4.7 Event and Allegation Response Program Elements

This section of the application addresses how the State of Indiana Radioactive Materials Control Program will respond to radioactive materials events and allegations. Indiana has modeled its program elements after those in the NRC procedures SA-300 *Reporting Material Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. The Indiana Radioactive Materials Control Program has four written procedures to address these elements: RMCPP 3.1 *Management of Allegations*, RMCPP 3.2 *Incident Response*, RMCPP 3.3 *Scrap Yard Incident Response*, and RMCPP 3.4 *Nuclear Materials Event Database (NMED) Input*. Section 4.7.1 of this application describes the procedure for responding to events and allegations and Section 4.7.2 describes procedures for identifying significant events and submittals for entry into the NMED.

4.7.1 Procedures for Responding to Events and Allegations

The procedures for responding to events and allegations are attached below. RMCPP 3.1 *Management of Allegations* describes how the Indiana Radioactive Materials Control Program will respond to allegations, while RMCPP 3.2 *Incident Response* describes the response actions for the broad range of radioactive materials incidents and RMCPP 3.3 *Scrap Yard Incident Response* describes the response to specific scrap yard incidents.

For event response, the procedures are consistent with, but not identical to, those of the NRC. They address immediate response and actions to mitigate an event; follow-up inspections and enforcement actions; notifications to licensing staff; reports to the incident file; and notification to other affected licensees of generic problems. The allegations procedure addresses allegation response, follow-up, and closeout. It provides for the protection of the identity of a person making an allegation and other confidential information.

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 3.1, Revision 0
Management of Allegations

Effective Date:

Revision	Date	Description of Changes
0		

Table of Contents

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 alleger. 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, (for example thefts and/or terrorist activity, as described in Section 3.1.3) contact the Local Law Enforcement Agency (LLEA) and/or the Indiana State Police and/or other state and federal agencies such as the U.S. Federal Bureau of Investigation (FBI), as appropriate. The FBI should be notified if an event involves the possibility of theft or terrorist activities. The Indiana Department of Homeland Security (Department) shall promptly notify the Nuclear Regulatory Commission (NRC) Operations Center (301-816-5100) after contacting the appropriate LLEA and/or FBI in cases involving actual or attempted theft, sabotage, or diversion of radioactive materials as indicated in Appendix A of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*.

1.2 References

1.2.1 NRC Management Directive 8.8, *Management of Allegations*.

1.2.2 NRC Inspection Manual Chapter 2800 *Materials Inspection Program*.

1.2.3 SA-300 *Reporting Material Events*.

1.2.4 SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*.

1.2.5 Indiana Radioactive Materials Control Rule.

1.3 Files

1.3.1 All allegation-related documentation is to be maintained in a secured Allegation File in the Radioactive Materials Control Program (RMCP).

1.3.2 Allegations Files are secured when not in use and access is controlled and limited to RMCP staff who are actively using a particular case file. Electronic Allegation Files shall be limited to RMCP staff required to address the allegation who have authorized access to the secured spaces.

1.4 Definitions

1.4.1 **Agency:** The Radioactive materials Control Program (RMCP) of the Indiana Department of Homeland Security (IDHS or Department).

1.4.2 **Allegation**: A declaration, statement, or assertation of impropriety or inadequacy associated with RMCP 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 RMCP staff members by a licensee's managers acting in their official capacity. Allegations regarding suspected improper conduct by an RMCP employee do not fall within the scope of this procedure and shall be promptly reported to the employee's immediate supervisor.

1.4.3 **Allegation File:** A secure hardcopy or electronic file that contains the documentation concerning the allegation, accessible to RMCP staff and secured by the RMCP.

1.4.4 **Alleger:** An individual or organization that makes an allegation. The alleger may be known or anonymous.

1.4.5 **Confidentiality:** 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 or the fact that a confidential source provided such information to the RMCP (see attachment 3.1-4).

1.4.6 **Confidential Source:** An individual who requests and, to the extent possible, is granted confidentiality in accordance with 3.2 of these procedures and the Access to Public Records Act, IC 5-14-3.

1.4.7 **Investigation:** For purposes of this procedure, an activity conducted by the RMCP used to gather information related to the allegation by seeking confirmation to substantiate, evaluate, and resolve an allegation.

1.4.8 **Overriding Safety Issue:** An issue that may represent an actual or potential immediate and/or significant threat to public health, safety, or security, warranting immediate action by the licensee to evaluate and address the issue.

1.4.9 **Requirement:** A legally binding obligation such as a statute, regulation, license condition, or order.

1.4.10 **Secure Files:** Allegation Files are secured when not in use and access is controlled and limited to RMCP staff who are actively using the particular case file because they are required to address the allegation.

1.4.11 **Willfulness:** There are two types of willfulness:

1.4.11.1 **Deliberate Misconduct:** Occurs when an individual voluntarily and intentionally (1) engages in conduct that the individual knows to be contrary to a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license; or (2) provides materially inaccurate or incomplete information to a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license.

1.4.11.2 **Careless Disregard:** Refers to situations in which an individual acts with reckless indifference to at least one of three things: (1) the existence of a requirement, (2) the meaning of a requirement, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless proceeds to engage in conduct that the individual knows may cause a violation. Although unaware that the actions might cause a violation, the individual proceeds without ascertaining whether a violation would occur.

2.0 RESPONSIBILITIES

2.1 Health Physicist (HP)

2.1.1 Any RMCP staff member may receive or recognize an allegation.

2.1.2 Allegations may be communicated to the Department in person, by telephone, by e-mail or in print.

2.1.3 An allegation also may be recognized by an RMCP staff member in information provided in a public forum such as television, radio, newspaper, internet, or social media.

2.1.4 RMCP staff will be courteous, professional, and responsive to the alleger and are responsible for recording the initial allegation, any contact information provided, and immediately referring the allegation to a Senior Health Physicist or the Radiation Control Program Director.

2.1.5 This staff member is also responsible for maintaining confidentiality of the alleger and all other confidential information, as allowed by the Access to Public Records Act, IC 5-14-3.

2.1.6 This information must be documented in attachments 3.1-1 to 3.1-6, and the attachments files, both electronically and in an Allegation File created specifically for each allegation, with access restricted to RMCP staff when evaluating the specific allegation.

2.1.7 When designated as the Lead Investigator, the HP coordinates with the S/HP or RCPD for the processing and disposition of the allegation. Throughout the investigation the HP is required to respond in a timely manner commensurate with the seriousness of the allegation and in consultation with the S/HP or RCPD. The response to the allegation will be determined using Attachments 3.1-1 and 3.1-3 to determine the impact and required response.

2.1.8 Prepare all records and reports concerning the allegation. Attachment 3.1-1 *Initial Allegation Contact Log* must be filled out in entirety, along with Attachment 3.1-3 *Allegation Screening Form*. These records and reports will be used if the allegation is required to be reported to the NRC and through the Nuclear Materials Event Database (NMED). The HP is responsible for discussing and providing a copy of Attachment 3.1-5 *Acknowledgement Letter to Alleger*.

2.1.9 Not all allegations will require immediate response. The HP must use Attachment 3.1-1 *Initial Allegation Contact Log* to determine if the reported allegation required immediate attention. The HP, in consultation with the S/HP and RCPD, will determine the required response to the allegation.

2.2 Senior Health Physicist (S/HP)

2.2.1 Manages the response to allegations and maintains a filing system to track, resolve, and conduct periodic reviews of the allegations for their resolution/disposition (Allegation File).

2.2.2 Informs the RCPD of the status of the investigation and recommends appropriate actions in response to allegations.

2.2.3 Upon being informed of an incident through an inspection or investigation of the allegation, the S/HP will respond in accordance with RMCPP 3.2 *Incident Response*.

2.2.4 This staff member is also responsible for maintaining confidentiality of the alleger and all other confidential information, as allowed by the Access to Public Records Act, IC 5-14-3.

2.2.5 When designated as the Lead Investigator, the S/HP coordinates with the RCPD for the processing and disposition of the allegation. Throughout the investigation, the S/HP is required to respond in a timely manner commensurate with the seriousness of the allegation and in consultation with the RCPD. The response to the allegation will be determined using Attachments 3.1-1 and 3.1-3 to determine the impact and required response.

2.2.6 Prepare all records and reports concerning the allegation. Attachment 3.1-1 *Initial Allegation Contact Log* must be filled out in entirety, along with Attachment 3.1-3 *Allegation Screening Form*. These records and reports will be used if the allegation is required to be reported to the NRC and through the Nuclear Materials Event Database (NMED). The HP is responsible for discussing and providing a copy of Attachment 3.1-5 *Acknowledgement Letter to Alleger*.

2.2.7 Not all allegations will require immediate response. The S/HP must use Attachment 3.1-1 *Initial Allegation Contact Log* to determine if the reported allegation required immediate attention. The S/HP, in consultation with RCPD, will determine the required response to the allegation.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Reviews and approves recommendations made by the HP and/or S/HP before actions are taken in response to allegations.

2.3.2 Authorizes the release of the identities of allegers as provided in section 3.2 after consultation with legal counsel.

2.3.3 Requests legal assistance, if required.

3.0 PROCEDURE

3.1 Initial Contact

3.1.1 Prior to an investigation, the NRC will be notified.

3.1.2 Evaluation is accomplished by technical review of the allegation, inspection, and information requested from the affected licensee, the individual informer, another Agreement State, or the NRC. As much information as possible is obtained and recorded from the alleger on the Initial Allegation Contact Log, (Attachment 3.1-1). If the notification is forwarded or received from the NRC, another state, or a local agency, use the same form, and record all the information from the agency, individual or organization contact. Note on the form the contacts information in case questions arise. For email, fax, regular mail, or any form of communication that may indicate the alleger's identity, RMCP staff must ensure that the identity is protected as indicated in section 3.2 of this procedure.

3.1.3 If the allegation involves discrimination on the basis of age, sex, race, etc., refer the alleger to the Indiana Civil Rights Commission (ICRC). If the allegation requires criminal investigatory capacity, notify and request assistance from the LLEA and/or the Indiana State Police, and/or other federal agency such as the FBI as appropriate.

3.1.4 If the alleger refuses to provide his/her name or other forms of identification, then obtain as much information as possible and advise the alleger that he/she may submit a public records request to obtain information regarding the response to the allegation.

3.1.5 Address the issue of confidentiality with the alleger in accordance with section 3.2.

3.1.6 Inform the S/HP or RCPD of the allegation and submit completed Attachment 3.1-3. Any employee who receives an allegation will document and forward it to the S/HP or RCPD and should do so within five calendar days of receipt. The alleger's identity, or information that could reveal the identity, should be imparted to staff on a need-to-know basis and should not be revealed to personnel outside the Department, unless as required by Indiana Access to Public Records Act.

3.1.7 Allegations received will undergo an initial screening (see Attachment 3.1-1 & 3.1-3). Generally, action will not be taken to determine the validity of an allegation, nor will an allegation be discussed with licensees or other affected organizations, until after the allegation has been discussed with the S/HP, RCPD, and IDHS General Counsel. If those parties determine that an allegation proves to be unsubstantiated (unconfirmed), the alleger will be notified of the findings of the allegation disposition with a letter (Attachment 3.1-6), and the allegation management process will be terminated.

3.1.8 Allegations received by the RMCP staff are given a sequential number (INA-25-001) and an Allegation File is created. Electronic documents are placed in files accessible only to RMCP staff. Hardcopy records are scanned to electronic files where they will be secured.

3.1.9 Provide the initial notification to the alleger by phone and document with a letter (Attachment 3.1-5) to the alleger. Include in the notification, that the Department will evaluate the licensee's activities and response, and that the alleger will be informed of the final disposition of the allegation.

3.2 Disclosure of Alleger's Identity

3.2.1 RMCP will make all reasonable efforts to maintain as confidential any information provided by the alleger that meets the criteria below. However, RMCP cannot guarantee confidentiality. Disclosure of an alleger's identity may be made in accordance with 3.2.2 and 3.2.3 below. RMCP will mark all information deemed confidential as such on both hard copy and electronic files. Prior to terminating initial contact with the alleger, inform the alleger of the degree to which their identity can be protected, including the following:

3.2.1.1 Confidential information, including that which would reveal that identity, will be shared with RMCP staff on a need-to-know basis. Confidential information that needs to be protected includes, but is not limited to the following:

- Birthdate;
- Date and place of birth;
- Social Security Number;
- State issued drivers identification number;
- Medicare card;
- Hospital medical records number;
- Passport;
- Mother's maiden name;
- Biometric records;
- Educational records; and/or
- Financial records.

3.2.1.2 All confidential information, including information regarding the alleger's identity, will be stored in a secure file electronically and the hard copy file will be locked at all times, and under the control of the RCPD in the same manner as Allegation Files.

3.2.1.3 Hard copy Allegation Files are stored in a locked location and access is controlled and limited to RMCP staff. Electronic Allegation Files are limited to RMCP staff required to address the allegation and authorized to access the electronically secured restricted drive.

3.2.1.4 Inspection reports and correspondence with licensees, other Agreement states, federal agencies (including NRC), other organizations, or individuals will contain

no confidential information or information that could lead to the identification of the alleger or confidential source.

3.2.1.5 The alleger's identity will not be disclosed outside of the RMCP, except under the conditions stipulated in section 3.2.2.

3.2.2 Inform the alleger that disclosure of his or her identity or of confidential information may occur on the criteria listed in Attachment 3.1-2.

3.2.3 Obtain approval from the RCPD with consultation with the RCPD and IDHS General Counsel prior to any mandated disclosure.

3.2.4 Regardless of means by which an allegation is made, if the alleger's identity is known, then inform the alleger by letter within 30 days of the degree to which his or her identity can be protected as described in 3.2.1 through 3.2.3 using Attachment 3.1-5 *Acknowledgement Letter to Alleger*.

3.2.5 If requested by the alleger, inform the alleger that a *Non-Disclosure Statement* (Attachment 3.1-2) is available and will be sent within 30 days.

3.3 Controlling Allegations

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

3.3.1.1 Overriding safety issues – shall be addressed immediately.

3.3.1.2 Safety significance issues, other than overriding safety issues will be initiated within 30 days.

3.3.2 Action by the RCPD or designee.

3.3.2.1 Appoint a Lead Investigator for the allegation.

3.3.2.2 Ensure an allegation File is opened for the allegation.

3.3.2.3 With the assistance of the Lead Investigator, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine if an overriding safety issue exists.

3.3.2.4 An allegation is a declaration, statement, or assertion of impropriety or inadequacy associated with RMCP 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 applicants' facility or in the public domain. Examples of allegations are:

3.3.2.4.1 Potential wrongdoing by a licensee, staff, or contractor;

3.3.2.4.2 A concern about a safety-conscious work environment problem at a facility;

3.3.2.4.3 Deliberately falsifying records; and/or

3.3.2.4.4 Bypassing safety interlocks.

If multiple allegations are made, as described above, the RCPD and S/HP must determine the priority of the allegations.

3.3.2.5 Any allegation determined to be an overriding safety issue will cause an immediate evaluation by the RMCP. This evaluation may include the RCPD, a legal representative, and other members of the RMCP staff. All discussions with a legal representative concerning suspected wrongdoing shall be documented and filed within the Allegation File, and, if appropriate, the licensee's folder within WBL.

3.3.2.6 As necessary, brief the RCPD on the evaluation findings and recommendations.

Note: Upon finding out about an incident, immediately implement RMCPP 3.2 *Incident Response*.

3.3.3 Evaluation by Lead Investigator

3.3.3.1 In consultation with the S/HP, perform an immediate assessment of the allegation in accordance with Attachment 3.1-3 to determine if an overriding safety issue exists.

3.3.3.2 Determine, in conjunction with the S/HP, the actions necessary for resolution of the allegation including an investigation, enforcement action (per RMCPP 4.1), etc.

3.3.3.3 Identify additional resources required for resolution of the allegation.

3.3.3.4 Develop a schedule for the resolution of each allegation consistent with the inspection schedule, unless the priority of the allegation causes immediate action.

3.3.3.5 With the approval of the S/HP, implement actions necessary for resolution of the allegation.

3.3.3.6 If an inspection is performed, focus should be placed not only on the particular allegation, but also on the overall area of concern, including safety culture. If the Lead Investigator receives notification of the finding of an incident, implement RMCPP 3.2 *Incident Response* and advise inspection staff of immediate actions taken to mitigate the incident and notify the S/HP.

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 Lead Investigator with the approval of the RCPD and based on the considerations delineated in 3.4.1 and 3.4.2. If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee, to confirm the issue

in writing of the reported allegation and to request pertinent information. In this instance, the 30-day waiting period (see subsection 3.4.3) will be waived.

3.4.1 Prohibitions on Referrals

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

3.4.1.1 The evaluation of the allegation would be compromised because of knowledge gained by the licensee.

3.4.1.2 The allegation is made against the licensee's management or those parties who would normally receive and address the allegation.

3.4.1.3 The allegation is based on information received from a federal agency that does not approve of the information being released to the licensee.

3.4.1.4 Allegation involving willfulness.

Note: If the above criteria conflicts with those for public release as described in Attachment 3.1-2, discuss the referral with legal counsel.

3.4.2 Referral Criteria

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

3.4.2.1 Could the release of information bring harm to the alleger or confidential source?

3.4.2.2 Has the alleger or confidential source objected to the release of the allegation to the licensee?

3.4.2.3 What is the licensee's history of addressing allegations?

3.4.2.4 What is the likelihood that the licensee will effectively investigate, document, and resolve the allegation?

3.4.2.5 Is there any other relevant reason to withhold the information?

3.4.3 Informing the Alleger

3.4.3.1 Prior to referring an allegation to a licensee, make all reasonable efforts to inform the alleger of the intent to refer, unless there is an overriding safety issue.

3.4.3.2 If the alleger or confidential source cannot be reached by telephone, then inform the alleger by letter of the intent to refer the allegation to the licensee.

3.4.3.3 If the alleger objects to the referral or does not respond to the letter within 30 calendar days, and the factors described in section 3.4.1 and 3.4.2 concerning the referral prohibitions and allowances and 3.3.2.5 concerning an overriding safety issue have been considered, then refer the allegation to the licensee.

3.4.3.4 Document on the Initial Allegation Contact Log (Attachment 3.1-1) the alleger's decision to be contacted in the future with the intent to refer allegation to the licensee and if the alleger wants to be contacted in the future, such as about the outcome of the allegation.

3.4.4 Referral Letter

3.4.4.1 Referrals should be made by RCPD or designated staff.

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

3.4.4.2.1 A complete description of the elements of the allegation.

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

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

3.4.4.2.4 A written report of the results of the review must be submitted to the Department within 10 days of receipt by the licensee of the referral letter.

3.4.4.3 If the allegation was received in writing, then do not include a copy or the original written information from the alleger.

3.4.4.4 Ensure a copy of the referral letter is entered into the Allegation File.

3.4.5 Licensee Response

3.4.5.1 The RCPD or designee is responsible for determining whether the licensee's response is adequate and for directing further actions to be taken in response to the licensee's review of an allegation.

3.4.5.2 Evaluation of the adequacy of licensee's response is completed by considering, at a minimum, all the following factors:

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

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

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

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

3.4.5.2.5 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?

3.4.5.3 If the licensee's response is adequate, then notify the licensee within 30 days that the response is adequate and that no further action is required. The response will be incorporated in the closeout letter to the alleger or confidential source.

3.4.5.4 If the licensee's response is considered to be inadequate, then determine the additional actions required to resolve the allegation, including an investigation, enforcement actions (per RMCPP 4.1), etc.

3.4.5.5 Ensure a copy of both the licensee's response and the Department's response letter are entered into the Allegation File.

3.5 Investigations

If the allegations cannot be referred to the licensee (see subsection 3.4.1); or, it involves possible willfulness, an investigation shall be performed, preferably by the Lead Investigator. 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 of the following techniques:

3.5.1.1 Inspect the issue, not the alleger.

3.5.1.2 Avoid prejudgment.

3.5.1.3 Do not communicate that the specific issue was raised by an alleger (see subsection 3.4.4).

3.5.1.4 Take extensive notes and obtain copies of pertinent records, if possible.

3.5.1.5 Interview employees regarding relevant procedures and activities.

3.5.1.6 Verify any assertions made by the licensee.

3.5.2 If an investigation of the allegation is determined to have a negative impact on public health or safety, immediately take action to mitigate the incident and immediately notify the RCPD or designee (see RMCPP 3.2 *Incident Response*).

3.5.3 Document the results of the investigation in a written report and submit it to the RCPD or designee.

3.5.4 Ensure a copy of the investigation report is entered into the Allegation File.

3.5.5 Send a closeout letter to the alleger (attachment 3.1-6), if possible, documenting the results of the investigation.

3.6 Closeout

3.6.1 The RCPD or designee shall determine when there is sufficient information to close out the allegation and indicate in the investigation report, or licensee response letter, a satisfactory response.

3.6.2 The Allegation File should be updated and closed. If appropriate, a copy of all information should be placed in the licensee's file.

3.6.3 If requested and reviewed by the RCPD or designee, a letter (attachment 3.1-6) should be forwarded to the alleger, or confidential source, of the findings of the allegation indicating that it has been considered closed.

3.6.4 Regardless of whether an investigation was conducted in response to the allegation or not, the Lead Investigator should place a note in the licensee's file.

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 RMCPP 3.2 *Inspection Response*. Refer to RMCPP 3.2 for follow up guidelines. Refer to RMCPP 4.1 *Enforcement* if enforcement actions are necessary. If the cause was a possible generic problem, notify other affected licensees.

3.7 Coordinating with Other Agencies

In the case of complaints or allegations involving other local, state, or federal agency's jurisdiction, the Health Physicist should withhold the information from the licensee and elevate the concerns to the attention of the S/HP or RCPD while still onsite.

4.0 ATTACHMENTS

3.1-1 Initial Allegation Contact Log

3.1-2 Nondisclosure Statement

3.1-3 Allegation Screening Form

3.1-4 Handling of Information and Files

3.1-5 Acknowledgement Letter to Alleger

3.1-6 Allegation Disposition Letter

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 3.1-1
Radioactive Materials Control Program
Initial Allegation Contact Log

INDIANA DEPARTMENT OF HOMELAND SECURITY
Radioactive Materials
Control Program

INITIAL ALLEGATION CONTACT LOG

INSTRUCTIONS:
This log is to be used to record the information gathered in an allegation against a licensee or registered user.

Date:
Time:
Individual taking Initial Allegation:

Has the individual been informed of the conditions regarding confidentiality. YES NO

ALLEGER INFORMATION:

Individual's full name:	Telephone number:
Position or relationship to the facility or activity involved:	Alleger's employer:
Home mailing address:	Facility/location:

What sort of activities or practices did this involve? What have they observed? Use back for additional information.

NATURE AND DETAILS OF THE ALLEGATION:

How long has this activity been occurring?	Description of Concern
Is this a current or past unsafe practice?	
How did the individual find out about the concern?	

Date(s) and times of occurrence:

Are there other individuals that should be contacted for additional information?
(list names, addresses, phone numbers if available)

What records does the individual think should be reviewed?

Has the individual raised the concerns with his/her management?
Yes What action has been taken?
No Why not?

** If the allegation involves discrimination because of age, sex, race, etc., inform the alleger that they should contact the Indiana Civil Rights Commission 1-800-628-2909.

** If this allegation was forwarded from another agency, indicate who the contact was that provided the notification:
Agency: Region/Office: Name: Telephone:

INFORMING THE ALLEGER OF FUTURE CONTACT:

Does the alleger want to be contacted with the intent to refer the allegation to the licensee?
YES* NO**

Does the alleger want to be contacted in the future, such as about the outcome of the allegation?
YES * NO**

*If YES, obtain contact information under ALLEGER INFORMATION.
**If NO, document in ADDITIONAL COMMENTS OR INFORMATION of the alleger's decision.

ACTIONS TO BE TAKEN:

Refer this to the Radiation Control Program Director

If this issue was referred to another agency, please list the name of agency:

ADDITIONAL COMMENTS OR INFORMATION:

Indiana Department of Homeland Security
Radioactive Materials Control Program

Attachment 3.1-2
Radioactive Materials Control Program
Nondisclosure Statement

Nondisclosure Statement

I have information that I wish to provide in confidence to the Indiana Department of Homeland Security (IDHS), Radioactive Materials Control Program (RMCP). I request that the RMCP do not reveal that I am the source of the information.

During an inquiry or investigation, the RMCP will make its best effort to avoid actions that would clearly be expected to result in disclosure of my identity.

My identity may be divulged outside the RMCP in any one or more of the following situations:

(1) When disclosure is necessary because of an overriding safety issue. The RMCP staff will attempt to contact me prior to any disclosure.
(2) When a court orders such disclosure.
(3) When the RMCP request disclosure for enforcement proceedings.
(4) In response to a legislative request. While such a request will be handled on a case-by-case basis, the RMCP will make its best effort to limit the disclosure to the extent possible.
(5) When requested by a federal or state agency in furtherance of its statutory responsibilities and the RMCP finds that furtherance of the public interest requires such release.
(6) When the State of Indiana Attorney General or a local or state law enforcement agency is pursuing an investigation, my identity may be disclosed without my knowledge or consent.
(7) When I have taken actions that are inconsistent with and override the purpose of protecting my identity.
(8) When I have taken actions that are inconsistent with and override the purpose of protecting my identity.
(9) Disclosure is mandated by the Access to Public Records Act (APRA), IC 5-14-3.

My identity will be withheld from the RMCP staff, except on a need-to-know basis. Consequently, I acknowledge that if I have further contact with RMCP personnel, I cannot expect that those people will be cognizant of my desire to remain anonymous, and it will be my responsibility to bring that point to their attention if I desire similar treatment for the information provided to them.

I have read and fully understand the information above.

Signature: _____Date: _____

Printed Name: _____

Address:_____

Indiana Department of Homeland Security
Radioactive Materials Control Program

Attachment 3.1-3
Radioactive Materials Control Program
Allegation Screening Form

ALLEGATION SCREENING FORM

a) Is there an immediate safety concern that must be quickly addressed?
b) Is the allegation a specific safety or quality issue or a generalized concern?
c) Has the staff previously addressed this issue or a similar issue?
d) Has there been a substantial number of allegations on similar concerns?
e) What is the time sensitivity of the allegation and what immediate actions are necessary?
f) What is the potential for wrongdoing, and will investigative assistance be needed?
g) Does the allegation package contain sufficient information for a thorough evaluation? If not, identify the additional information needed.
h) Can the issues be adequately addressed by a routine technical inspection? If not, determine the best way to address the issues.
i) Identify any peripheral issues that could develop.
j) Are any licensing actions or enforcement actions pending that could be affected by the allegation? When an allegation involves a case with pending licensing action, the HP or S/HP working on the case should be promptly notified.
k) Can inspection resources be effectively utilized pursuing the issue of is the allegation too vague or frivolous?
l) Is further consideration of the allegation required? If not, inform the alleger in a courteous and diplomatic manner of the rationale for not considering it further. Consult the Radiation Control Program Director and the IDHS General Counsel for a final decision before doing so.
m) Can licensee resources reasonably be used in resolving the allegation to conserve staff resources?
n) Does the allegation have the potential to require escalated enforcement action?

Indiana Department of Homeland Security
Radioactive Materials Control Program

Attachment 3.1-4
Radioactive Materials Control Program
Handling of Information and Files

Handling of Information and Files

Upon receipt of an allegation and during the investigation of an allegation, the alleger may expect that his/her identity will be protected. While the RMCP cannot withhold information in the situations outlined in Attachment 3.1-2, the RMCP will take all reasonable steps to minimize the use of the alleger's identity and/or any identifiable information. Basic program rules to protect the identity of the alleger and other identifiable information are outlined below.

1) Restrict staff discussions to those individuals who truly need-to-know.

The alleger's identity and other information that would reveal their identity should be restricted to only those RMCP staff that are involved in the investigation.

2) Restrict access to the hardcopy and computer files by storing in a secure file.

All information regarding the alleger's identity and other confidential information will be stored in the specific Allegation File. The Allegation File will be maintained in a secured filing cabinet and an electronic restricted drive accessible only to those working directly with the investigation. When an electronic or paper copy is in use, the RMCP staff member using the file is responsible for always controlling access to it when the file is not locked up or closed electronically.

3) Protect access to information during work.

Files are not left lying open if the work area is not occupied. Computer screens are not left open if the work area is not occupied. At the end of the day, the hardcopy Allegation File is placed in the secured filing cabinet. Computer files are saved on the secured computer space. Drafts are not developed outside this computer space. Field notes, received forms, etc. are kept secured or are disposed of.

4) Be wary of emails if you must use them.

Emails are to be sent encrypted and being very careful to enter the correct email address. Prior to sending emails including documents/attachments, calls should be made to alert the recipient, and a read receipt should be requested to confirm the email was received.

Indiana Department of Homeland Security
Radioactive Materials Control Program

Attachment 3.1-5
Radioactive Materials Control Program
Acknowledgement Letter to Alleger

Acknowledgement Letter to Alleger

Date

Mr. John Doe

1234 ABC Street

Anytown, IN 46XXX

Dear Mr. Doe:

This letter refers to your contact with <specify individual> of the Indiana Department of Homeland Security (IDHS), Radioactive Materials Control Program (RMCP) on <specify date>, in which you expressed concern related to <specify licensee/company/etc.>. <Specify concern e.g., you were concerned that you used a Troxler portable gauge without receiving proper training and transported the device in your personal vehicle.>

In addition, according to your contact with RMCP staff, we understand that you did/did not object to having your allegation referred to <specify licensee/company/etc.>.

<Specify actions taken in response and include detailed information such as: On October 18th RMCP staff performed a routine health and safety inspection of Company X and focused on an investigation of your allegation. During this investigation, RMCP staff determined that you logged out the Troxler portable gauge at the Sample Jobsite in July prior to your August 2nd training certificate. Specify any other relevant information found related to the allegation such as: We were also able to determine that authorized users including yourself were allowed to perform work with the portable gauge without being issued dosimetry, which is a violation of the license.>

<Specify agency actions such as: subsequently, the IDHS has issued violations based upon the inspection and investigation.>

If you have any questions or further concerns, please contact me at <specify contact number> or <specify email address>.

Sincerely,

Name

Title

Indiana Department of Homeland Security
Radioactive Materials Control Program

Attachment 3.1-6
Radioactive Materials Control Program
Allegation Disposition Letter

Response to Concerns Allegation

NO. INA-XX-001

Date

Mr. John Doe

1234 ABC Street

Anytown, IN 46XXX

Dear Mr./Mrs./Ms. Doe:

This letter refers to your contact with <specify individual> of the Indiana Department of Homeland Security (IDHS), Radioactive Materials Control Program (RMCP) on <specify date>, in which you expressed concern related to <specify licensee/company/etc.>. <Specify concern e.g., you were concerned that you used a Troxler portable gauge without receiving proper training and transported the device in your personal vehicle.>

<Provide a direct answer to each of the alleger's concerns, stating what was evaluated, how it was evaluated, and providing RMCP's conclusions regarding the validity of the concern. It is preferable that an overall conclusion be provided indicating that the concern was substantiated, unsubstantiated, or partially substantiated, as long as that overall conclusion is well supported by the accompanying discussion regarding the evaluation of the concern. However, if providing such an overall conclusion will be confusing to the alleger (e.g., if aspects of the concern were substantiated, but the alleged impropriety or inadequacy was not found to be valid), alternate wording may be used, such as…"while the RMCP was unable to substantiate that certain (facts/statements/conditions regarding ____) were true, the RMCP was unable to confirm or validate an impropriety or inadequacy associated with RMCP-regulated activity." (If appropriate add: We have documented our findings in Allegation No. INA-XX-00 dated XX/XX/XXXX. A copy can be obtained through a FOIA request.)

Name:

Title:

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 3.2, Revision 0
Incident Response

Effective Date:

Revision	Date	Description of Changes

Table of Contents

1.0 PURPOSE

1.1 Applicability

1.1.1 This applies to all Indiana Department of Homeland Security, Radioactive Materials Control Program (RMCP) staff responding to an incident involving real or suspected radioactive materials. This procedure does not apply to a known or suspected terrorist incident. If terrorism is known or possible, contact the Local Law Enforcement Agency (LLEA) and/or the Indiana State Police, and/or the U.S. Federal Bureau of Investigation (FBI), as appropriate.

1.1.2 This addresses preparation for responding to a radiological incident and an abnormal occurrence (AO), which is any unscheduled incident or event which the NRC/RMCP determines to be significant from the standpoint of public health and safety.

1.1.3 This procedure describes radiation detection instruments and other equipment potentially required for response to a radiological incident, safety precautions for RMCP staff and other responders during a response effort and options for identifying unknown radioactive material in the field and laboratory.

1.1.4 This procedure establishes guidelines for voluntary reports on lost and stolen events involving any types of radioactive material, as well as situations that cannot be specifically tied to a reporting requirement (such as "found" sources that were not reported as lost, material contaminated with radioactive material, and landfill alarm trips).

1.1.5 This procedure establishes notification requirements to other federal (including NRC), state, and local agencies as well as event notification of a possible generic problem to other affected licensees, etc.

1.2 References

1.2.1 Indiana Radioactive Materials Control Rules.

1.2.2 NRC Procedure, SA-300 *Reporting Material Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*.

1.3 Definitions

1.3.1 **Abnormal Occurrence (AO):** An unscheduled incident or event significant from the standpoint of public health or safety.

1.3.2 **Agency:** The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security.

1.3.3 **Apparent Violation:** A potential noncompliance with a regulatory requirement that has not yet been formally cited as a violation or order.

1.3.4 **Deviation:** A licensee's failure to satisfy a non-legally binding commitment (e.g. failure to tie-down a commitment during licensing and the licensee has not implemented that commitment).

1.3.5 **Escalated Enforcement Action:** An enforcement action for any Severity Level I, II, or III violations. Violations with willful aspects (i.e. careless disregard or deliberate misconduct) will typically be considered for escalated enforcement.

1.3.6 **Immediate Notification:** For this procedure, notification is required to be made to the Indiana Department of Homeland Security.

2.0 RESPONSIBILITIES

2.1 Health Physicist (HP)

2.1.1 Informs the S/HP of all radioactive materials incidents.

2.1.2 Assumes the lead role in immediate response as required to incidents involving radioactive materials and coordinates with the S/HP or the Radiation Control Program Director (RCPD).

2.1.3 Incidents involving Nuclear Power Plants, the Radiological Emergency Preparedness Manager assumes the lead role.

2.1.4 Incidents involving transportation of radioactive materials, the Radiological Transportation Manager assumes the lead role while the HP provides subject matter expertise.

2.1.5 Responds to incidents involving radioactive materials within the established time frame, as directed by the RCPD or designee.

2.1.6 Assists the RCPD or designee with incident response and documentation, including report preparation, as needed.

2.2 Senior Health Physicist (S/HP)

2.2.1 Notifies the RCPD of radiological incidents.

2.2.2 Assigns staff to respond to incidents involving radioactive materials.

2.2.3 Coordinates immediate response effort during normal working hours.

2.2.4 In coordination with the RCPD and general counsel, makes decisions to impound radioactive materials found in the public domain.

2.2.5 Advises the RCPD whether legal assistance is required.

2.2.6 Ensures that notifications are made of reportable and required reports as indicated in SA-300 *Reporting Materials Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*, including immediate, 24-hour, and 5 to 30-day event reporting requirements.

2.2.7 Has the responsibility to ensure that written documentation of reportable incidents is completed and for assuring the quality of the reports to the Nuclear Materials Events Database (NMED) within the appropriate time period as required by the incident. Abnormal occurrences should be managed in accordance with NRC's Management Directive 8.1 *Abnormal Occurrence Reporting Procedures*.

2.2.8 If necessary and in consultation with the RCPD, request federal assistance from the NRC Headquarters Operations Officer (HOO) at (301) 816-5100.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Final authority, if needed, for radiological incident response activities (conflict resolution).

2.3.2 Requests legal assistance if required.

2.3.3 Coordinates immediate response effort outside normal working hours.

3.0 PROCEDURE

3.1 Incident Type and Classification

3.1.1 Transportation Incident: An incident which occurs in association with any activity involving the movement of radioactive materials by a motorized conveyance on roadways, to include trucks, planes, automobiles, etc. This does not include movement of materials at a facility by forklift, hand-truck, or other transfer methods. Such incident would be considered as a fixed facility incident.

3.1.2 Fixed Facility Incident: An incident which occurs in association with any activity involving radioactive material at a fixed location. This would include temporary work sites (soil testing and non-destructive testing of welds), manufacturing sites (thickness gauges, etc.), or any other location which does not involve the movement of radioactive materials by a motorized conveyance on roadways as indicated above.

3.1.3 Terrorism Incident: An incident which occurs in association with any deliberate act of sabotage or destruction which includes the use of radioactive materials. This type of incident may include transportation or fixed facility, but due to the initiating event, it will require coordination of response actions to ensure crime scene issues are considered.

3.1.4 Incident Classification: Level I – an incident in which no release of radioactive materials has occurred. This is determined by visual assessment of the incident scene. If there is not a high confidence level by the response personnel in declaring a Level I incident, it should default to a Level II incident.

3.1.5 Incident Classification: Level II – an incident in which there may be a release of radioactive materials. This is determined by a visual assessment of the incident scene. Level II would be declared when there is reasonable doubt of the integrity of the containment of the radioactive materials (package shows significant damage, but there is no visible sign of material release).

3.1.6 Incident Classification: Level III – an incident in which there is a release of radioactive material. This is determined by visual assessment of the incident scene. There must be a high level of confidence by the response personnel before declaring a Level III incident.

3.2 Initial Notification

When the Indiana Department of Homeland Security is notified that an incident has occurred, the Radiation Section's on-call staff member will obtain as much information as

possible in order to determine the level of response required. If upon notification of the radioactive material incident, the on-call staff member, with consultation with the RCPD, will contact the applicable agencies listed in SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* Appendix A for assistance. Not all incidents will require an immediate response. If immediate response is not required, the on-call staff member will notify the appropriate program director (i.e. transportation program manager will be notified for transportation incidents; the S/HPs within the RMCP will be notified for incidents involving licensed materials; etc.). Document in the notes section of Attachment 3.2-1 *Radiological Incident Notification* Form the reason that an immediate response is not required such as it is being evaluated. The appropriate response can be ascertained by obtaining as much information as possible and based on the guidance from SA-300 *Reporting Materials Events*, the program's response plan, and/or in Appendix A of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. In the event that multiple simultaneous incidents are being reported, the RCPD or designee will coordinate the response activities to ensure the incidents are properly categorized and prioritized.

An incident may be received in a number of ways, including in-person, phone, email, letter, news media, and/or internet social media. If the incident is assigned to RMCP staff, the incident is screened to determine the level of response required. A licensed facility may require a reactive inspection, have an inspection due that can be assigned, or have just had an inspection that the incident had been identified and documented during the inspection. RMCP personnel should use this section as guidance when responding to byproduct, source, or special nuclear material incidents. Radiological material incidents should be recorded on Attachment 3.2-1 *Radiological Incident Notification* Form and the incident reported with guidance fromSA-300 *Reporting Materials Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. For major radiological emergencies, IDHS radiation program staff should coordinate with other state agencies, the NRC 24-hour Headquarters Operations Center Office at (301) 816-5100, the Radiation Emergency Assessment Center/Training Site (REAC/TS) at (865) 576-1005, and EPA Region 5 at (312) 353-2000.

The below procedures should be performed for events classified as Significant Events, meaning events identified as having generic concerns or issues with a significant potential to impact public health and safety and/or the environment, requiring immediate (within 4 hours) or 24-hour reporting as specified in SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* Appendix A. For example:

- Multiple occurrences of an event tracked as a performance measure (medical events, overexposures, lost or stolen sources of concern)
- A single occurrence of an event tracked as a strategic goal (deaths, loss of organ function, significant releases to the environment);
- Events involving possible generic concerns or issues (equipment malfunctions, equipment failure, inadequate user procedures, software problems); or
- Consequences or casual factors not previously seen in the event assessment.

3.2.1 Obtain as much information as possible.

3.2.2 For incidents involving quantities of Category 1 and Category 2 radioactive materials, make the required notifications in accordance with the provisions of 10 CFR 37.57.

3.2.3 Inform the S/HP and RCPD of the incident. If the S/HP or RCPD is unavailable, notify any other RMCP staff.

3.2.3.1 Criteria for determining the level of response required follows the reporting requirements listed in SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*, based on the relative risk to public health and safety and the factors in 3.2.3.2. The primary responsibility for responding to an incident remains with the licensee. However, the RMCP may give advisory support and may assist the licensees in diagnosing the situation and determining potential courses of action.

3.2.3.2 Factors that should be considered for determining the appropriate response include:

- Potential to escalate.
- Location of incident.
- Potential for exposure or contamination.
- Media interest.
- Type of release.
- Involvement of other responders.
- Request for specific type of assistance.

3.2.4 Upon receipt of a notification of an incident, advise the notifier on proper measurements to limit exposure and minimize the spread of contamination.

3.2.5 As necessary, keep the public informed through the IDHS Public Information Office. Attachment 3.2-2 *Radiological Incident Response Question and Answer Sheet* may be helpful and can be provided to the IDHS Public Information Office. Regarding communication with the public, consider the following factors:

- Extent of public risk and perception of the risk.
- Extent of media interest.
- Confidence in validity of information reported to the Department.
- Reassessment of the measures that have been taken (e.g., health physics and medical services that have been made available to the public).
- Coordination of information among the NRC, federal agencies, and state and local agencies. Ensure that other federal agencies are informed of any information to be released to the media or the public.
- Assurance of correctness of information provided to the news media and public.

3.2.6 Further information can be found in SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* Section 8 pertaining to the reportability threshold for the following topics: Leaking sealed sources, Orphan sources, Found source, Landfill radiation monitor alarms, Scrap metal recycling facilities and incinerator Facilities, Well logging source rupture, Irretrievable well logging source, Industrial radiography, and Fixed gauge with shutter failure.

3.2.7 The notifications to be made to NRC can be found in SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* Appendix A.

3.3 On Scene Response

3.3.1 If possible, a minimum of two people should provide immediate response to a radiological incident.

3.3.2 The following equipment should be obtained and transported to the incident scene for immediate response:

- Appropriate survey instrumentation,
- An instrument capable of field identification of unknown isotopes,
- Personally assigned dosimetry,
- Cellular phone,
- Other instruments and supplies, as necessary.

3.3.3 Site approach for immediate response team:

- Approach the incident site/material from upwind.
- Turn on exposure rate instrument before approaching the incident site.
- Obtain current information from on scene personnel.
- Coordinate response efforts prior to approaching the material.
- Ask for a shipping manifest if applicable.
- If there is a potential for contamination, wear plastic booties and gloves.
- Establish a 2mR/hr. exclusion zone around the material if not already done.
- Determine who may enter the exclusion zone and under what conditions.

3.3.4 Document the following, as it occurs:

- Date and time of all major activities related to the incident.
- Model and serial numbers of all instruments used.
- Calibration date of all instruments used.
- Names of responders.
- A physical description of the incident site.
- Location or orientation of any materials.
- Background radiation levels.
- Survey results.
- Amount of material that is present.
- Any markings or inscriptions associated with the material.
- Disposition of the material.
- Names, phone numbers, and addresses of all individuals involved, for follow-up when performed.

3.3.5 Determine if material needs packaging. If the material must be bagged, double bag the material. Survey the outer surface of packaging for contamination prior to transport and take appropriate precautions should external contamination be measured.

3.3.6 After the material has been safely packaged or ensured to be in safe condition, do the following:

- Determine best location for temporary storage.
- Ensure that decontamination issues are addressed.
- Initiate attempts to locate owner of material.

- Contact the RCPD or designee for direction and authorization for management of the material (see Attachment 3.2-3 *Impoundment Guidelines*).

3.3.7 Materials being transported for analysis or storage must be packaged to Department of Transportation (DOT) requirements.

3.4 Report

3.4.1 The Radiation Personnel assigned to the incident shall prepare a report within 15 business days documenting all information gathered, date of the response, the disposition of the material, type of response, and a list of all the parties involved. The report is required for all incident responses, including phone consultation for reportable incidents. If it is determined that no field response is warranted, the date of evaluation and basis for the determination should be documented.

3.4.2 Provide a copy of the report to the S/HP and RCPD.

3.4.3 The S/HP shall ensure the quality and completeness of the report and ensure that a copy of the report, analysis results, and all notes and related paperwork are properly filed in accordance with SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. This report and any subsequent follow-up reports should be utilized to forward data to NMED and to the NRC in accordance with SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* as well as any other federal, state, or local agency, as necessary.

3.4.4 Input incident data to NMED and forward event reports to the NRC, as necessary. For more information on reporting events, see *SA-300 Reporting Material Events and SA-300 "Handbook on Nuclear Material Event Reporting for the Agreement States"*.

3.5 Follow-up

3.5.1 In consultation with the RCPD, or designee, determine if any whole-body counts, bioassays, or personal dose determinations are warranted, and if medical assistance is required or referral to Oak Ridge Radiation Emergency Assistance Center (REAC/TS) for analysis is necessary. See NRC Inspection Manual Chapter 1360 *Use of Physician and Scientific Consultants in the Medical Consultant Program* for guidance.

3.5.2 In consultation with the S/HP, determine if training or information for any individuals involved in the incident is warranted.

3.5.3 In consultation with the S/HP determine the need for a follow-up inspection and/or any enforcement actions against the licensee. This incident should be addressed during the next routine inspection. If it is determined that enforcement actions are required, refer to RMCPP 4.1 *Enforcement*.

3.5.4 Ensure a copy of the incident report is in the licensee file and make notification to the appropriate RMCP staff, as necessary.

3.5.5 Make notifications to appropriate federal and state agencies specified in section 5.0, including the NRC and NMED within the appropriate time period of any new information, and status of event including final close of the event.

3.5.6 In consultation with S/HP and RCPD, determine the need to notify other licensees of the problem if a known or possible general fault is involved that could affect those licensees.

4.0 RECORDS

Records include completed attachments from this procedure, other documents related to incidents, and NMED-related documents.

Efforts will be made to maintain records primarily in an electronic form. Those that are paper will be scanned electronically and may be kept as paper or shredded after determination as to what is best for the particular record and its form for regulatory purposes.

5.0 COMMUNICATING EVENTS TO THE APPROPRIATE STATE AND FEDERAL AGENCIES

- Events and allegations may be reported to the Indiana Radioactive Materials Control Program at 301 W. Washington St. E-208, Indianapolis, IN 36204, or via the IDHS Watchdesk at (317) 233-6615.
- U.S. NRC Region 3, 2056 Westings Ave Suite 400, Naperville, IL 60563-2657.
- NRC Headquarters Operation Office (HOO) (301) 816-5000.
- U.S. EPA Region 5, 77 W. Jackson Blvd, Chicago, IL 60604, (312) 353-2000.
- Oak Ridge Institute for Science and Education, Radiation Emergency Assistance Center/Training Site (ORISE REAC/TS) (865) 576-1005.

6.0 ATTACHMENTS TO RMCPP 3.2

Attachment 3.2-1 Radiological Incident Notification Form

Attachment 3.2-2 Radiological Incident Response Question & Answer Sheet

Attachment 3.2-3 Impoundment Guidelines

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 3.2-1
Radiological Incident Notification Form

RADIOLOGICAL INCIDENT NOTIFICATION FORM	
Contact Information	Incident Number: _____
Name: _____ __	Notification Date/Time: _____
Incident Reported By: _____	On-site Contact: _____
Title/Organization: _____	Title/Organization: _____
Phone Number: _____	Phone Number: _____
Location of Incident (Include Directions): _____ _____ _____ ___	
Description of Incident: _____ _____ _____ _____ _____ _____	
Radiation Assessment: 1. Why do you believe radioactive material is involved? 2. Describe the radioactive material including packaging. 3. Did you observe any writing or inscriptions on the materials? 4. Are shipping papers available? 5. Are there any indications of a possible spread of contamination based on meter readings, broken source housing, leaking packaging, etc.? 6. Has the source or contaminated area been isolated or access to the area restricted? 7. What other agencies or personnel are involved? _____ _____ _____	
Additional Notes:	

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 3.2-2
Radiological Incident Response Question and Answer Sheet

RADIOLOGICAL INCIDENT RESPONSE QUESTION AND ANSWER SHEET

What is a radiological incident?

A radiological incident is an emergency involving radioactive materials. Examples of radiological incidents include situations where radioactive materials are lost, stolen, or involved in a transportation accident. In most cases, radiological incidents can be successfully resolved by emergency responders with state assistance.

What state assistance is available to respond to a radiological incident?

The Indiana Department of Homeland Security, Radiation Program, is available on a 24-hour basis to support and advise emergency responders during an incident involving radioactive materials. IDHS emergency response resources include highly trained personnel and specialized radiation monitoring equipment. IDHS Radiation Program staff can be quickly dispatched to provide assistance remotely, and if needed, on-site assistance at the scene of a radiological incident.

How are radioactive materials regulated to minimize public risk?

Radioactive materials are stringently regulated by state and federal government agencies by licensing or registration. Devices and products containing radioactive materials are required to incorporate safety features that minimize the exposure risk to the public from a radiological incident.

What should I do if involved in a radiological incident?

Remain calm. Follow instructions given by on-scene officials. Indiana Department of Homeland Security Radiation staff will quickly assess the situation and recommend any further actions. Most radiological incidents do not result in harmful levels of radiation exposure to the public.

Where can I get more information?

Indiana Department of Homeland Security, Radiation Programs – hazmat@dhs.in.gov

Center for Disease Control and Prevention – https://www.cdc.gov/nceh/radiation/emergencies/index.htm

Nuclear Regulatory Commission – https://www.nrc.gov/about-nrc/emerg-preparedness/prepare-for-radiological-emerg.html

Indiana Department of Homeland Security
Radioactive Materials Control Program

ATTACHMENT 3.2-3
Impoundment Guidelines

IMPOUNDMENT GUIDELINES

Management will consider the following questions before approving a request to impound radioactive materials.

Regulatory Control:

- Are the radioactive materials under the direct control and responsibility of a licensee?
- Are the materials in a controlled location?
- Are the materials directly and negatively impacting public health and safety?
- Is there a possible public perception problem with the current location?

Physical/Chemical Form:

- What is the isotope and physical/chemical form of the material?
- Are other hazardous or explosive materials involved?
- What is the activity of the material?

Physical Condition:

- Are the materials intact, crushed, leaking, or damaged in some way?
- Are the materials concentrated or dispersed over a large area?
- Are the materials separate or part of a larger device?

Amount:

- What is the volume of the material?

Transportation:

- Can the material be transported safely?

Waste Management:

- Does managing the material involve simple storage or is any processing involved in disposing of the materials?

Alternatives:

- Are there any safe and reasonable alternatives to the State impounding the material?
- Is there a temporary storage location and responsible party available?

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 3.3, Revision 0
Scrap Yard Incident Response

Effective Date:

Revision	Date	Description of Changes

Table of Contents

1.0 PURPOSE

1.1 Applicability

1.1.1 Applies to all Indiana Department of Homeland Security Radiation Program staff responding to a scrap yard incident involving real or suspected radioactive materials.

1.1.2 Describes options for determining the appropriate response to a scrap yard incident by Radiation Program (RP) staff.

1.1.3 Addresses preparations for a site response to a scrap yard incident.

1.1.4 Describes appropriate radiation detection instruments and other equipment potentially required for use during a site response to a scrap yard incident.

1.1.5 Describes safety precautions for RP staff and other responders during a site response effort to a scrap yard incident.

1.1.6 Establishes guidelines for managing, including impounding radioactive material that is, or could be, a threat to public health and safety.

1.2 References

1.2.1 Indiana Radioactive Materials Control Program Rules

1.2.2 DOT Special Permit SP 10656

1.2.3 SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* and SA-300 *Reporting Material Events*.

1.3 Definitions

1.3.1 **Agency:** The Radioactive Materials Control Program (RMCP) of the Indiana Department of Homeland Security.

1.3.2 **Radiation Program:** All IDHS radiation focused staff; includes both Radioactive Materials Control Program (RMCP) staff and Radiation Response staff (i.e., REP Coordinator, Radiological Transportation/RND Program Manager, and Emergency Preparedness Specialist)

1.3.3 **U.S. DOT Special Permit SP 10656:** (Also called "DOT Exemption" form) is a form signed by the authorized radiation Program staff that authorizes the on-way transportation in commerce of (rail or motor vehicle) shipments of scrap metal and related metal recycled material which have been found, during or at the conclusion of transportation, or during inspection of the shipment following receipt, to contain unexpected and unidentified radioactive material or contamination.

2.0 RESPONSIBILITIES

2.1 On-call Radiation Program Staff members

2.1.1 Receive initial notification from the scrap facility, via the Watchdesk, of potential discovery of radioactive material.

2.1.2 Complete all immediate documentation required, including, but not limited to, DOT SP 10656, instructions to scrap yard, etc.

2.1.3 If warranted due to public health and safety, provide immediate response to incidents involving radioactive materials, as directed by the RCPD or designee.

2.1.4 If necessary, notify the NRC and inputs report into NMED.

2.2 Assigned Radiation Program Staff member

2.2.1 Conducts on-site response.

2.2.2 Determines appropriate remedial action of any identified radioactive material.

2.2.3 Determines if notifications should be made to the NRC within the time period specified in RMCPP 3.2 *Incident Response* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* and SA-300 *Reporting Material Events*.

2.2.4 Coordinate landfill disposal with Indiana Department of Environmental Management, if appropriate.

2.2.5 Ensures a complete report is prepared documenting the incident response, including all notes, pictures, forms, surveys, and analysis results.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Final authority within the RMCP for radiological incident response activities (conflict resolution).

2.3.2 Requests legal assistance, if required.

2.3.3 Requests federal assistance, if required.

3.0 PROCEDURE

3.1 Initial Notification

3.1.1 If a radiation portal monitor, or hand-held detector, at a scrapyard detects radiation, the scrap yard will notify IDHS RP staff via the IDHS Watchdesk at (317) 233-6615.

3.1.2 IDHS RP will assign two individuals to provide on-call support for all radiological incidents 24/7/365. There will be a primary on call and a secondary on call. All radiation staff will provide response for unknown radioactive materials. RMCP staff will provide response for any known licensed material.

3.1.3 Once notification is received, obtain as much of the following information as possible:

3.1.3.1 Caller's name, affiliation, and location.

3.1.3.2 Phone number where caller can be reached.

3.1.3.3 Location of the incident.

3.1.3.4 Overall description of the incident, including any injuries.

3.1.3.5 Indications that radioactive material is involved.

3.1.3.6 Any writing or inscription on visible materials.

3.1.3.7 Radiation reading on sides of vehicle and in driver compartment containing scrap, or other survey results.

3.1.3.8 Type of survey instrumentation used.

3.1.3.9 Other agencies or personnel involved.

3.1.4 Determine the level of immediate response required. Factors that should be considered include:

3.1.4.1 Likelihood of health and safety concerns such as significant personnel radiation exposure or personal or environmental contamination.

3.1.4.2 Location of incident.

3.1.4.3 Impact of facility (i.e., ability to secure material and maintain safety of workers and the public).

3.1.4.4 Potential for exposure or contamination.

3.1.4.5 Security of storage area.

3.1.4.6 Media interest.

3.1.4.7 Involvement of other responders.

3.1.4.8 Request for specific type of assistance.

3.1.4.9 Training and experience of scrap yard personnel.

3.1.5 Advise the caller on proper measures to limit exposure and minimize the spread of contamination (e.g., isolate the vehicle, do not disturb load, etc.)

Note: People should not handle contaminated or high exposure rate materials unless trained, qualified and aware of the hazards. If there is any doubt, isolate the material until Radiation Program staff or other authorities can attend to the materials safely.

3.2 Determining Use of U.S. DOT Special Permit SP 10656

3.2.1 Ask the scrap yard if they will accept or reject the load containing potential radioactive materials.

3.2.2 Issue a U.S. DOT Special Permit SP 10656 to the shipper that allows transportation of the load back to point of origin or another pre-designated location.

3.2.2.1 Radiation readings are needed for SP 10656 form.

3.2.2.2 The reading may be supplied by scrap yard personnel or others if RP staff believe they are accurate.

3.2.2.3 The Special Permit is available from the Conference of Radiation Control Program Director (CRCPD) at:

https://crcpdpro.wpenginepowered.com/document/dot-10656-fillable-form/

3.2.3 If warranted, the on-call staff member schedules a site visit to the scrap facility, point of origin, or the designated location by Radiation Program staff to assess the incident.

3.3 On Scene Response

3.3.1 If possible, a minimum of two people should respond to a scrap yard incident including a member of the RP staff.

3.3.2 Prior to use, all instruments shall be battery and source checked and have a current calibration. Obtain the following equipment:

3.3.2.1 Appropriate survey instrumentation.

3.3.2.2 An instrument capable of field identification of unknown isotopes.

3.3.2.3 Personally assigned dosimetry.

3.3.2.4 Cellular phone.

3.3.2.5 Other instruments and supplies, as necessary.

3.3.3 Upon arrival:

- Obtain current information from facility personnel.
- Turn on exposure rate instruments before approaching.

Wear safety equipment (boots, hard hat, gloves), as necessary.

3.3.3.4 Wear contamination clothing, as appropriate.

3.3.3.5 Perform radiation surveys.

3.3.3.6 Establish a 2mR/hr. exclusion zone if required and not already done.

3.3.3.7 Determine who may enter the exclusion zone and under what conditions.

3.3.4 Determine the level of resources needed.

3.3.4.1 If RP resources are available to resolve the incident, evaluate the scrap load, determine the cause of the alarm, and advise the facility, as appropriate.

3.3.4.2 If RP resources are unavailable:

Advise the facility to obtain the services of a health physics contractor to investigate the load, determine cause of the alarm, and assist with radioactive material management.

Inform the contractor to provide results of the investigation to the Indiana Department of Homeland Security Radiation Programs at hazmat@dhs.in.gov .

3.3.5 Document the following:

- Date and time of all major activities related to the incident.
- Model and serial numbers of all instruments used.
- Names of responders.
- A physical description of the incident site.
- Location or orientation of any materials.
- Background radiation levels.
- Survey results.
- Activity of material.
- Confidence levels from RIID.
- Amount of material that is present.
- Any marking or inscriptions associated with the material.
- Disposition of the material.
- Names, phone numbers, and e-mail addresses of all individuals involved, in case follow-up is required.

3.3.6 If radioactive material is removed from the load, determine if material needs packaging. If it does, double bag the material and incorporate any other US DOT transportation packaging requirements.

3.3.7 Materials being transported for analysis or storage must be packaged to meet US DOT requirements.

3.4 Report

3.4.1 The report shall be prepared within 15 business days of the notification, documenting all information gathered, the disposition of the material, and a list of parties involved. The report is required for scrap yard incidents response, including phone consultation for reportable incidents.

3.4.2 Provide a copy of the report to RCPD.

3.4.3 The RCPD or designee shall ensure that a copy of the report, analysis results, and all notes and related paperwork are properly filed.

3.4.4 If required, input incident data to the Nuclear Materials Events Database (NMED) and forward event reports as specified in Appendix A of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*.

3.5 Follow-up

3.5.1 Replace all inventories supplies used from the response kit.

3.5.2 In consultation with RCPD or designee, determine if any whole-body counts, bioassays, or personnel dose determinations are warranted.

3.5.3 In consultation with RCPD or designee, determine if training or information for any individuals involved in the incident is warranted.

3.5.4 If appropriate, obtain copy of reports by any health physics contractors involved in the incident.

3.5.5 If the owner is an IDHS Radioactive materials Control Program licensee, consult with the RCPD and the S/HP to determine if a follow up inspection and/or any enforcement actions against the licensee. The next inspection should address this item. If it is determined that enforcement actions are required, refer to RMCPP 4.1 *Enforcement*.

3.5.6 In consultation with the RCPD, if the owner is found and not an IDHS RMCP licensee, determine need to notify the appropriate regulatory agency.

3.5.7 Ensure that any notifications required to be made to any federal, state, and local agencies are made within the appropriate time period, updated of any new information and notified of the final close.

4.0 RECORDS

RMCPP 3.2 Attachment 3.2-1 *Radiological Incident Notification Form*

Local NME Database: Provide an electronic NMED report to the NMED contractor by using the local NMED Agreement State software from the NMED website or following the upload function instructions on the NMED website.

As much as possible, records should be electronically filed. Where possible, paper records should be scanned to be filed electronically.

5.0 ATTACHMENTS to RMCPP 3.3

None

4.7.2 Procedures for Identifying Significant Events and Submittals for Entry into the *Nuclear Material Event* Database

The State of Indiana has modeled its procedures for identifying significant events and submittals for entry into the Nuclear Medical Event Database (NMED) on the SA-300 *Reporting Material Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States"*. This is done in RMCPP 3.4 *Nuclear Material Event Database (NMED) Input*, which is attached in this section of the application. It describes how Indiana will generate event reports and submit them to NMED within required time frames and as required by regulation. Responsibilities are assigned for the completion of reports and for ensuring the quality of reports. Criteria are included for identifying abnormal occurrences that are reportable, and guidance is provided for notification, follow-up and closeout of reports.

Indiana Department of Homeland Security
Radioactive Materials Control Program

Radioactive Materials Control Program Procedure 3.4, Revision 0
Nuclear Material Events Database (NMED) Input

Effective Date:

Revision	Date	Description of Changes

Table of Contents

1.0 PURPOSE

To provide guidance for Indiana Department of Homeland Security (IDHS) Radioactive Materials Control Program (RMCP) licensing and inspection personnel on the proper reporting requirements for incidents involving lost, stolen, misplaced, orphaned or damaged source, medical events, and other incidents involving radioactive material to the NRC via the *Nuclear Material Event*s Database (NMED). All RMCP staff members involved with the reporting of events to NEMD shall use the guidance of *SA-300 Reporting Material Events and SA-300 "Handbook on Nuclear Material Event Reporting for the Agreement States"*.

2.0 BACKGROUND

From SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*: At the request of the Conference of Radiation Control Program Directors (CRCPD), the *Nuclear Material Event*s Database (NMED)...captures voluntary reports on lost and stolen events, for any type of nuclear material, as well as situations that cannot be specifically tied to a reporting requirement (such as 'found' sources that were not reported lost, materials contaminated with radioactive material, and landfill alarm trips). The reported information aids in understanding why the events occurred and in identifying actions to help ensure public and occupational safety and security and improves the overall effectiveness of the NRC and Agreement State regulatory programs.

Guidance is provided on:

1. Reporting events requiring notification within 24 hours to the NRC Operations Center;
2. Providing 5 to 30-day notification and follow-up event information;
3. A schedule for event reporting;
4. Reporting formats; and
5. Providing event information for events meeting the abnormal occurrence (AO) criteria.

Note: An accident or event will be considered an AO if it involves a major reduction in the degree of protection of public health or safety, security, and/or the environment. This type of incident or event would have a moderate or severe impact and could include, but need not be limited to the following:

1. Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the RMCP;

2. Major degradation of essential safety-related equipment; or

3 Major deficiencies in design, construction, or use of management controls for facilities or radioactive material licensed by or otherwise regulated by the RMCP.

3.0 REPORTING EVENTS REQUIRING NOTIFICATION WITHIN 24 HOURS

The RMCP shall report events requiring notification within 24 hours to the NRC Operations Center Headquarters Operations Officer (HOO). Information should be initially reported to

the HOO by telephone at (301) 816-5100. Follow-up information for the event may also be provided to the HOO by fax at (301) 816-5151 or by email at HOO.HOC@nrc.gov.

3.1 NMED Record for Events Reported Within 24 hours

The NMED contractor uses the initial event notification (EN) information, which was provided to the NRC Operations Center from the RCPD, to establish a record in the national NMED database. The NMED contractor will reference the IDHS event reporting identification number in the record. The RMCP event report identification number will be reflected in the "Reference" field of the NMED record and will be used to ensure any subsequent updates are correctly associated with the initial event record. In addition, each event entered into NMED is assigned a unique NMED item number.

3.2 5 to 60-Day Event Reporting

The RMCP shall report events that require reporting within 5 to 60 business days to the NRC. These reports may be provided in writing by mail or electronically. NRC staff encourages Agreement States to electronically report these events using the local NMED Agreement State software or the document "Upload" program on the NMED website.

A. Assign Event Report Identification Number.

The IDHS event report identification number should appear on all reports, including preliminary, initial notification reports (e.g., EN's), and any follow-up reports. The event report identification number should consist of the two-letter state agency ID (IN), two-digit year corresponding to the reporting year, and a sequentially assigned four-digit ID number. The event report identification number should be referenced by the IDHS for all telephone, electronic, or written notifications involving each specific event. The S/HPs will keep a log of event reports up to date.

B. Basic Event Information.

Appendix C "Minimum Required Event Information" of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* provides a list of the minimum event information that should be provided. When submitting an initial event report, provide as much information known at the time the report is prepared regarding the items listed in the Appendix.

C. Electronic Reporting to NMED.

The RMCP may provide an electronic NMED report to the NMED contractor by using the NMED Agreement State software, which may be downloaded from the NMED website, or by using the document "Upload" tab of the NMED website.

D. Access to NMED.

A search of the nationally collected data is available on the NMED website with several drop-down, point-and-click menus available. To obtain access to NMED, contact the NRC NMED Project manager at NMEDNRC@nrc.gov.

E. Written Event Reports.

Written event reports should be sent to the Branch Chief, Medical Safety & Events Assessment Branch at the address listed in Appendix B of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. Reports should be provided in an optical character recognition (OCR) format. Include an event report cover page for all written event information provided to the NRC. Department personnel should refrain from providing information that is considered confidential (e.g., personal privacy, proprietary, or security related information, including sensitive unclassified non-safeguards information (SUNSI)). If such information is required to describe the event, the RCPD should provide a bracketed copy of the information that deletes such information.

3.3 Reporting Follow-up Event Information

Follow-up information for NMED reports (e.g., providing additional information regarding initial event reports) should provide the results of the investigation as to what, where, when, and how the event or conditions occurred. The following items should be provided when reporting follow-up information:

A. Follow up reports including appropriate updates, event completion and event closeout of the event should be provided in writing to the Radioactive Materials Safety Branch Chief at the address listed in Appendix B of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* or electronically to the NMED contractor via the NMED website. A complete event report should include all investigative information obtained through closeout of the event.

B. When providing follow-up event information, provide document(s), or clear reference to documents on file that the RMCP used to generate the NMED event report (e.g., a licensee inspection report dated mm/dd/yyyy), if applicable and appropriate.

C. Provide any follow-up event information that revises earlier information or provides additional information on a given event to ensure a complete historical record.

3.4 Radiological Response Assistance Available to the States

The RMCP may request radiological emergency response assistance by contacting the NRC's Operation Center. The Federal Government, upon request, has the capability to provide assistance to state in responding to radiological emergencies. Under the National Response Framework, NRC is the coordinating agency for domestic incident management for incidents involving nuclear materials or facilities licensed by the NRC or Agreement States.

3.5 Voluntary Reporting on Lost, Stolen and Abandoned Sources

The RMCP should follow the guidelines provided above in section 3.2, "5 to 60-Day Reporting" to report any lost, stolen, and abandoned non-Atomic Energy Act and unlicensed material.

3.6 Reporting Theft or Terrorist Activity

The U.S. Federal Bureau of Investigation (FBI) notification should be considered in an event involves the possibility of theft or terrorist activities. The RMCP will promptly notify the NRC Operations Center (i.e., the HOO) after contacting the appropriate Local Law Enforcement Agency (LLEA) and/or the FBI in cases involving actual or attempted theft, sabotage, or diversion of radioactive material containing quantities greater than or equal to the Category 1 or 2

radioactive material as defined in Appendix A of 10 CFR Part 37. The RMCP should consider notifying the FBI or LLEA in all cases of actual theft, sabotage, or diversion and possible terrorism of radioactive materials, regardless of the quantity of radioactive material involved. This includes intentional use of radioactive material that could be used in an unauthorized malevolent manner that could lead to serious consequences. The RMCP should coordinate with the NRC, their communication with other local, Federal and State agencies, to ensure that shared information is accurate and consistent. Based on health and safety significance the RMCP should also consider the issuance of a press release. If it is not clear whether and event should be categorized as a possible theft of terrorist activity, the RMCP should contact the NRC Headquarters Operations Center for assistance in determining if the event should be reported.

If an event involves suspicious activity involving the possibility of theft, sabotage, or diversion, or the actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 licensed material, as defined in Appendix A of 10 CFR 37, the RMCP shall promptly notify the NRC's Operation Center at (301) 816-5100 within 4 hours of the event notification, after contacting the appropriate local law enforcement authority.

4.0 CLOSING AND COMPLETING EVENTS

4.1 Events Closed in NMED

The RMCP should notify the NMED contractor when the event record has been officially closed (i.e., no further follow-up is planned and/or no additional information is expected). The RMCP should ensure that the record contains all pertinent technical information, including follow-up information before closing the record.

4.2 Records Complete in NMED

A "complete record" refers to an NMED record that contains a specified minimum set of information. This minimum set of information is defined in Appendix C of SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* and may also be found on the NMED website under "Help". Once the minimum information is provided, the NRC/NMED contractor marks the NMED record as "complete". A "complete" record still remains open in NMED until the RMCP has indicated the record should be closed.

5.0 AGREEMENT STATE SAFETY REVIEWS OF MATERIAL EVENT REPORTS

5.1 Agreement State Review of Material Events for Safety Significance and Generic Assessment.

The RMCP should review events occurring in Indiana, or related to products registered or licensed in Indiana, to identify any event that may involve generic concerns or issues or could have significant impact on public health and safety, security, and/or the environment. Events that warrant such a review include:

A. Multiple occurrences of an event (e.g., medical events, overexposures, lost or stolen sources of concern), or

B. A single occurrence of a significant or serious event (e.g., deaths, loss of organ function, significant release to the environment), or

C. Events involving possible generic concerns or issues (e.g., equipment malfunctions, equipment failures, inadequate user procedures software problems), or

D. Consequences or causal factors not previously seen in the event assessment process.

5.2 Actions Agreement State May Take after Review of Significant Events

Events identified as having a significant potential risk to public health and safety, security, and/or the environment may receive additional RMCP or NRC management review. The RMCP should continue to follow-up and review material events through the closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential risks identified as a result of event review and analyses, the RMCP may take actions to reduce potential risks identified as a result of issuing safety-related notifications to licensees. The RMCP is encouraged to share with the NRC and other states any findings, assessments, or trending studies. These can be forwarded to the NMED Project Manager for posting on the NMED website, or distribution in the NMED newsletter and/or Agreement State Letter.

6.0 ABNORMAL OCCURRENCE GUIDELINES AND CRITERIA

RMCP staff should routinely screen events against the Abnormal Occurrence (AO) criteria as part of their routine program. Section 208 of the Energy Reorganization Act of 1974 defines an AO as an unscheduled incident or event that the NRC has determined to be significant from the standpoint of public health or safety. The RMCP will follow SA-300 *Reporting Material Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States* and MD 8.1 *Abnormal Occurrence Reporting Procedure* to routinely screen events against the AO criteria as part of the routine incident response. Any events identified as potential Abnormal Occurrences should be reported to the NRC in accordance with SA-300 *Reporting Material Events* and SA-300 *Handbook on Nuclear Material Event Reporting for the Agreement States*. Examples of abnormal occurrences are being provided so that an abnormal occurrence can potentially be identified in an expedited manner. Additionally the U.S. Nuclear Regulatory Commission Report to Congress on Abnormal Occurrences NUREG-0090 Volumes 36-47 can be reviewed by following the Link: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/index.html

Examples of Abnormal Occurrences from NUREG-0090 Volumes 36-47

I. ALL LICENSEES

Example Security Event at ARC Inspection Services LLC, Krum Texas
An event shall be considered for reporting as an AO if there was any substantial breakdown of physical security or material control (e.g., of access control containment or accountability systems) that significantly weakened the facility's protection against theft, diversion, or sabotage. Additionally, an event shall be considered for reporting as an AO if it involves a serious safety-significant deficiency in management or procedural controls.

Date and place – August 7, 2024, Krum, TX

Nature and Probable Consequences – On August 4, 2024, the Texas Department of State Health Services (DSHS) received information alleging a radiography licensee (ARC Inspection Services, LLC), abandoned a truck carrying Category 2 radioactive sources and that the vehicle was previously under the control of an individual who was not designated by the company's security program as trustworthy and reliable. The DSHS conducted investigations of the licensee's facilities in Krum, Texas, from August 7 – 9, 2024. Though the investigations did not substantiate that Category 2 radioactive sources had been abandoned, the DSHS found that the licensee had not completed background checks for multiple personnel. Background checks are required to determine whether employees are trustworthy and reliable prior to being assigned access to licensed radioactive material sources. Further, DSHS found (1) numerous instances where security related information and equipment associated with the Category 2 material were accessed by unauthorized licensee personnel before the trustworthy and reliability process was completed; (2) the licensee exceeded their radioactive material possession limit without prior approval from DSHS; (3) the licensee failed to maintain appropriate records and information associated with background checks for personnel and inventories of radioactive materials; and (4) the licensee appeared to have conducted radiography activities in surrounding states without obtaining appropriate regulatory approval through licensing or reciprocity. Despite the violations identified, DSHS found no indication that any individual would have received an exposure to radiation that would have exceeded any regulatory limits.
Cause(s) – The primary root cause for the violations identified by DSHS was the licensee's Radiation Safety Officer (RSO) not adequately implementing the licensee's security plans and procedures. In particular, DSHS determined that several of the licensee's employees were performing duties associated with the RSO role, without authorization.

Actions Taken to Prevent Recurrence:

Licensee – The licensee reorganized its organizational structure and appointed a single individual as RSO. In addition, by early September 2024, the licensee sufficiently

corrected the violations identified by DSHS in its initial investigation activities to comply with the Texas Radiation Act and Applicable rules.

State – The DSHS initiated a prompt investigation, identifying numerous violations of the Texas Radiation Act and applicable rules associated with the licensee's activities. On August 26, 2024 DSHS issued an impound order to the licensee which reclaimed all the licensee's radioactive sources and radiography devices until satisfactory corrective actions had been taken. On September 5, 2024, the impound order was rescinded following DSHS determination that the licensee had satisfactorily completed corrective actions. The DSHS further heightened its oversight of the licensee's activities, requiring the licensee to provide frequent reporting of its activities, and increasing the frequency of inspections. Ultimately, DSHS issued an administrative penalty to the licensee of $235,500 with conditions associated with nine violations of the Texas Radiation Act. This event is closed for the purposes of this report.

Example Human Exposure Event at Christiana Care Health Services, Newark, Delaware

A human exposure event shall be considered for reporting as an AO if any unintended radiation exposure to any minor (an individual less than 18 years of age) results in an annual total effective dose equivalent (TEDE) of 50 millisieverts (mSv) (5 rem) or more, or if any unintended radiation exposure to an embryo/fetus results in a dose equivalent of 50 mSv (5 rem) or more.

Date and place – January 9, 2020, Newark, DE

Nature and Probable Consequences – On January 29, 2020, Christiana Care Health Services reported that an embryo/fetus received an unintended radiation dose when a patient, not known to be pregnant received the first of four doses of lutetium-177 (Lu-177) Dotatate for treatment of a neuro-endocrine tumor. On January 9, 2020, immediately before administration, the patient responded "No" to the question "Is there any chance that you are pregnant?" and was administered the prescribed dose 7.53 gigabecquerel (GBq) (203.5 millicuries (mCI)) of Lu-177 Dotatate and counseled to use contraception for several months following the therapy. On January 28, 2020, the patient notified her medical oncologist that she was pregnant. The treating physician was notified on the same day. The licensee stated that the patient had a negative serum pregnancy test on January 3, 2020. It is believed the patient became pregnant after the test, with a possible conception date of between January 3 and January 5, 2020. The licensee calculated the dose to the embryo/fetus to be 143 mSv (14.3 rem). The treating physician reviewed the radiation effects with the patient and stated that there was no expected increased risk of fetal death or anatomical malformations at delivery. An independent medical consultant concurred with the licensee's evaluation of the event, including the dose calculation. Subsequently, the patient chose to terminate the pregnancy and continue the treatment. The patient was then scheduled for her next treatment in March 2020.

Cause(s) – The cause of the event was determined to be a weakness in the pregnancy policy to address limitations and contraceptive measures between collecting the

pregnancy test and therapy dosage administration. The policy in place during the event required a negative pregnancy test 7 days before the administration and relied on a negative declaration of pregnancy immediately before the administration. Patients were counseled to refrain from becoming pregnant between the pregnancy test and the administration but were not specifically counseled to refrain form becoming pregnant between the pregnancy test and the administration.
Actions Taken to Prevent Recurrence

Licensee – The licensee revised its patient policy to require a negative serum pregnancy test within 48 hours before treatment instead of 7 days, and to require a nuclear medicine physician to reemphasize with each therapy patient the need to avoid pregnancy and to use contraception, particularly between the pregnancy test and the therapy date.

NRC – The NRC performed a special inspection on February 5, 2020, to review the event and concluded that the licensee met regulatory requirements, took measures to provide added assurance, and reported the medical event as required by Title 10 of the Code of Federal Regulations (10 CFR) 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child."

This event is closed for the purpose of this report.

Stolen Industrial Radiography Cameras from Western Technologies, Ind., Phoenix, Arizona

Any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," shall be considered for reporting as an AO.

Date and place – April 28, 2019, Phoenix, AZ

Nature and Probable Consequences – On April 28, 2019, Western Technologies, Inc. reported the theft and recovery of three industrial radiography cameras, each containing an activity that exceeded the threshold for a Category 2 quantity of radioactive material. An employee, who had been authorized for unescorted access to radioactive material, stole three industrial radiography cameras from the licensee's secure storage area after normal working hours. Law enforcement was notified, and the cameras were recovered and returned to secure storage on the day of the theft.

Cause(s) – This event remains under law enforcement investigation.

Actions Taken to Prevent Recurrence

Licensee – The licensee upgraded its access security measures for after normal business hours to prevent a single individual with unescorted access from removing Category 2 quantities of radioactive materials.

NRC – The NRC is monitoring the progress of the licensee's response to this event.

State – The Arizona Agreement State regulator is monitoring the licensee's response to this event.
This event is closed for the purpose of this report.

II. EVENTS AT FACILITIES AND ALL TRANSPORTATION EVENTS

Medical Event at Providence Sacred Heart Medical Center, Spokane, Washington

A medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 grays (Gy) (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive, and involves a dose or dosage that is at least 50 percent greater than that prescribed.

Date and place – June 14, 2023, Spokane, Washington

Nature and Probable Consequences – On June 14, 2023, the Providence Sacred Heart Medical Center (licensee) reported an event during a high dose rate (HDR) brachytherapy treatment with an iridium-192 source. The written directive prescribed a series of three fractionated treatments for two separate skin lesions. The two locations were supposed to receive 5 Gy (500 rad) and 4 Gy (400 rad) per fractionated treatment, for total doses of 15 Gy (1,500 rad) and 12 Gy (1,200 rad) to the respective locations were administered to the patient. After treatment, the physician noticed that the incorrect doses had been administered and immediately notified the patient. After treatment, the physician noticed that the incorrect doses had been administered and immediately notified that patient. No adverse health effects were expected for the patient because the total doses did not exceed the treatment plan.

Cause(s) – The primary cause was a breakdown in communication. Because of the high volume of treatments scheduled for that day, the medical physicist initially planning the treatment was called to the operating room, and a second medical physicist finished the treatment planning. The first medical physicist failed to communicate that the treatment was supposed to be fractionated, and the second medical physicist instead planned 15 Gy (15,00 rad) and 12 Gy (1,200 rad) for the respective locations in one treatment. The authorized user reviewed the treatment plan and failed to notice the deviation from the written directive.

Actions Taken to Prevent Recurrence

Licensee – The licensee revised the HDR policy to specify that a single medical physicist should be present and accountable throughout the planning and treatment process. The revised policy also details a formal plan for the handoff procedure should a transition between medical physicists need to occur during planning or treatment. Lastly, the revised HDR policy now includes a timeout before the start of the treatment, during which all involved staff are verbally briefed on the treatment plan to confirm that there are no concerns before proceeding.

State – The Washington Department of Health conducted an investigation of the licensee 30 days after the incident. The investigation resulted in the issuance of a Notice of Correction enforcement action, which required, in part, that the licensee complete an independent third-party audit of the facility's radioactive materials program. The Washington Department of Health reviewed the results of the independent audit and other corrective actions, including its revised HDR policies and protocols, as part of onsite inspections taking place through July 2024 and determined that the revised policies and protocols adequately addressed the program's deficiencies.

This event is closed for the purposes of this report.

Medical Event at an Unspecified Medical Licensee, Unspecified City, New York

A medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) form the administration defined in the written directive, and involves a prescribed dose or dosage that is delivered to the wrong treatment site.

Date and place – November 6, 2023, Unspecified City, New York

Nature and Probable Consequences – On November 6, 2023, the licensee reported that a dose was delivered to the wrong treatment site during a gamma knife radiosurgery treatment. The patient was intended to receive a single dose of 80 Gy (8,000 rad) to the left-side trigeminal nerve (a cranial nerve). The full treatment dose was delivered to the right-side trigeminal nerve. The patient was immediately notified, and no adverse health consequences are expected.

Cause(s) – The medical physicist incorrectly identified the right-side trigeminal nerve as the treatment site. Both the neurosurgeon and the radiation oncologist reviewed the treatment plan and failed to notice the incorrectly labeled treatment site. All three individuals then signed off on the treatment plan before administration.

Actions Taken to Prevent Recurrence

Licensee – The licensee implemented new procedures for gamma knife radiosurgery treatments, including a medical physics check to determine laterality, an additional peer review by a gamma knife-trained radiation oncologist, and a verbal timeout, during which the treatment plan is confirmed by attending staff, for all cases before the plan is signed by the appropriate medical professionals.

State – The State conducted an inspection for this event and a related complaint on April 19, 2024. There were no enforcement actions as a result of the inspection, and the State closed the event.

This event is closed for the purposes of this report.

Medical Event at Saint Francis Medical Center, Cape Girardeau, Missouri

A medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 Gy (1,000 rad), the expected dose to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive, and involves a dose or dosage that is at least 50 percent greater than that prescribed.

Date and Place – May 6, 2024, Cape Girardeau, Missouri

Nature and Probable Consequences – On May 7, 2024, the Saint Francis Medical Center (the licensee) reported an event associated with an yttrium (Y)-90 microsphere administration. On May 6, 2024, during a palliative treatment of a liver tumor, the patient received a dose to the treatment site approximately 300 percent greater than the prescribed dose. The written directive prescribed a dose of 90 Gy (9,000 rad) to the left lobe of the liver; however, the patient received 360 Gy (36,000 rad). The authorized user planned a treatment consisting of one dosage of an activity of 7.0 gigabecquerels (GBq) (190 millicuries (mCi)), with a calibration date of Sunday, April 28, 2024, or a second dosage option of 3.0 GBq (82 mCi), with a calibration date of Sunday, May 5, 2024. Either of these single dosages would have delivered the prescribed dose of 90 Gy to the treatment site. However, the authorized user provided unclear instructions to the nuclear medicine staff, who interpreted the treatment plan to include both dosages. As of January 27, 2025, the patient's referring physician indicated that the patient did not have any identifiable health effects on the liver as a result of the procedure and the patient continued with their cancer treatment plan.

Actions Taken to Prevent Recurrence

Licensee -Corrective actions from the licensee included closing the Y-90 microsphere program

NRC – The NRC conducted an inspection on May 14, 2024, and May 15, 2024, and the licensee is continuing to monitor the patient for potential health effects. On March 20, 2025, the NRC notified the licensee of a Notice of Violation for four violations, including failure to have a written directives dated and signed by an authorized user prior to a therapeutic administration of radiation from byproduct material; failure to develop, implement, and maintain written procedures; failure to provide training to individuals involved in Y-90 microsphere administration; and failure to ensure that radiation safety activities are performed in accordance with licensee-approved procedures. Updates received from the licensee regarding patient outcome will be provided in future reports.

This event is closed for the purposes of this report.

Medical Event at Holston Valley Medical Center, Kingsport, Tennessee

A medical event shall be considered for reporting as an AO if it results in a dose that exceeds, by 10 grays (Gy) (1,000 rad), the expected dose to any organ or tissue (other

than a major portion of the bone marrow, the lens of the eye, or the gonads) from the administration defined in the written directive, and involves a dose or dosage that is at least 50 percent greater than the prescribed.

Date and place – November 14, 2022, Kingsport, Tennessee

Nature and Probable Consequences – On November 14, 2022, Holston Valley Medical Center (the licensee) reported an event during a cervical cancer treatment with a 327.45 GBq (8.85 Ci) Ir-192 source in an Elekta Model 136149A02 Flexitron-high dose rate (HDR) remote afterloader brachytherapy unit. The written directive prescribed five fractionated treatment doses of 6 Gy (600 rad), for a total of 30 Gy (3,000 rad) for the entire treatment. However, during the first treatment, the medical physicist misread the written directive and administered the total treatment dose of 30 Gy (3,000 rad) instead of the prescribed fractionated dose of 6 Gy (600 rad). The physician notified the patient and began to monitor the patient for adverse health effects. Following the monitoring period, no adverse effects were noted.

Cause(s) – The cause was human error. The licensee uses two treatment planning systems, a main high dose rate planning system and one used as a secondary check. The secondary system displays the total dose prescribed and not the fractionated dose. The medical physicist misread the treatment plan in the secondary system and ran a plan in the main system such that the total dose prescribed as shown in the secondary system was covering the target volume.

Actions Taken to Prevent Recurrence

Licensee – The licensee implemented a program in which one person performs the treatment planning and another person performs the verification plan. Both must then sign off before the treatment is implemented. Additionally, the licensee developed a generic table of expected treatment times based on dose and distance of treatment from the sources. Finally, the licensee contacted Elekta to request a periodic maintenance inspection of the treatment unit and to see if any software or firmware updates were available.

State – The State of Tennessee followed up with the licensee after receipt of the post-event report. Additionally, Tennessee maintained contact with the licensee to verify that no adverse effects to the patient were being reported. Finally, the state reviewed the licensee's corrective actions for this event and found them acceptable. The success of these actions will be reviewed and verified through routine inspection of the licensee.

This event is closed for the purpose of this report.