

State of Vermont Department of Health

Radioactive Materials Program

Procedure 3.1, Revision 0



Management of Allegations

Prepared By: _____ **Date:** _____

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Approved By: _____ **Date:** _____

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Radioactive Materials Program Procedure 3.1, Revision 0

Management of Allegations

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Management of Allegations

1.0 PURPOSE

1.1 Applicability

This procedure is to ensure that any allegation made against a licensee is properly addressed and to provide guidance to protect the identity of the alleged. Actions taken in response to an allegation include investigation, documentation, and enforcement, as appropriate. If, at any time, the need for criminal investigatory capacity is required, (for example thefts and/or terrorist activity) contact the Local Law Enforcement Agency (LLEA) and/or the Vermont 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 Vermont Department of Health (Department) shall promptly notify the NRC Operations Center (301-819-5100) 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 G of SA-300.

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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 Vermont Radioactive Materials Rule.

1.3 Files

- 1.3.1 All allegation-related documentation is to be maintained in a secured allegation file (AF) in the Radioactive Materials Program.
- 1.3.2 Allegation files are padlocked when not in use and access is controlled and limited to Radioactive Materials Program Staff who are actively using the particular case file. Electronic allegation files shall be limited to RMP staff required to address the allegation and authorized access to the electronically secured space.

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1.4 Definitions

- 1.4.1 Agency: The Radioactive Materials Program (RMP) of the Vermont Department of Health (Department).
- 1.4.2 Allegation: A declaration, statement, or assertion of impropriety or inadequacy associated with Radioactive Materials Program (RMP) regulated activities, the validity of which has not been established. This

term includes all concerns identified by individuals or organizations regarding activities at a licensee's or applicant's facility. Excluded from this definition are inadequacies provided to RMP staff members by licensee's managers acting in their official capacity. Allegations regarding suspected improper conduct by an RMP 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 (AF): A secure hardcopy file that contains the documentation concerning the allegation, accessible to Radioactive Materials Program Staff and has a lock controlled by the RMP.
- 1.4.4 Allegor: An individual or organization that makes an allegation. The allegor may be known or anonymous.
- 1.4.5 Confidentiality: The protection of the allegor's identity. Every effort will be made to protect information that could directly or otherwise identify an individual by name and/or the fact that a confidential source provided such information to the RMP (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 Department procedures.
- 1.4.7 Investigation: For purposes of this procedure, an activity conducted by the program used to gather information related to the allegation by seeking confirmation to substantiate, evaluate and resolve an allegation.
- 1.4.8 Overriding Safety Issue: Events are initially screened by RMP staff to determine if an immediate threat to public health, safety, or security, warranting immediate action by the licensee to evaluate and address the issue is required. Events involving potential overriding safety issues will be addressed as soon as possible, while other events, not fully vetted, will be assessed for determination if an overriding safety issue is present.
- 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 padlocked when not in use and access is controlled and limited to Radioactive Materials Program Staff who are actively using the particular case file. Electronic allegation files shall be limited to RMP staff required to address the allegation and authorized access to the electronically secured space.
- 1.4.11 Willfulness: There are two types of willfulness:
 - a. Deliberate Misconduct: An intentional act or omission that a person

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knows, (1) would cause a violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Department; or (2) constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a license, applicant, contractor, or subcontractor.

b. 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 Radioactive Materials Program (RMP) Staff

- 2.1.1 Any RMP staff member may receive or recognize an allegation. Allegations may be communicated to the Department in person, by telephone, by e-mail or in print. An allegation also may be recognized by an RMP staff member in information provided in a public forum such as television, radio, newspaper, internet, or social media.

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RMP 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 the Radioactive Materials Program Manager (RMPM). This staff member is also responsible for maintaining confidentiality of the alleger and all other sensitive information. This information must be documented in attachments 3.1-1 to 3.1-5, and the attachments filed, both electronically and in allegation file created specifically for each allegation, with access restricted to RMP staff when evaluating the specific allegation.

2.2 Radiological Health Specialist (RHS)

- 2.2.1 When designated as the Lead Investigator (LI), the RHS coordinates with the RMPM and RCPD for the processing and disposition of an allegation. Throughout the investigation, the RHS is required to respond in a timely manner commensurate with the seriousness of the allegation and in consultation with the RMPM and 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.

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- 2.2.2 Prepares all records and reports concerning the allegation. Attachment 3.1-1 **Initial Allegation Contact Phone 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 Nuclear Regulatory Commission (NRC) and through the Nuclear Materials Event Database (NMED). The RHS is responsible for maintaining confidentiality of the alleged and any other information deemed sensitive and must discuss and provide a copy of Attachment 3.1-4 **Acknowledgement Letter to Alleged**.
- 2.2.3 Not all allegations will require immediate response. The RHS must use Attachment 3.1-1 **Initial Contact Log** to determine if the reported allegation requires immediate attention. The RHS in consultation with the RMPM and RCPD, will determine the required response to the allegation

2.3 Radioactive Materials Program Manager (RMPM)

- 2.3.1 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).
- 2.3.2 Informs the Radiation Control Program Director of the status of the investigation and recommends appropriate actions in response to allegations.
- 2.3.3 Instructs RMP staff on requirements of confidentiality and informs RMP staff who received original information and the LI of their responsibility to protect the confidentiality of the alleged and all other sensitive information within the allegation.
- 2.3.4 Upon being informed of an incident through an inspection or investigation of the allegation, the RMPM will respond in accordance with RMPP 3.2 *Incident Response*.

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2.4 Radiation Control Program Director (RCPD)

- 2.4.1 Reviews and approves recommendations made by the RHS and RMPM before actions are taken in response to allegations.
- 2.4.2 Authorizes the release of the identities of alleged or confidential sources as provided in section 3.2. after consultation with legal counsel.
- 2.4.3 Requests legal assistance, if required.

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3.0 PROCEDURE

3.1 Initial Contact

3.1.1 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 alleged on the Initial 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 contact's information in case questions arise. For e-mail, fax, regular mail, or any form of communication that may contain the alleged's identity, RMP staff must ensure that the identity is protected as indicated in section 3.2 of this procedure.

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3.1.2 If the allegation involves discrimination on the basis of age, sex, race, etc., refer the alleged to the State of Vermont Human Rights Commission (802) 828-1625. If the allegation requires criminal investigatory capacity, notify and request assistance from the LLEA and/or the Vermont State Police, and/or other federal agency such as the FBI, as appropriate. Examples that may require criminal investigatory measure would be an actual or attempted theft or threatened hijacking of a shipment or device containing radioactive materials, or an incident involving radioactive materials that are subject to 10 CFR 37.57 reporting requirements.

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3.1.3 If the alleged refuses to provide his/her name or other form of identification, then obtain as much information as possible and advise the alleged that he/she may contact the RMPM in 30 working days for information regarding the response to the allegation.

3.1.4 Address the issue of confidentiality with the alleged in accordance with section 3.2.

3.1.5 Inform the RMPM of the allegation and submit completed Attachment 3.1-3. The alleged's identity, or information that could reveal that identity, should be imparted to staff on a need-to-know basis and should not be revealed to personnel outside the Department. All documentation pertaining to the allegation shall be securely stored. Electronic allegation files are secured in a file folder dedicated to Radioactive Materials Program allegations. Hard copies, when not in use, are limited to the RMP staff in a padlocked secure file cabinet. See attachment 3.1-4.

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3.1.6 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 RMPM, RCPD, and the Department of Health Legal Division. If it is determined by a review with the RMP and the Legal Division that an allegation proves to be unsubstantiated (unconfirmed), in all situations notify the alleged of the findings of the allegation disposition.

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- 3.1.7 Allegations received by the Radioactive Materials Program staff, are given a sequential number (e.g., VTA-19-001) and an allegation file is created. Electronic documents are placed in files accessible only to RMP staff. Hardcopy records are scanned to electronic files where they will be secure.

3.2 Disclosure of Allegor's Identity and Sensitive Information

- 3.2.1 RMP will make all reasonable efforts to maintain the confidentiality of the alleged's identity and any other sensitive information; however, RMP cannot guarantee confidentiality. Disclosure of an alleged's identity may be made in accordance with 3.2.2 and 3.2.3 below. Indicate all information deemed sensitive as confidential. Prior to terminating initial contact (see 3.1 for the various methods to receive allegations) with an alleged, inform the alleged of the degree to which their identity can be protected, including the following:

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- The alleged's identity and sensitive and/or confidential information including that which would reveal that identity, will be shared with RMP staff on a need-to-know basis. Sensitive and confidential information that need to be protected include, but are not limited to the following:

- Birthdate
- Name
- Date and place of birth
- Social security number
- State issued drivers identification
- Medicare card
- Hospital medical record number
- Passport
- Mother's maiden name
- Biometric records
- Educational records
- Financial records

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- All sensitive information including information regarding the alleged'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.
- Allegation files are padlocked when not in use and access is controlled and limited to Radioactive Materials Program Staff who are actively

using the particular case file. Electronic allegation files shall be limited to RMP staff required to address the allegation and authorized access to the electronically secured space.

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- Inspection reports and correspondence with licensees, other agreement states, federal agencies (including NRC), other organizations, or individuals will contain no sensitive information or information that could lead to the identification of the alleged or confidential source.
- The alleged's identity and all sensitive information regarding the alleged's identity will not be disclosed outside of RMP, except under the conditions stipulated in section 3.2.2.

Commented [IW19]: NRC Comment 56.c.

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

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3.2.3 Obtain approval from the Radiation Control Program Director with consultation with the Environmental Health Division Director and Department of Health Legal Division prior to any mandated disclosure.

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3.2.4 If the allegation is received by any of the means indicated in section 2.1.1 and the alleged's identity is known, then inform the alleged by letter within 30 working 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 Alleged**.

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3.2.5 If requested by the alleged, inform the alleged that a non-disclosure statement (Attachment 3.1-2) is available and will be sent within 30 working days.

3.3 Controlling Allegations

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

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

3.3.2 Action by the RMPM.

3.3.2.1 Appoint an LI for the allegation.

3.3.2.2 Ensure an AF is opened for the allegation.

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

3.3.2.4 If the LI is not to perform an investigation, designate an individual to notify the inspection staff of the allegation and keep updated to the findings.

3.3.2.5 As stated in section 1.4.2, an allegation is a declaration, statement, or assertion of impropriety or inadequacy associated with Radioactive Materials Program (RMP) regulated activities, the validity of which has not been established. This term includes all concerns identified by individuals or organizations regarding activities at a licensee's or applicant's facility or in the public domain. Examples of allegations are:

- Potential wrongdoing by a licensee, staff, or contractor;
- A concern about a safety-conscious work environment problem at a facility;
- Deliberately falsifying records;
- Bypassing safety interlocks.

If multiple allegations are made, as described above, the RCPD and RMPM must determine the priority and broaden the scope to determine the extent of the situation.

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3.3.2.6 Any incident determined to have a significant impact on public health and/or safety will cause an immediate evaluation by the RMP. This evaluation may include the Radiation Control Program Director, a legal representative, and other members of the RMP staff. All discussion with a legal representative concerning suspected wrongdoing shall be documented, stamped confidential, and filed within the Allegation File and, if appropriate, the licensee's folder.

3.3.2.7 As necessary, brief the Radiation Control Program Director on the evaluation findings and recommendations.

Upon finding of an incident, immediately implement RMPP 3.2 *Incident Response*.

3.3.3 Evaluation by Lead Investigator

3.3.3.1 In consultation with the RMPM, 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 RMPM, the actions necessary for resolution of the allegation including an investigation, enforcement actions (per RMPP 2.5), 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 RMPM, 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 LI receives notification of the finding of an incident, implement RMPP 3.2 *Incident Response* and advise inspection staff of immediate actions taken to mitigate the incident and notify the RMPM.

3.4 Referral of Allegations to Licensees

The decision whether or not to refer an allegation to the licensee will be made upon the recommendation of the LI with the approval of the RMPM 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 regardless of the need to protect the identity of the allegor or the sensitive information, if release of the information is necessary to protect public health, safety, or security. In this instance, the 30-day waiting period (see subsection 3.4.3 following) will be waived if the allegor or confidential source cannot be reached in a timely manner for feedback regarding the request for information.

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3.4.1 Prohibitions on Referrals

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

- The identity of the allegor or confidential source who has requested protection of anonymity, and sensitive information, would be compromised by the information being released to the licensee.
- The evaluation of the allegation would be compromised because of knowledge gained by the licensee.
- The allegation is made against the licensee's management or those parties who would normally receive and address the allegation.

- The allegation is based on information received from a federal agency that does not approve of the information being released to the licensee.
- The alleged has previously addressed the allegation with the licensee with unsatisfactory results and/or the alleged objects to a referral.
- Allegation involving willfulness.
- Conflicts with public release criteria (overriding safety issue).

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3.4.2 Referral Criteria

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

- Could the release of information bring harm to the alleged or confidential source?
- Has the alleged or confidential source objected to the release of the allegation to the licensee?
- What is the licensee's history of addressing allegations?
- What is the likelihood that the licensee will effectively investigate, document, and resolve the allegation?
- Is there any other relevant reason to withhold the information?

3.4.3 Informing the Alleged

3.4.3.1 Prior to referring an allegation to a licensee, make all reasonable efforts to inform the alleged or confidential source of the intent to refer.

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

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

3.4.3.4 If the alleged or confidential source objects to the referral or does not respond to the letter within 30 calendar days, and the factors described in section 3.3.1 concerning the relative safety issue associated with the allegation, 3.3.2.5 concerning Department regulated activities, and 3.3.2.6 concerning impact on public health and safety have been considered, then refer the allegation to the licensee.

3.4.4 Referral Letter

3.4.4.1 Referrals should be made by RMPM or designated staff.

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

- A complete description of the elements of the allegation, excluding the identity of the alleged or confidential source, and any sensitive information that could result in the licensee identifying the alleged or confidential source.
- A statement that the referral is a result of an allegation against the licensee.
- A request to the licensee to thoroughly review the elements of the allegation in a manner that is objective, of sufficient scope, and of sufficient depth to resolve the allegation.
- A written report of the results of the review must be submitted to the Department within 10 working days of receipt by the licensee of the referral letter.

3.4.4.2 If the allegation was received in writing, then do not include a copy or the original written information from the alleged or confidential source in the written referral to the licensee, unless written permission from the alleged or confidential source has been obtained.

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

3.4.5 Licensee Response

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

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

- Was the evaluation conducted by an entity independent of the organization in which the alleged event occurred?
- Was the evaluator competent in the specific functional area in which the alleged event occurred?
- Was the evaluation of adequate depth to establish the scope of the problem?
- Was the scope of the evaluation sufficient to establish that the alleged event or problem was not a systemic defect?
- If the allegation was substantiated, did the evaluation consider the root cause and generic implications of the allegation?

- Was the licensee's corrective action sufficient to prevent, alleviate, or correct deficiencies in both the specific and generic instances, and in the short and long term?
- 3.4.5.3 If the licensee's response is adequate, then notify the licensee within 30 working days that the response is adequate and that no further action is required. The response will be incorporated in the closeout letter to the alleged 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 RMPP 2.5), etc.
- 3.4.5.5 Ensure a copy of both the licensee's response and the Department's response letter are entered into the AF.

3.5 Investigations

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

- 3.5.1 When conducting an investigation in response to an allegation, use all of the following techniques:
- Inspect the issue not the alleged or confidential source.
 - Avoid prejudice.
 - Do not communicate that the specific issue was raised by an alleged or confidential source (See subsection 3.4.4).
 - Take extensive notes and obtain copies of pertinent records, if possible.
 - Interview employees regarding relevant procedures and activities.
 - Verify any assertions made by the licensee.
- 3.5.2 If investigation of the allegation is determined to have a negative impact on public health and/or safety, immediately take action to mitigate the incident and immediately notify the RMPM (see RMPP 3.2 *Incident Response*).
- 3.5.3 Document the results of the investigation in a written report and submit to RMPM.
- 3.5.4 Ensure a copy of the investigation report is entered into the AF.
- 3.5.5 Send a closeout letter to the alleged, if possible, documenting the results of

the investigation.

3.6 Close Out

- 3.6.1 The RMPM shall determine when there is sufficient information to close out the allegation and indicate in the investigation report or licensee response letter satisfactory response.
- 3.6.2 The AF 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 RMPM, a letter should be forwarded to the alleged 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 LI 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 RMPP 3.2 *Incident Response*. Refer to RMPP 3.2 for follow up guidelines. Refer to RMPP 2.5 *Enforcement, Escalated Enforcement, and Administrative Actions* 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 Radiological Health Specialist should withhold the information from the licensee and elevate the concerns to the attention of the RMPM or RCPD while still onsite.

4.0 ATTACHMENTS TO RMPP 3.1

Attachment 3.1-1 Initial Contact Log

Attachment 3.1-2 Nondisclosure Statement

Attachment 3.1-3 Allegation Screening Form

Attachment 3.1-4 Confidential Information and Files

Attachment 3.1-5 Acknowledgement Letter to Allegor