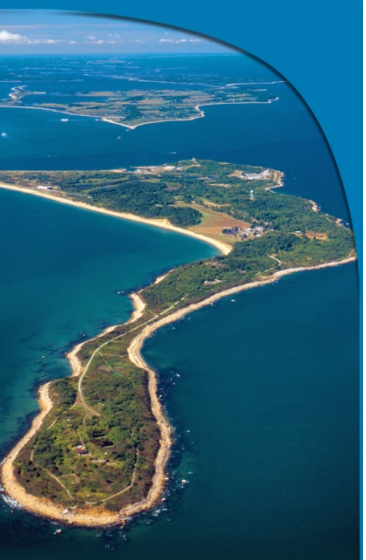

Plum Island Animal Disease Center

Personnel Reliability Assessment Board Charter

June 2020

Revision History

Rev. Date	Reason for Revision
June 15, 2020	Initial Release

Personnel Reliability Assessment Board Charter

1.0. Purpose

The purpose of this Charter is to ensure the Plum Island Animal Disease Center (PIADC) is compliant with the United States Code of Federal Regulations 9 part 121 (9 CFR 121) requirement that individuals with access to Tier 1 select agents are subject to ongoing assessment of personal reliability for continued access to select agents. To this end, PIADC has chartered a select agent Personnel Reliability Assessment Board (PRAB) to ensure the PIADC select agent program is in compliance with 9 CFR 121 requirements.

The purpose of the PIADC Personnel Reliability Assessment Board is to evaluate and disposition personnel incidents that risk the loss, theft or release of Tier 1 select agents. To ensure compliance with federal and PIADC Personnel Reliability Program (PRP) policies, regulations and management directives, the Personnel Reliability Assessment Board will review staff reliability incidents concerning actions by PIADC staff registered with the PIADC select agent program (DHS, ARS, APHIS and contractors) including, but not limited to, information regarding the behavior of registered staff at PIADC facilities or off-site.

2.0. Introduction

The mission of Plum Island Animal Disease Center (PIADC) is to protect the United States from the accidental or intentional introduction of transboundary or foreign animal diseases (FADs) such as foot-and-mouth disease virus (FMDv) that may harm livestock industries, food security and the economy. PIADC is a biosafety-level 3 laboratory facility and the only United States laboratory that can possess and manipulate live, viable FMD virus. The U.S. Code of Federal Regulations (CFR) 9 Part 121 classifies viable FMD virus as a Tier 1 select agent requiring strict security and personnel reliability procedures. Federal select agent regulations define requirements for an individual to access Tier 1 biological select agents and toxins (BSAT), including the requirement for enrollment in a personnel reliability program to help ensure the ongoing reliability of staff approved for access to Tier 1 select agents.

3.0. Scope

The scope of this Charter establishes the PIADC Personnel Reliability Assessment Board to ensure compliance with 9 CFR 121 and the PIADC Personnel Reliability Program. The PRP guidance and operating procedures are specified in the PRP program documents as defined in the current PIADC Personnel Reliability Plan.

4.0. Roles and Responsibilities

4.1 Plum Island Animal Disease Center

PIADC acknowledges its responsibility to administer a personnel reliability program to be compliant with Federal Select Agent Program (FSAP) guidelines. The FSAP regulates access to select agents and specifies personnel reliability requirements for continued access to select agents. The PIADC Personnel Reliability Assessment Board is a key tool to safeguard biosurety of the select agents and the reliability of personnel at PIADC.

4.2 **Personnel Reliability Assessment Board (PRAB)**: The PIADC PRAB is responsible for evaluating the reliability and trustworthiness of individuals to have continued access to select agents based on incidents of unacceptable behavior or other potentially disqualifying information. The PRAB provides the Responsible Official with recommendations concerning the continued access of reported individuals to biocontainment, select agents or select agent information.

The PRAB will be composed of the following PIADC staff members:

- Entity Official
- Responsible Official
- Director of Biorisk Management
- Certifying Official (Biosurety Officer)
- Reviewer (Security Manager)
- Biosafety Officer
- Other Subject Matter Experts, as needed

4.2.1 **Entity Official (EO):** The EO is responsible for overall implementation of the PIADC personnel reliability plan. The PIADC Director acts as the EO and has the authority to immediately restrict or deny access to biocontainment areas (select agent exclusion areas) based on behavioral, medical or administrative grounds. The EO has the authority to deny or reinstate biocontainment access. The RO has the authority to approve or deny select agent access at PIADC.

4.2.2 **Responsible Official (RO):** The RO is responsible for ensuring entity compliance with the select agent regulations and establishing and implementing procedures for conducting reliability assessments. The RO has the authority to immediately restrict or deny access to all BSATs based on behavioral, medical or administrative grounds. The RO is responsible for notifying the Federal Select Agent Program of permanent restrictions of personnel access to select agents and toxins through the submission of amendments to the entity's FSAP registration. The RO convenes and conducts the PRAB meetings, and receives recommendations from the PRAB for personnel actions regarding access to select agents. The RO has the ultimate decision making authority for approving personnel access to select agents or select agent information at PIADC. The RO makes the final decision with input from the PRAB.

4.2.3 **Director of Biorisk Management:** The Director of Biorisk Management is responsible for overall management and coordination of biorisk mitigations and actions at PIADC. The Director of Biorisk Management has authority to take action against any violation of PIADC policies or procedures which affect the safety and security of personnel, the PIADC mission and the environment.

4.2.4 **Certifying Official (CO):** The Biosurety Officer is an Alternate Responsible (ARO) that serves as the CO to ensure that personnel meet the requirements of PIADC's Personnel Reliability Program. In the absence of the RO, the CO/ARO has the authority to act on the behalf of the RO and convene the PIADC Select Agent Personnel Reliability Assessment Board (PRAB) when potentially disqualifying information is found, and notify FSAP of changes in personnel status.

4.2.5 **Reviewer (REV):** The Security Manager will serve as the Security Officer to monitor the reliability assessments for security concerns, to recommend law enforcement actions and to review warranted reliability mitigations through periodic audits. The Security Officer has the authority to immediately restrict or deny access to PIADC based on security violations or concerns.

The Security Officer provides an alternate and complementary perspective on the suitability assessment program and Tier 1 BSAT access decisions to the RO.

4.2.6 **Biosafety Officer:** The Biosafety Officer is responsible for overall biosafety at PIADC. The Biosafety Officer will provide determinations of biosafety violations, incident severity and risk assessments to guide PRAB decisions. In the absence of the RO and the CO, has the authority to act on the behalf of the RO and convene the PIADC Select Agent Personnel Reliability Assessment Board (PRAB) when potentially disqualifying information is found, and notify FSAP of changes in personnel status.

4.2.7 **Federal Officer :** A Federal Officer / Criminal Investigator is a member of the RAB as needed. The Federal Officer / Criminal Investigator is responsible for leading the investigation of any potential crimes at PIADC.

4.2.8 **Other subject matter experts:** Other subject matter experts may be called to participate in PRAB proceedings for specific incidents as appropriate, such as the ONL Biosurety Manager, the Occupational Health Physician, the senior manager for the staff member involved or human resources representative(s).

5.0. Policies and Procedures

Procedures for the PIADC Personnel Reliability Assessment Board to assess reports of potentially disqualifying behaviors or information to ensure the reliability of personnel with access to select agents and toxins, include:

5.1 Annual Review Meeting

The PRAB shall meet as necessary, but no less than once a year to conduct an annual meeting to review changes to FSAP regulations or PIADC policies pertinent to the personnel reliability program. At the annual review meeting, the PRAB shall review biosurety concerns within the scope of PRAB, including current status of corrective actions implemented over the previous 12 months. Prior to the annual review meeting, the Certifying Officer will submit an annual written report to the PRAB which will include an overview of PRAB incidents and actions over the previous 12 months. During the annual review meeting, the PRAB will consider if additional actions are necessary to address changes to PIADC personnel reliability risk or regulatory profile.

5.2 Investigation Procedures

A person's reliability to access to Tier 1 BSAT is defined as not displaying behaviors determined by the entity that would likely increase the risk of a theft, loss or release of a select agent or toxin. See 9 CFR 121.10(g) for a list of possible concerning behaviors. Individuals are responsible for their own actions, and for reporting actions of both themselves and other individuals that violate FSAP and PIADC PRP guidelines.

Reportable conditions, behaviors or other information must be brought to a supervisor as soon as possible after the incident, observation or awareness. Reporting procedures are contained in the PRP Policy, Section 10 "How Information Should be Reported."

5.2.1 For significant incidents, the PIADC RAB will meet and:

5.2.2 Determine whether the concern merits involvement of Human Resources, whereupon a member of the RAB shall refer the person reporting the concern to the appropriate HR representative as soon as possible.

5.2.3 If the concern involves a potential criminal violation, then the referral is made to the Federal Officer/ Criminal Investigator. For criminal investigations, the information is shared with the Security Manager, RO and EO. The Federal Officer/Criminal Investigator will consult with the DHS Privacy Office or other appropriate official before disclosing information involving investigations. The Federal Officer/Criminal Investigator in conjunction with the RO will determine the need to inform the FBI.

5.2.4 Inform the reporting individual of the provisions of these reliability assessment procedures;

5.2.5 Notify the supervisor of the reported individual(s);

5.2.6 The supervisor will inform the reported individual of the existence of the concern and the provisions of these reliability assessment procedures;

5.2.7 Refer the concern to the PIADC Security Department for investigation, if required;

5.2.8 The PRAB will meet with the supervisor, reporting individual or reported individual to obtain information and evidence, including the identity of any witnesses;

5.2.9 Attempt to obtain information from the identified witnesses, written or electronic documentation, photographs, video or audio recordings, online evidence, or other sources of factual information regarding the report;

5.2.10 Maintain appropriate documentation;

5.2.11 Disclose only appropriate information to others consistent with state and federal law;

5.2.12 Determine whether the reported individual is eligible for access to classified information or occupies a sensitive national security position, and if it creates a concern about the individual's continued eligibility for the position, in which case the information is provided to the Personnel Security Division in the DHS Office of the Chief Security Officer;

5.2.13 Make a recommendation to the RO whether access to biocontainment, BSATs or BSAT information should be restricted for the reported individual, pending further investigation or a final decision; The Security Manager will also evaluate the risk of the individual having access to PIADC property.

5.2.14 As needed, the RO may reconvene the PRAB to consider any new information, to perform a Whole Person Assessment of the individual, to determine if additional investigation is required, or to render a recommendation to the RO;

5.2.15 The RO makes a final decision regarding access of the reported individual to biocontainment, BSATs or BSAT information.

5.2.16 If the RO restricts reported individual access, or imposes requirements for continued access, then the reported individual has the right to appeal the decision. See Section 5.3.7 below.

5.2.17 If the RO finds for permanent restriction, then the reported individual has the right to appeal before the decision is communicated to the Office of National Laboratories and FSAP. See Section 5.3.7 below.

A PRAB quorum will require the RO and more than 50% of other board members to be present. A majority vote from the quorum is required for consensus on PRAB recommendations to the RO.

During this process, the PRAB will keep the reported individual's supervisor or administrator informed of the status of the concern and will seek input from the appropriate supervisor/administrator when implementing any corrective action. If the PRAB recommends that a personnel action or additional training is required, this will be referred to the reported individual's first level supervisor, or agency/company Human Resources Office, for action as appropriate. The supervisor will report back to the PRAB of the corrective actions taken.

5.3 Other considerations;

5.3.1 Corrective action may not be possible and may be superseded if the issue concerns a potential violation of the law.

5.3.2 False reporting: The purpose of the reliability assessment procedures is to guard Tier 1 BSAT from misuse by an insider. Discovery of the abuse of the peer-reporting process (e.g., as a means to discredit others without just cause) will be reviewed by the PRAB as a reportable concern in itself. Depending on the severity of the abuse, the person who conducts the false reporting could have their access to Tier 1 BSAT, or all access to BSAT, removed for a period of time or indefinitely.

5.3.3 Investigative Data: During the investigation, the PRAB will keep private the information gathered during the investigation to the extent required by state and federal law. The PRAB shall restrict sharing identifiable information about staff or others involved on an authorized need-to-know basis.

5.3.4 Summary Action: The RO may impose a summary suspension of access to BSAT agents or information prior to the completion of the investigation and resolution of a concern when, in the judgment of the simple majority of the PRAB, the reported individual's access to Tier 1 BSAT would constitute a threat to the safety and well-being of members of the PIADC community or the theft, loss, or release of a BSAT. If the reported individual's access to BSAT is suspended, the formal process should be completed within the shortest reasonable time period possible, normally not to exceed 10 working days. During the summary suspension, the reported individual may not have access to BSAT without written permission from the RO or ARO.

Note: The RO can restrict access to BSATs or BSAT information at any time to protect the security of personnel and agents.

5.3.5 PRAB Action: The amount of time needed to conduct an investigation will depend in part on the nature of the allegation and the evidence to be investigated (e.g., the number and/or availability of witnesses involved). The PRAB will provide notice of the outcome of the investigation or will advise the reported individual's management of the additional estimated amount of time needed for the investigation. Upon conclusion, the PRAB will notify the reported individual's supervisors of the results of the investigation. In the event the investigation reveals that a violation of select agent regulations or other inappropriate or unprofessional conduct (even if not unlawful) has occurred, the PRAB may make a recommendation for the suspension of access. The RO will consult with the DHS S&T Legal Counsel before taking any permanent actions.

5.3.6 Notification to Agricultural Select Agent Services: Self-reporting and "opt-outs" or voluntary removal (where defined periods of time are established) would not be reportable to the Federal Select Agent Program, whereas permanent restriction enforced by the RO, ARO or CO, or termination of access based on employment or need for access, will be reported to the Federal

Select Agent Program and an amendment to the entity's registration will be filed that reflects this change.

5.3.7 Appeal Process: If an individual believes that a determination is made in error, he/she may appeal to the RO in writing within 30 days from the date of the final decision. The individual is entitled to the information upon which the PRAB relied on in making its recommendation, to the extent the documents would be provided under the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act (3 U.S.C. 552a), as applicable. The written appeal must be directed to the Responsible Official. The appeal must state all the facts and include written documentation as to why the determination is in error. Original documentation, when appropriate, must be included and may not be returned to the reported individual. The denial of access to BSATs will remain in effect during the appeal process. The RO may convene the PRAB and may include The Office of National Laboratories (ONL) Director to review the appeal documentation. The RO has the ultimate decision making authority regarding access to select agents and can override recommendations made by the PRAB or make a final decision when there is no consensus among PRAB members. The individual will be informed of the final decision in writing within 30 days of receiving the appeal.

5.3.8 Restoration of access to Tier 1 BSAT: If a person has had access to Tier 1 BSAT suspended or removed, or if a person opted out of Tier 1 BSAT access and believes he/she should regain that access, the individual will appeal to the RO in writing and the PRAB shall make recommendations to the RO on restoring access for that individual.