance in RMPP 3.2 "Incident Response".

3.6.2 Medical Events

Inspections of medical events shall be conducted in accordance with the guidance in RMPP 3.2 "Incident Response".

3.6.3 Allegations

Allegations shall be processed in accordance with RMPP 3.1, "Management of Allegations".

3.7 Special Inspections

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 shall be under the direct supervision of the DRMP. Narrative reports shall be prepared, if required by the DRMP, for special inspections. Inspection frequencies for special inspections are defined in RMPP 2.1 "Scheduling of Inspections".

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).

3.7.1 Reciprocity Inspections

Performing reciprocity inspections should be completed in accordance with RMPP 2.2 “Inspection Preparation.” In order to meet the inspection goals for inspection of reciprocity activities, unannounced inspection of actual field work locations have preference over announced inspections of actual field work.

3.7.2 Temporary Job Site Inspections

For a licensee 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).

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

3.7.2.2 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.

3.7.2.3 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).

3.7.2.4 If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the “next inspection date” data element in the RAM database may indicate a reduced inspection interval.

3.7.3 Permanent Field Offices

If the license does not authorize licensed activities 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 (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the DRMP should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

3.8 Special Inspection Activities

3.8.1 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 review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys.

The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to VDH 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.

3.8.2 Abandonment of Licensed Activities

Returned, 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, then an inspector should be sent to the licensee's site. The DRMP's decision of 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.

3.8.3 Inspections After Escalated Enforcement

If escalated enforcement action has taken place for a particular licensee, a follow-up inspection to focus on the Severity Level I, II or III violation(s) 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 in response to the previous violations. The agency may perform this follow-up inspection as a part of a routine inspection.

3.9 Team Inspections

The agency shall schedule and conduct team inspections of major licensee within Virginia on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside VDH shall be made by the DRMP.

Examples of situations where team inspections may be appropriate are:

- 3.9.1 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.
- 3.9.2 Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).
- 3.9.3 Routine inspections of major licensees within the year before license 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.
- 3.9.4 Inspections of any type (routine or reactive) that include team members from outside VDH, such as members from the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA).

3.10 Reduction of Inspection Frequency

The inspection interval shall not be extended beyond that specified by the priority system indicated in RMPP 2.1 "Scheduling of Inspections". 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. If there was a reduction in inspection frequency, ensure that frequencies are reduced as discussed in RMPP 2.1 "Scheduling of Inspections".

At the discretion of DRMP, 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. 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 specifically focus on higher risk licensee activities.

3.11 Coordination with Other Agencies

VDH does not conduct inspections of licensee compliance with the requirements of other local, state or federal agencies, except the U.S. Department of Transportation (DOT). However, a Radiation Safety Specialist may identify concerns that are within another agency's regulatory authority. If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the DRMP should inform the appropriate liaisons within the other agency about the concerns. Except for DOT regulations, it is important that all Radiation Safety Specialists recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. Thus, in discussing the concerns with the licensee, Radiation Safety Specialists 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 licensee awareness. For example, if a Radiation Safety Specialist identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation. The Radiation Safety Specialist would also advise the licensee of the obligation to inform the DRMP who may coordinate the information with the other lead agency.

4.0 RECORDS

4.1 Hardcopy

- 4.1.1 Letter with Notice of Violation or Clear Inspection Letter or VA 591 form
- 4.1.2 Inspection Field Notes/Inspection Report maintained in File

4.2 Computer Based

- 4.2.1 Computer based field notes located on K:\EPI\RH\RADMAT-NRC\

5.0 ATTACHMENTS TO RMPP SECTION 2.3

None

Virginia Department of Health

Radioactive Materials Program



Radioactive Materials Program Procedure Section 3.1

Management of Allegations

Prepared By: _____ Date _____
Kimberly M. Gilliam, Radiation Safety Specialist

Reviewed By: _____ Date _____
Michael Welling, Director, Radioactive Materials Program

Approved By: _____ Date _____
Leslie Foldesi, Director, Division of Radiological Health

Effective Date: _____

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1.0 PURPOSE

1.1 Applicability

This procedure is to ensure that any allegation made against a licensee is properly addressed and to provide guidance to protect the identity of the alleged. Actions taken in response to an allegation include investigation, documentation and enforcement, as appropriate. If, at any time, the need for criminal investigatory capacity is required, contact the Local Law Enforcement Agency (LLEA) and/or the Virginia State Police and/or the Federal Bureau of Investigation (FBI), as appropriate.

1.2 References

- 1.2.1 NRC Management Directive 8.8, "Management of Allegations"
- 1.2.2 NRC Handbook 8.8, "Management of Allegations"
Handbook 8.8 contains detailed guidelines and procedures for the management and processing of allegations.
- 1.2.3 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program"
- 1.2.4 NRC STP, SA 300, "Reporting Material Events".
- 1.2.5 12VAC5-481 'Virginia Radiation Protection Regulations'

1.3 Computer Based Letters, Forms, and Reports

- 1.3.1 Allegation Management System (AMS)
- 1.3.2 Blank report forms and log

1.4 Hardcopy Files

- 1.4.1 Allegation File (AF)

1.5 Definitions

- 1.5.1 Allegation means a declaration, statement or assertion of impropriety or inadequacy associated with Radioactive Materials Program (RMP) regulated activities, the validity of which has not been established. This term includes all concerns identified by individuals or organizations regarding activities at a licensee's or applicant's facility. Excluded from this definition are inadequacies provided to RMP staff members by licensee's managers acting in their official capacity.

- 1.5.2 Allegation File (AF) means a secure hardcopy file that contains the documentation concerning the allegation
- 1.5.3 Allegation Management System (AMS) means a secure computerized system that contains a summary of significant data pertinent to each allegation.
- 1.5.4 Alleger means an individual or organization that makes an allegation. The alleger may be known or anonymous.
- 1.5.5 Confidentiality means the protection of the alleger's identity. Every effort will be made to protect information that could directly or otherwise identify an individual by name and/or the fact that a confidential source provided such information to the RMP.
- 1.5.6 Confidential Source means an individual who requests and, to the extent possible, is granted confidentiality in accordance with state procedures.
- 1.5.7 Investigation means, for purposes of this procedure, a special activity conducted by the program and used to evaluate and resolve an allegation.
- 1.5.8 Overriding Safety Issue means an immediate threat to public health, safety, or security, warranting immediate action by the licensee or registrant to evaluate and address the issue.
- 1.5.9 Requirement: a legally binding obligation such as a statute, rule, license, or order.
- 1.5.10 Secure Files means files that are locked when not in use and for which access is controlled on a need-to-know basis.
- 1.5.11 Willfulness: a characteristic of a licensee's actions whereby violations result from deliberate intent to falsify documentation pertaining to license requirements, to violate license or registration requirements, or from careless disregard for license or registration requirements.
- 1.5.12 Wrongdoing means either an intentional violation of requirements or a violation resulting from careless disregard of or reckless indifference to requirements.

2.0 RESPONSIBILITIES

2.1 Radioactive Materials Program (RMP) Staff

Any RMP staff member is responsible for recording the initial allegation, any contact information provided and immediately referring the allegation to the Director, Radioactive Materials Program (DRMP). This staff member is also responsible for maintaining confidentiality of the identity of the alleger and all other sensitive information.

2.2 Radiation Safety Specialist

When designated as the Lead Investigator (LI) coordinates the processing of an allegation. Performs the investigation of the allegation and prepares all records and reports concerning the allegation; these records and reports will be used if the allegation is determined to be an event requiring notification to the Nuclear

Regulatory Commission (NRC) and Nuclear Materials Event Database (NMED). The LI is responsible for maintaining confidentiality of the alleged and any other information deemed sensitive.

Upon finding of an incident through an investigation of the allegation, the LI would be responsible to act as the immediate response and take actions to mitigate the incident and notify the DRMP immediately to notify of the incident and request assistance.

2.3 Director, Radioactive Materials Program (DRMP)

Manages the development and implementation of the Allegation Management Program (AMP), manages the Allegation Management System (AMS), and conducts periodic reviews of the program.

Informs the DDRH of all AMS activity.

Recommends appropriate actions to the DDRH in response to allegations.

Instructs RMP staff on requirements of confidentiality and informs RMP staff who received original information and LI of their responsibility to protect the confidentiality of the alleged and notice of all other sensitive information within the allegation requiring confidentiality.

Upon being informed of an incident through an inspection or investigation of the allegation, the DRMP will respond in accordance with RMPP 3.2, "Incident Response".

2.4 Director, Division of Radiological Health (DDRH)

Reviews recommendations made by the DRMP and approves actions to be taken in response to allegations.

Authorizes the release of the identities of alleged or confidential sources.

Requests legal assistance, if required.

Directs the AMS, as appropriate.

3.0 PROCEDURE

3.1 Initial Contact

Note: The alleged's identity, or information that could reveal that identity, should be imparted to section staff on a need-to-know basis and should not be revealed to personnel outside the RMP. All documentation pertaining to the allegation shall be securely stored. Computer files are only accessible to the RMP staff and hard copy files will be returned to secure files when not in use. See attachment 3.1-4.

Note: Allegations regarding suspected improper conduct by a RMP employee do not fall within the scope of this procedure and shall be promptly reported to the employee's immediate supervisor.

- 3.1.1 Obtain and record as much information as possible from alleged on the Initial Contact Phone Log (see Attachment 3.1-1). If the notification is forwarded from the NRC, State, or local agency, use the same form and receive all the information from the agency contact. Note on the form the agency contact's information in case questions arise.
- 3.1.2 If the allegation involves discrimination on the basis of age, sex, race, etc., refer the alleged to the Virginia Council on Human Rights, (804) 225-2292. If the allegation requires criminal investigatory capacity, notify and request assistance from the LLEA and/or the Virginia State Police and/or FBI, as appropriate.
- 3.1.3 If the alleged refuses to provide his/her name or other form of identification, then obtain as much information as possible and advise the alleged that he/she may contact the DRMP in 30 working days for information regarding the response to the allegation.
- 3.1.4 Address the issue of confidentiality with the alleged in accordance with section 3.2.
- 3.1.5 Inform the appropriate program supervisor of the allegation and submit completed Attachment 3.1-3.
- 3.1.6 If the RMP staff member who received the initial contact determines the alleged/allegation is not credible, consult with the DRMP and then terminate the allegation process and log the information into the local AMS. Notify the alleged of the findings of the allegation.

3.2 Disclosure of Alleger's Identity and Sensitive Information.

Note: RMP will make all reasonable efforts to maintain confidentiality of the alleged's identity and any other sensitive information; however, RMP cannot guarantee confidentiality. Disclosure of an alleged's identity may be made in accordance with 3.2.2 and 3.2.3 below.

- 3.2.1 Indicate all information deemed sensitive as confidential. Prior to terminating initial contact (see 3.1) with an alleged, inform the alleged of the degree to which their identity can be protected, including the following:
- The alleged's identity and sensitive information including that which would reveal that identity will be withheld from RMP staff except on a need-to-know basis.
 - All sensitive information including information regarding the alleged's identity will be stored in a secure file under the control of the DRMP.
 - Inspection reports and correspondence to licensees, other Agreement States, Federal Agencies (including NRC), other organizations or individuals will contain no sensitive information or information that could lead to the identification of the alleged or confidential source.
 - The alleged's identity and all sensitive information regarding the alleged's identity will not be disclosed outside of RMP, except under the conditions stipulated in section 3.2.2.
- 3.2.2 Inform the alleged that disclosure of his or her identity or of sensitive information may occur if:
- The alleged has clearly indicated no objection to being identified.
 - Disclosure is necessary because of an overriding safety issue.
 - Disclosure is necessary pursuant to a legal order.
 - Disclosure is necessary to continue a wrongdoing investigation, including an investigation of a discrimination allegation.
 - Disclosure is necessary to support a hearing on an enforcement matter.
 - The alleged has taken actions that are inconsistent with and override the purpose of protecting the alleged's identity.
 - Disclosure is mandated by Commonwealth of Virginia's Open Records law.
- 3.2.3 If the alleged's identity or sensitive information must be disclosed, then obtain approval from DDRH prior to disclosure.

- 3.2.4 If the allegation is received by means other than telephone and the alleged's identity is known, then inform the alleged, by letter within 10 working days of the degree to which his or her identity can be protected as described in 3.2.1 through 3.2.3 (see Attachment 3.1-5).
- 3.2.5 If requested by the alleged, then inform the alleged that a Non-disclosure Statement (Attachment 3.1-2) is available and will be sent within 10 working days.

3.3 Controlling Allegations

Note: Allegations should be addressed according to the guidelines listed below:

- Overriding safety issue – shall be addressed immediately
- High safety significance - should be addressed expeditiously, usually within 30 working days
- Low safety significance - should be addressed as priorities and resources permit, usually within 6 months of receipt.

3.3.1 Action by the DRMP.

- Appoint a LI for the allegation (see subparagraph 3.3.2).
- Ensure an AF is opened for the allegation and entered in the AMS.
- With the assistance of the LI, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine if an overriding safety issue exists.
- If the LI is not to perform an investigation, designate an individual to notify the inspection staff of the allegation and keep updated to the findings.
- If multiple allegations are made, broaden the scope of the evaluation to determine the extent of the problem.
- If an overriding safety issue exists, immediately convene a review group consisting of the DRMP, the DDRH, the LI and a member of the legal staff, as available.
- If no overriding safety issue exists, as soon as possible but within 30 calendar days, convene a review group consisting of the DRMP, the DDRH, and the LI. The DRMP may include a member of the legal staff.
- Ensure findings of the review group are entered into the appropriate AF.

Note: All discussion with the legal representative on the review group concerning suspected wrongdoing shall be documented, stamped confidential and filed separately within the AF.

- As necessary, brief the DDRH on the review group's findings and recommendations.
- Upon finding of an incident by the inspection staff or the LI,

immediately implement RMPP 3.2, 'Incident Response Procedure'.

3.3.2 Evaluation by Lead Investigator

- In consultation with the DRMP, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine if an overriding safety issue exists.
- Determine, in conjunction with the DRMP and review group, the actions necessary for resolution of the allegation including an investigation, enforcement actions (per RMPP 2.5), etc.
- Identify additional resources required for resolution of the allegation.
- Develop a schedule for the resolution of each allegation consistent with the inspection schedule; unless, the priority of the allegation causes immediate action.
- With the approval of the DRMP, implement actions necessary for resolution of the allegation.
- If an inspection is performed and the LI receives notification of the finding of an incident, implement RMPP 3.2, 'Incident Response Procedure' and advise inspection staff of immediate actions taken to mitigate the incident and notify the DRMPP.

Note: Follow-up of allegations should focus not only on the particular allegation but also on the overall area of concern, including the potential for generic implications and wrongdoing.

3.4 Referral of Allegations to Licensees

The decision whether or not to refer an allegation to the licensee will be made upon the recommendation of the LI with the approval of the DRMP, and based on the considerations delineated in 3.4.1 and 3.4.2.

Note: If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee, regardless of the need to protect the identity of the allegor or the sensitive information, if release of the information is necessary to protect public health, safety, or security. The 30-day waiting period (see subsection 3.4.3 following) may be waived if the allegor or confidential source cannot be reached in a timely manner.

3.4.1 Prohibitions on Referrals

Do not refer the allegation to the licensee if any of the following apply:

- The identity of the allegor or confidential source and sensitive information, who has requested protection of anonymity, would be compromised by the information being released to the licensee.
- The evaluation of the allegation would be compromised because of knowledge gained by the licensee from information released to the

licensee or registrant.

- The allegation is made against the licensee's management or those parties who would normally receive and address the allegation.
- The allegation is based on information received from a Federal agency that does not approve of the information being released to the licensee.
- The allegor has previously addressed the allegation with the licensee with unsatisfactory results and the allegor objects to a referral.

3.4.2 Referral Criteria

Consider the following when determining whether to refer an allegation(s) to a licensee:

- Could the release of information bring harm to the allegor or confidential source or release of sensitive information?
- Has the allegor or confidential source objected to the release of the allegation to the licensee?
- What is the licensee's history of addressing allegations?
- What is the likelihood that the licensee will effectively investigate, document and resolve the allegation?

3.4.3 Informing the Allegor

Note: The DRMP or designated staff shall be responsible for informing the allegor or confidential source of the intent of the RMP to refer the allegation to the licensee or registrant.

- Prior to referring an allegation to a licensee, make all reasonable efforts to inform the allegor or confidential source of the intent to refer.
- Provide the initial notification to the allegor by phone and document with a letter to the allegor. Include in the notification that VDH will evaluate the licensee's activities and response and that the allegor or confidential source will be informed of the final disposition of the allegation.
- If the allegor or confidential source cannot be reached by telephone, then inform the allegor or confidential source by letter of the intent to refer the allegation to the licensee.
- If the allegor or confidential source objects to the referral, or does not respond to the letter within 30 calendar days, and the factors described in sections 3.3.1 and 3.3.2 have been considered, then refer the allegation to the licensee.

3.4.4 Referral Letter

Note: The DRMP or designated staff shall be responsible for submitting a referral to the licensee.

- If a referral of an allegation is to be made to the licensee, then ensure the referral letter contains the following:

A complete description of the elements of the allegation, excluding the identity of the alleged or confidential source, or any sensitive information that could result in the licensee identifying the alleged or confidential source.

A statement that the referral is a result of an allegation against the licensee.

A request to the licensee to thoroughly review the elements of the allegation in a manner that is objective, of sufficient scope, and of sufficient depth to resolve the allegation.

A request for a written report of the results of the review must be submitted to VDH within 10 working days of receipt by the licensee of the referral letter.

- If the allegation was received in writing, then do not include a copy or the original written information from the alleged or confidential source in the written referral to the licensee, unless written permission from the alleged or confidential source has been obtained.
- Ensure a copy of the referral letter is entered into the AF.

3.4.5 Licensee Response

Note: The DRMP is responsible for determining whether the licensee response is adequate and for directing further actions to be taken in response to the licensee's review of an allegation.

- Evaluate the adequacy of licensee's response considering, at a minimum, all the following factors:

Was the evaluation conducted by an entity independent of the organization in which the alleged event occurred?

Was the evaluator competent in the specific functional area in which the alleged event occurred?

Was the evaluation of adequate depth to establish the scope of the problem?

Was the scope of the evaluation sufficient to establish that the alleged event or problem was not a systemic defect?

If the allegation was substantiated, did the evaluation consider the root cause and generic implications of the allegation?

Was the licensee's corrective action sufficient to prevent, alleviate, or correct deficiencies in both the specific and generic instances, and in the short and long term?

- If the licensee's response is adequate, then notify the licensee within 10 working days that the response is adequate and that no further action is required. The response will be incorporated in the closeout letter to the allegor or confidential source and documented in the AMS.
- If the licensee's response is considered to not be adequate, then determine the additional actions required to resolve the allegation including an investigation, enforcement actions (per RMPP 2.5), etc.
- Ensure a copy of both the licensee's response and the VDH response letter are entered into the AF.

3.5 Investigations

Note: If the allegation cannot be referred to the licensee (See subsection 3.4.1); is not resolved by the licensee; or, involves possible wrongdoing (willfulness) an investigation shall be performed, preferably by the LI. The investigation may be included as part of a routine inspection or may involve only the allegation(s).

3.5.1 When conducting an investigation in response to an allegation, use all the following techniques:

- Inspect the issue not the allegor or confidential source.
- Avoid prejudice.
- Do not communicate that the specific issue was raised by an allegor or confidential source (See subsection 3.4.4).
- Take extensive notes and obtain copies of pertinent records, if possible.
- Interview employees regarding relevant procedures and activities.
- Verify any assertions made by the licensee.

3.5.2 If investigation of the allegation leads to the finding of an incident, act as immediate response, take actions to mitigate the incident, and immediately notify the DRMP (see RMPP 3.2, 'Incident Response Procedure').

3.5.3 Document the results of the investigation in a written report and submit to DRMP.

- 3.5.4 Ensure a copy of the investigation report is entered into the AF.
- 3.5.5 Send a closeout letter to the alleged, if possible, documenting the results of the investigation.

3.6 Close Out

- 3.6.1 DRMP shall determine when there is sufficient information to close out the allegation and indicate the investigation report or licensee response letter as satisfactory.
- 3.6.2 The AF should be updated and closed as well as the information in the AMS.
- 3.6.3 A letter should be forwarded to the alleged or confidential source of the findings of the allegation and indicate that it has been considered closed.
- 3.6.4 Regardless of whether an investigation was conducted in response to the allegation or not, the LI should notify the inspection staff of the allegation, omitting any information that is not a need-to-know.
- 3.6.5 If an incident was found through inspection or investigation, ensure all notifications required to NRC and NMED were made in accordance with RMPP 3.2, "Incident Response." Refer to RMPP 3.2, "Incident Response" for follow up guidelines. Refer to RMPP 2.5, "Enforcement, Escalated Enforcement and Administrative Actions" if enforcement actions are necessary. If cause was a possible generic problem, notify other affected licensees.

3.7 Coordinating with Other Agencies

In the case of complaints or allegations involving another local state or federal agency's jurisdiction, the Radiation Safety Specialist should withhold the information from the licensee and elevate the concerns to the attention of the DRMP while still onsite.

4.0 RECORDS

4.1 Hardcopy

The AF is a secure file that contains the hardcopy documentation concerning the allegation.

4.2 Computer Based

The AMS is a secure computerized system that contains a summary of significant data pertinent to each allegation.

5.0 ATTACHMENTS TO RMPP SECTION 3.1

- 5.1 3.1-1 Initial Contact Phone Log**
- 5.2 3.1-2 "Nondisclosure Statement" – Example**
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- 5.5 3.1-5 Acknowledgement Letter to Allegor**

Virginia Department of Health Radioactive Materials Program



Radioactive Materials Program Procedure Section 1.3

License Termination

Prepared

By: _____ Date _____
Dante Laciste, Radiation Safety Specialist

Reviewed

By: _____ Date _____
Michael Welling, Director, Radioactive Materials Program

Approved

By: _____ Date _____
Leslie Foldesi, Director, Division of Radiological Health

Effective Date _____

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- 1.3-1 VDH form, 'Certificate of Disposition of Materials'**

1.0 PURPOSE

1.1 Applicability

This procedure defines the process for terminating a license to possess, use, store and dispose of licensed radioactive material (refer to Attachment 2.1-1 for Program Codes specific to each type of license) granted by the Virginia Department of Health (VDH), including those transferred from the Nuclear Regulatory Commission (NRC).

This procedure applies to the disposal of licensed material, decommissioning of the site and facilities, and surveys adequate to demonstrate that residual radioactivity is within regulatory limits at such time that a license is terminated.

This procedure does not address the personnel qualifications required to review a specific license of each type, refer to RMPP 5.1, "Qualifications and Training" for these guidelines. For this purpose of this procedure, qualification of the license reviewer for a specific license type is verified by the Director, Radioactive Materials Program, prior to determining the reviewer.

1.2 References

- 1.2.1 12VAC5-481 'Virginia Radiation Protection Regulations'
- 1.2.2 Code of Virginia 32.1-229
- 1.2.3 Title 10 Code of Federal Regulations, Part 20, Subpart E - Radiological Criteria for License Termination
- 1.2.4 NUREG 1727, NMSS Decommissioning Standard Review Plan, October, 2000 (evaluation of License Termination Plans, offers suggestions for evaluation of residual contamination in subsurface soil)
- 1.2.5 NUREG/BR-0241 NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees (replaced by NUREG 1727, however, Type I, II, III, and IV Decommissioning Types only addressed in this guidance)
- 1.2.6 NUREG-1575 - EPA 402-R-97-016, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), August, 2000 (evaluation of residual contamination of building surfaces and in surface soil)
- 1.2.7 NUREG/CR-5849, Manual for Conducting Radiological Surveys in Support of License Termination, December 1993 (replaced by MARSSIM)
- 1.2.8 Draft Regulatory Guide DG-4006, "Demonstrating Compliance with the Radiological Criteria for License Termination" (replaced by NUREG 1727, however, contains guidance on how to implement MARSSIM)
- 1.2.9 NUREG-1549, (Draft) "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination" (replaced by NUREG 1727, discusses use of site specific modeling)
- 1.2.10 D & D, Dose Modeling Code (Buildings)

- 1.2.11 RESRAD, Dose Modeling Code (Soil Concentration Levels)
- 1.2.12 RESRAD-Build, Dose Modeling Code (Buildings)
- 1.2.13 Regulatory Guide 1.86 Termination of Operating Licenses For Nuclear Reactors (1974) (provides values for acceptable levels of surface contamination, however, not dose based)

1.3 Computer Based Letters, Forms and Reports

- 1.3.1 Standard Termination Letter
- 1.3.2 VDH form, 'Certificate of Disposition of Materials'

1.4 Hardcopy Files

- 1.4.1 Terminated License File

1.5 Definitions

- 1.5.1 Background radiation means radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of a licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by VDH.
- 1.5.2 Critical group means the group of individuals reasonably expected to receive the greatest exposure to radiation for any applicable set of circumstances.
- 1.5.3 Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.
- 1.5.4 Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.
- 1.5.5 Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental release of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of **12VAC5-481-910**.
- 1.5.6 Voluntary termination means that a licensee has requested that a license be terminated.

- 1.5.7 License revocation means a license is terminated because the licensee has allowed the license to expire; did not respond after being informed that the license had expired; and/or, did not request that the license be terminated or renewed. NOTE: The department must take formal action in order to revoke a license under **12VAC5-481-580**.

2.0 RESPONSIBILITIES

2.1 Program Assistant

The Program Assistant is responsible for:

Identifying those licenses that have expired and for notifying the Director, Radioactive Materials Program (DRMP).

Sending out acknowledgment letters for receipt of termination requests.

Maintaining hardcopy and computer based files.

2.2 Radiation Safety Specialist

The Radiation Safety Specialist is responsible for:

Processing requests for license termination or for processing expired licenses, as assigned.

Conducting final decommissioning surveys, as assigned, or

Over-seeing contractors that are conducting, final decommissioning surveys, as assigned.

Providing an exchange of information to the appropriate, qualified member of the inspection staff.

2.3 Director, Radioactive Materials Program (DRMP)

The DRMP is responsible for:

Assigning a request for license termination or an expired license to a Radiation Safety Specialist for processing. The DRMP will instruct the technical staff member in the required scope of the termination or expired license process, i.e., whether the licensee is required to submit a license termination plan (LTP).

Reviewing, approving and signing the license termination.

In concert with legal counsel, initiating a petition for revocation of the license or other sanction.

2.4 Director, Division of Radiological Health (DDRH)

The Director, Division of Radiological Health (DDRH) is responsible for reviewing and concurring or not concurring in the recommended petition for revocation of the license or other sanctions. The DDRH is responsible for approving the implementation of a revocation action and for signing the final order. The initial decision to proceed with a revocation can be delegated to the DRMP.

3.0 PROCEDURE

3.1 General Provisions

The criteria for termination of a license is listed in **12VAC5-481-510**. The cross-reference to the federal regulation is shown below.

VA Rule	NRC Section	Title
12VAC5-481-1161	10 CFR 20.1401	Radiological criteria for license termination
12VAC5-481-1161 B	10 CFR 20.1402	Radiological criteria for unrestricted use
12VAC5-481-1161 C	10 CFR 20.1403	Criteria for license termination under restricted conditions
12VAC5-481-1161 D	10 CFR 20.1404	Alternate criteria for license termination
12VAC5-481-450 A 4	10 CFR 20.1406	Minimization of contamination

The licensee shall determine the peak annual TEDE expected within the first 1000 years after decommissioning, when calculating TEDE to the average member of the critical group.

3.2 Request for Termination

Within **5 working days** following the receipt of the request for license termination, the receipt shall be acknowledged and the licensee informed that the Radioactive Materials Program may request additional information.

Following the receipt of a request for termination, a determination of the potential for residual radioactive contamination of the facility shall be made. The license and inspection history shall be reviewed to determine the potential risk of residual radioactive contamination.

The highest risk would be licensees that utilize significant quantities of unsealed radioactive material such as, but not limited to, nuclear pharmacies; waste disposal processing and repackaging services; manufacturing and distribution; nuclear laundries; academic, or medical Type A Broad; and, research and development, Type A Broad.

The lowest risk would be licensees that utilize radioactive materials only in the form of sealed sources. Unless there has been a significant leak of a sealed source the probability of residual contamination is essentially zero. (NOTE: However, there have been a number of cases of residual contamination resulting from melting sealed sources contained in measuring gauges.)

For licenses that authorize both sealed and unsealed sources of radioactive material the highest risk use shall dictate the decommissioning process.

3.3 License Termination - Sealed Sources

Upon the receipt of a request for termination of a license that authorizes the possession and use of radioactive materials only in the form of sealed sources, the following information shall be requested from the licensee:

- a) A listing of sealed sources currently or last possessed including type, isotope, quantity, serial number, vendor, date received and use;
- b) Copies of the results of leak tests for each sealed source, if appropriate;
- c) Copies of the records of disposal, decay or transfer to an authorized recipient, for each sealed source;
- d) Copies of periodic inventories, if appropriate;
- e) A copy of the results of the final survey of the area where sources were used and stored. The record should include the type of instrument used and the last calibration date; and
- f) Licensee has submitted a properly completed VDH form, 'Certificate of Disposition of Radioactive Materials'.

If the above information, when compared to the license and the inspection history, appears to be accurate and complete, the license shall be terminated.

If the information is incomplete or appears to be inaccurate an inspection of the facility shall be conducted and if warranted, enforcement action taken prior to license termination.

3.4 License Termination - Solid, Liquid and Gaseous Sources

Upon receipt of a request for termination of a license that authorizes the possession and use of any radioactive materials in solid, liquid or gaseous form, the licensee shall be requested to submit the following information:

- a) A listing of licensed radioactive materials currently or last possessed including type, isotope and quantity, vendor, date received and use;
- b) Copies of the records of disposal, decay or transfer to an authorized recipient, for each radioactive material listed above;
- c) Copies of periodic inventories, if appropriate;
- d) A copy of the results of the final survey of the area where radioactive materials were used and stored. The record should include the type of instrument(s) used and the last calibration dates; and
- e) Licensee has submitted a properly completed VDH form 'Certificate of Disposition of Radioactive Materials'.

If the above information, when compared to the license and the inspection history, appears to be accurate and complete, and with the exception of sealed sources, the licensee has not possessed radioactive material with a half life greater than 120, the license(s) shall be terminated.

If the information is incomplete, appears to be inaccurate, the final survey revealed radioactive contamination or the licensee has possessed unsealed radioactive material with a half life greater than 120 days, an inspection of the facility shall be conducted.

If the inspection reveals that all radioactive material has been properly disposed of and an independent survey reveals no residual activity, the license shall be terminated. However, if items of noncompliance were noted during the inspection enforcement action shall be taken prior to license termination.

If survey results reveal possible residual activity the licensee shall be requested to submit a sufficient License Termination Plan (LTP) such that the facility will be decontaminated to levels acceptable for unrestricted use. NUREG-1575 and NUREG/CR-5849 (see sub-Section 1.2 of this procedure) can be used in the development, implementation of the LTP and the termination of the license. NUREG-1727 can be used to evaluate the LTP by the Radioactive Materials Program. In addition, other guidance and/or modeling codes may address specific issues and may be used as needed (see sub-Section 1.2 of this procedure).

3.5 Expired License

3.5.1 Licensee Contacted

Within ten (10) working days following the expiration date of a license without the receipt of a request for license termination or license renewal, the licensee shall be contacted by telephone or in person and informed that the license expired. The licensee shall be informed that any activity using radioactive material under the license shall cease, the licensed material shall be placed in storage or disposed of, and an application for license termination shall be submitted within 30 days.

If the licensee intends to continue license operations and states that the failure to submit an application for license renewal was just an oversight, the licensee shall be informed that operations shall cease and that an application for license renewal (extension) should be submitted as quickly as possible. The licensee shall be informed that operation without a current license constitutes noncompliance and that appropriate enforcement action will result.

The licensee shall be informed that only the DRMP may authorize continued use of radioactive material without a current license, i.e., grant an exemption.

The above contact shall be recorded in a Confirmatory Action Letter and transmitted to the licensee by Registered Mail, Return Receipt Requested (a sample letter is attached to RMPP 1.2, "Renewal of Licenses").

3.5.2 Licensee Not Contacted

If the licensee cannot be contacted either by telephone, visit to the address on the license or all other reasonable efforts, the authorized place of use shall be inspected and surveyed. If no radioactive materials are found and the survey indicates the facility is free of radioactive contamination, necessary legal action may proceed in order to revoke the license.

If residual contamination is discovered, the facility shall be decontaminated to acceptable levels and the license revoked.

4.0 RECORDS

4.1 Hardcopy

4.1.1 Terminated License File

4.2 Computer Based

4.2.1 Standard Termination Letter

4.2.2 VDH form, 'Certificate of Disposition of Radioactive Materials'

5.0 ATTACHMENTS TO RMPP SECTION 1.3

1.3-1 VDH form, 'Certificate of Disposition of Radioactive Materials'