Personnel
Reliability
Program

Plum Island
Animal Disease Center

Personnel Reliability Program

June 11, 2021

Revision History

Revision Date	Reason for revision
12/09/14	New signature not required. Administrative updates; added Revision History page, added attachment numbers, added "Sample" to each attached form to refer users to the electronic version, saved the document as a .pdf portfolio.
12/10/14	Signature required. Edited form; PDI Disclosure to Medical Reviewing Official
12/12/14	Signature not required. Administrative update to the PDI Disclosure Form with the approval from Dr. Barrett.
12/16/15	Updated formatting. Updated section 5. Responsibilities, Item E. PIADC Select Agent Personnel Reliability Assessment Board. Updated section 11. Investigation Procedures, Item F. Appeal Process. Updated all four forms; PIADC Personnel Reliability Program Enrollment Form, PIADC Ongoing Reliability Assessment Form, Potentially Disqualifying Disclosure (PDI) to Medical Reviewing Official, PIADC Interim Notification of PDI.
7/18/16	Revised PRP Enrollment Form and Annual Supervisor Assessment Form. Omitted the Ongoing Assessment Form. Modified the appeal section. Revised PIADC Pre-Access Reliability Assessment Guide
9/9/16	Removed the requirement for annual NCIC checks for the Ongoing Full Reliability Assessment.
10/9/18	Admin Update to address grammatical errors and restructured for clarity
7/30/20	Editorial changes throughout. Section 5.7 added Federal Officer as a Security Specialist role. Section 7 added Director of Biorisk Management to 'Entity Leadership', added definition of 'Select Agent Exclusion Areas'. Added Section 8.2.4 which established a 45-day deadline for personnel to complete overdue medical evaluations, or access to biocontainment will be revoked by EO until physical is complete. Updated Attachments E-H. Added Attachments I &J.
6/11/2021	Administrative review.

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1.0 INTRODUCTION

The mission of the Plum Island Animal Disease Center (PIADC) is to protect the United States from the accidental or intentional introduction of foreign animal diseases (FADs) that seriously harm livestock industries, food security or the economy. PIADC is a biosafety-level 3 laboratory facility and the only U.S. laboratory that can possess and manipulate foot-and-mouth disease virus (FMDv). The U.S. Code of Federal Regulations (CFR) 9 Part 121 classifies FMDv as a Tier 1 select agent requiring strict security and personnel reliability procedures. Federal select agent regulations specify the personnel reliability requirements necessary for an individual to access Tier 1 biological select agents and toxins (BSAT). Therefore, a personnel reliability program is required to help ensure the reliability of staff approved for access to Tier 1 select agents at PIADC. The purpose of this personnel reliability plan is to guard Tier 1 BSATs and Tier 1 BSAT security information from misuse by a PIADC insider.

2.0 POLICY

The policy of PIADC is to comply with all federal laws related to the security of the BSAT in the facility. Supervisors will ensure that staff members follow all relevant federal laws, regulations and guidelines associated with the security of BSAT. The PIADC Senior Leadership Group and senior management will provide support to achieve the personnel reliability program requirements stated in this document. The following PIADC policies and procedures are defined in this document:

2.1. Procedures for conducting a pre-access reliability assessment of persons requesting access to a Tier 1 BSAT and Tier 1 BSAT security information.

2.2. Procedures for coordination and communication between PIADC's responsible official (RO) and PIADC safety and security professionals to ensure the security of Tier 1 BSAT.

2.3. Procedures for the ongoing assessment of the reliability of personnel with access to a Tier 1 BSAT and Tier 1 BSAT security information. These procedures include:

- **2.3.1.** Procedures for self- and peer-reporting of incidents or conditions that could affect a staff member's ability to safely have access to or work with BSAT or to safeguard BSAT from theft, loss or release;
- **2.3.2.** Training requirements for employees with access to Tier 1 BSAT on PIADC policies and procedures for reporting, evaluation and corrective actions concerning the assessment of personnel reliability;
- **2.3.3.** Procedures for the ongoing reliability monitoring of individuals with access to Tier 1 BSAT;
- **2.3.4.** Procedures that limit access to Tier 1 BSAT and Tier 1 BSAT security information to only individuals who (a) are approved by the Health and Human Services (HHS) Secretary or Administrator, following a security risk assessment (SRA) by the Attorney General of the United States; and (b) who have had an PIADC-led pre-access reliability assessment; and (c) who are in compliance with PIADC's ongoing reliability assessment program;

2.3.5. Procedures that limit access to laboratory and storage facilities outside of normal business hours to only personnel specifically approved by the responsible official or designee; and

2.3.6. Procedures for approving visitors, their property and their vehicles to access registered space or other designated points of entry to PIADC buildings, facility or biocompound based on PIADC's site-specific risk assessment.

2.4. This Personnel Reliability Plan will be reviewed annually and revised as necessary.

3.0 PURPOSE

This document defines the PIADC policies, responsibilities and requirements for verifying the reliability of all persons who have access to Tier 1 BSAT and Tier 1 BSAT security information at PIADC. An ongoing personnel reliability assessment program is required for entities registered for Tier 1 BSAT per 9 CFR 121.11(f) (3), including:

3.1. Mechanisms for self and peer-reporting of behaviors of concern. Specifically, incidents or conditions that could affect an individual's continued ability to access, or work safely with, Tier 1 BSAT or to safeguard Tier 1 BSAT from theft, loss or release.

3.2. Ongoing monitoring of reliability for individuals with access to Tier 1 BSAT and Tier 1 BSAT security information.

3.3. Training on PIADC policies and procedures for reporting, evaluating and corrective actions concerning personnel reliability for employees with access to Tier 1 BSAT and Tier 1 BSAT security information.

United States 9 CFR 121 requires both pre-access and ongoing reliability assessments to reduce the risk of BSAT misuse by an "insider," and to ensure that individuals granted access to Tier 1 BSAT continue to merit access. The purpose of the pre-access reliability assessment is to evaluate the fitness, character and conduct of incoming personnel before access to Tier 1 BSAT is granted. Subsequent annual and ongoing whole-person assessments for each individual determine the overall reliability for continued access to Tier 1 BSAT and Tier 1 BSAT security information. A person's reliability to have access to Tier 1 BSAT is defined as not displaying behaviors determined by PIADC that would increase the risk of a theft, loss or release of BSAT. See 9 CFR 121.10(g) for a list of possible concerning behaviors.

This document defines PIADC's program to comply with these personnel reliability requirements in coordination with the PIADC *Visitor Control and Authorization Policy*, PIADC *Employee Physical Access Control Policy* and the PIADC *Security Plan*.

4.0 SCOPE AND AUTHORITY

This Personnel Reliability Plan applies to all personnel granted unescorted access to PIADC spaces registered with the Federal Select Agent Program (FSAP), known as select agent exclusion areas, including biocontainment and liquid waste decontamination space (Buildings 101, 102 and 111). These requirements apply to all PIADC DHS and USDA employees, and to contractors, but not necessarily to escorted visitors (e.g., for the purposes of maintenance, repairs, tours, audits and inspections).

PIADC is registered and inspected by the U.S. Department of Agriculture (USDA) Select Agent Program under Title 9 CFR Part 121, "Animals and Animal Products: Possession, Use, and Transfer of Select Agents and Toxins" to ensure compliance with all regulations.

Additional authorities and guidance can be found in (a) the PIADC Security Plan, (b) the PIADC Occupational Health Program, (c) the DHS Instruction Handbook 121-01-007 for the Department of Homeland Security Personnel Suitability and Security Program, and (d) The Federal Select Agent Program Suitability Guide (https://www.selectagents.gov/suit-intro.html).

5.0 RESPONSIBILITIES

5.1. 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 (select agent exclusion areas) based on behavioral, medical or administrative grounds. The Director will:

5.1.1. Designate the Responsible Official (RO) and provide support to the RO in the development and implementation of a reliability assessment program for persons with access to Tier 1 BSAT at PIADC.

5.1.2. Support the RO in the establishment of policies and procedures to execute an effective personnel reliability program. These policies and procedures will include:

5.1.2.1. Routine pre-access and ongoing reliability assessment protocols;
5.1.2.2. Policies that allow an individual to voluntarily "opt-out" of Tier 1 BSAT work (e.g., through coordination with human resources, supervisors);
5.1.2.3. Procedures for initial and recurring training of individuals on these policies;
5.1.2.4. Policies that address the temporary or permanent denial of access to Tier 1 BSAT; and
5.1.2.5. Policies and procedures to manage appeals of administrative actions that may result from reliability assessments.

5.1.3. Establish communication channels for the sharing of personnel reliability program information among relevant stakeholders and the RO.

5.1.4. Support the development of reporting mechanisms and support the RO in carrying out reporting tasks.

5.1.5. Support efforts to protect individuals from retribution for reporting adverse information that may ultimately be used against individuals in assessing their reliability.

5.1.6. Foster trust between individuals with access to Tier 1 BSAT and the PIADC Select Agent Personnel Reliability Assessment Board (PRAB, as defined in Section 5.5.).

5.1.7. Promote a culture of reliability, safety and security in all matters dealing with access to Tier 1 BSAT at PIADC.

5.2. Responsible Official (RO): The RO is responsible for ensuring compliance with the federal select agent regulations and establishing and implementing procedures for conducting reliability assessments and training using PIADC resources. The RO will:

5.2.1. Have the authority to immediately restrict or deny access to all BSATs and Tier 1 BSAT security information based on behavioral, medical or administrative grounds and

is ultimately responsible for notifying the Federal Select Agent Program of terminations to personnel access to select agents and toxins through the submission of amendments to the PIADC's registration.

5.2.2. Ensure that the USDA Animal and Plant Health Inspection Service (APHIS) and Centers for Disease Control and Prevention (CDC) Form 1 indicates those individuals that will have access to Tier 1 BSATs.

5.2.3. Participate in the development of the Tier 1 BSAT reliability assessment program and lead its implementation and administration.

5.2.4. Designate a Certifying Official (CO) and a Reviewer (REV).

5.2.5. Coordinate with other PIADC resources (e.g., safety and security personnel, agency legal counsel, human resources) to develop, implement and administer the Tier 1 BSAT reliability assessment program.

5.2.6. Determine who should have Tier 1 BSAT access based on need and Personnel Reliability Assessment Board recommendations.

5.2.7. Ensure that access to Tier 1 BSAT and Tier 1 BSAT security information is limited to individuals who have undergone a pre-access reliability assessment, are part of PIADC's ongoing reliability monitoring, and who have current Federal Select Agent Program approval (i.e., SRA clearance) to access select agents or toxins.

5.2.8. Ensure that appropriate annual training is completed and documented prior to the approval or continuance of access to Tier 1 BSAT and Tier 1 BSAT security information.

5.2.9. Promote a culture of reliability, safety and security in all matters dealing with access to select agents and toxins.

5.2.10. Annually review the legal prohibitions and restrictors for individuals who are working with Tier 1 BSATs and Tier 1 BSAT security information.

5.2.11. Determine and document staff need to access to Tier 1 BSAT outside normal work hours (6 a.m. to 6:45 p.m.).

5.2.12. Ensure training is conducted on "Insider Threat Awareness" and the PIADC "Personnel Reliability Plan."

5.3. Certifying Official (CO): The Biosurety Officer (Alternate Responsible Official) will serve as the CO to ensure that personnel meet the requirements of PIADC's Personnel Reliability Program. In the absence of the RO, the CO has the authority to act on the behalf of the RO. The CO will:

5.3.1. Prepare the APHIS/CDC Form 1 indicating those individuals granted access to Tier 1 BSAT and Tier 1 BSAT security information.

5.3.2. Manage enrollment into the PIADC Personnel Reliability Program.

5.3.3. Gives final approval for access to Tier 1 BSATs and Tier 1 BSAT security information.

5.3.4. Convene the PIADC Select Agent Personnel Reliability Assessment Board (PRAB) when potentially disqualifying information is found.

5.3.5. Participates in the development of the Tier 1 BSAT reliability assessment program and assists with its implementation and administration.

5.3.6. Documents that access to Tier 1 BSAT is limited to individuals who have undergone a pre-access reliability assessment, are part of PIADC's ongoing reliability monitoring, and who have current Federal Select Agent Program approval (i.e., SRA clearance) to access BSAT.

5.3.7. Documents and maintains appropriate annual training including "Insider Threat Awareness" and the PIADC "Personnel Reliability Program" for each individual and ensures that training is completed prior to the approval or continuance of access to Tier 1 BSAT and Tier 1 BSAT security information.

5.4. Reviewer (REV): The Security Manager will serve as the REV for PIADC. The REV will monitor the reliability assessment program and review warranted reliability actions. The REV is a direct report of the Director of Biorisk Management. The Director of Biorisk Management reports to the EO.

5.4.1. The REV has the authority to immediately restrict or deny access to PIADC based on behavioral or administrative grounds.

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

5.4.3. The REV will protect and evaluate the personal information required to administer a suitability assessment program.

5.4.4. Establish communication channels for the sharing of reliability program information among relevant stakeholders and the CO.

5.4.5. Support the development of reporting mechanisms and support the RO in carrying out reporting tasks.

5.4.6. Support efforts to protect individuals from retribution for reporting adverse information that may ultimately be used against individuals in assessing their reliability.

5.4.7. Foster trust between individuals with access to Tier 1 BSAT and the PIADC Select Agent Personnel Reliability Assessment Board (PRAB, as defined in Section 5.5.).

5.4.8. Promote a culture of reliability, safety and security in all matters dealing with access to Tier 1 BSAT at PIADC.

5.5. PIADC Personnel Reliability Assessment Board (PRAB): The PRAB is responsible for evaluating the reliability and trustworthiness of an individual to have continued access to BSAT and Tier 1 BSAT security information when potentially disqualifying information becomes known. If the board recommends a personnel action (suspended or terminated access) or additional training, the RO will refer the action to the personnel's first level supervisor or agency/company Human Resources Office for action as appropriate. The supervisor will report back to the RO of the actions taken. See **Attachment I**: *Personnel Reliability Assessment Board Charter*.

The RO has the ultimate decision making authority for granting access to BSAT or BSAT information. The RO can override recommendations made by the PRAB or make a final decision when a consensus opinion among PRAB members is not reached. The PRAB will be composed

of the following members: EO, RO, Biosafety Officer, CO, REV and The Director of Biorisk Management. Other subject matter experts, such as the ONL Biosurety Manager, Occupational Health Physician or Security Specialist, may participate as PRAB members as needed. The senior manager for the reported staff member(s) and the human resources representative, as appropriate, may participate in PRAB meetings. The RO will consult with S&T council prior to taking permanent actions.

5.6. Individuals with Access to Tier 1 BSAT: Individuals with access to Tier 1 BSAT and Tier 1 BSAT security information have a responsibility to monitor their own reliability as well as the reliability of their colleagues with access to Tier 1 BSAT. Individuals with access to Tier 1 BSAT and Tier 1 BSAT security information will:

5.6.1. Report to their supervisors or a member of the PRAB any issues that could have an adverse impact on their performance, reliability or safety while performing Tier 1 BSAT duties. (See Table 1: SRA Prohibitions and Restrictors).

5.6.2. Follow PIADC policies and procedures for the safe and secure use of Tier 1 BSAT and comply with the local and federal select agent regulations.

5.6.3. Participate in and understand training associated with the personnel reliability assessment program.

5.6.4. Report any situations that may affect the safety and/or security of Tier 1 BSAT.

5.6.5. Respect the privacy and confidentiality of colleagues and support a work environment where direct or indirect retribution is not tolerated.

5.6.6. Have the right to appeal a negative personnel reliability assessment decision.

5.6.7. Self-report arrests to the PIADC Security Office as soon as possible.

5.7. Security Specialist(s): The Security Specialist or Federal Officer is responsible for leading the investigation of any potential crimes at PIADC. The Security Specialist or Federal Officer is a member of the PRAB as needed.

6.0 RECORDS

All records and databases that are part of the PIADC Personnel Reliability Program must be accurate, have controlled access and be authenticated. Records that must be maintained as part of the PIADC Personnel Reliability Program include, but are not limited to, Program Enrollment Form, Communications related to self, peer and incident reporting, ongoing assessments, communications regarding status updates and PRAB decisions and inquiries. Records must be maintained by the PIADC Biosafety and Select Agent Program Office (BSAPO) for a minimum of three years, and be promptly produced upon request by the Federal Select Agent Program. Records can be destroyed after three years in accordance with 9 CFR 121.

Record corrections will be made by using a single-line strike through and be dated and initialed by the person making the change. This Personnel Reliability Program document will be reviewed annually, and edited as needed according to the PIADC controlled document procedures.

7.0 DEFINITIONS

Access to Tier 1 BSAT: An individual will be deemed to have access to Tier 1 BSAT at any point in time if the individual has possession or ability to gain possession of a Tier 1 BSAT (e.g., ability to carry, use or manipulate) (See 9 CFR 121.10(b)) or Tier 1 BSAT security information.

Bioterrorism Security Risk Assessment Form (FD-961 Form): The FBI Application for Security Risk Assessment that assists the FBI's Criminal Justice Information System (CJIS) with performing an electronic records check to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins, and/or exhibits a statutory restrictor that would either prohibit or restrict access.

BSAT: Biological select agents and toxins as listed in Title 9 CFR Part 121.

Entity: Refers to PIADC.

Entity Leadership: Includes all PIADC officials who have responsibilities for science, safety and security at PIADC including the Senior Leadership Group, Director of Biorisk Management, RO, Alternate Responsible Officials, Biosurety Officer, Biosafety Officer and Security Manager.

Entity Official: The PIADC Center Director or his/her designee.

Federal Select Agent Program (FSAP**):** The Federal Select Agent Program includes regulations under 9 CFR Part 121, 7 CFR Part 331 and 42 CFR Part 73.

Agricultural Select Agent Program (AgSAS): The USDA APHIS's Agricultural Select Agent Program part of the select agent regulations, 9 CFR Part 121.

Individuals with Access to Tier 1 BSAT: Individuals with access to Tier 1 BSAT includes access to Tier 1 select agent exclusion areas, Tier 1 BSAT and Tier 1 BSAT security information.

Ongoing Full Reliability Assessment: After the initial pre-access reliability assessment, a standardized procedure (see Section 8.2) used during an individual's tenure to determine if an individual displays behaviors determined by the entity that would increase the risk of a theft, loss, or release of a select agent or toxin.

Personnel Reliability: A process or status by which an individual is determined not likely to display behaviors that would increase the risk of a theft, loss or release of BSAT or Tier 1 BSAT security information.

PIADC Suitability Background Investigation: Positions that entail unescorted access to Tier 1 BSAT and Tier 1 BSAT security information at PIADC are considered high-risk, public trust positions. Accordingly, a final suitability determination based upon a Background Investigation (BI) conducted by the U.S. Office of Personnel Management must be verified by the PIADC Security Office prior to granting unescorted access. A Periodic Reinvestigation at the same level of BI must be conducted every five years. However, backlogs of Background Investigation cases are often reported by the Office of Personnel Management National Background Investigation Bureau which delay PIADC staff clearances and leave many personnel pending reinvestigation completion, some in excess of a year. As a result, and in order to assure staff can accomplish mission requirements, PIADC Security Office, with Center Director and Responsible Official concurrence, has permitted ongoing

unescorted biocontainment access as long as the investigation is in process. Previously-approved staff with a re-investigation in process are considered PRP compliant.

Pre-Access Reliability Assessment: The evaluation of an individual using a standardized procedure (see Section 8.1) to determine if the individual displays behaviors determined by the entity that would increase the risk of a theft, loss, or release of BSAT or Tier 1 BSAT security information. This assessment is completed by the hiring supervisor and/or human resources, the PIADC Security Office and the Certifying Official.

Principal Investigator (PI): An individual designated by the entity to direct a project or program, and who is responsible for the scientific and technical direction of that project or program.

Security Risk Assessment (SRA): An electronic records check performed by the FBI's CJIS to determine if an individual who has been identified by a registered entity as having a legitimate need to access BSATs and Tier 1 BSAT security information exhibits one of the statutory restrictors that would either prohibit or restrict access.

Security Specialist / Federal Officer: A federal employee reporting to the DHS S&T Office of Chief Security Officer. Responsible for investigations of potential criminal activity and law enforcement at PIADC.

Select Agent Exclusion Areas: **S**paces within the biocontainment and liquid waste decontamination buildings (Buildings 101, 102 and 111) that are registered with the Federal Select Agent Program.

Select Agent Regulations: Refers to Title 7 CFR Part 331; Title 9 CFR Part 121; and Title 42 CFR Part 73.

Select Agents and Toxins: BSAT listed in Sections 3 and 4 of the select agent regulations.

Summary Suspension: A temporary suspension of access to biocontainment, or BSAT or BSAT security information prior to the completion of an investigation and resolution of a concern. This action is typically taken when, in the judgment of the PRAB, the alleged behavior of a reported individual would constitute a threat to the safety and well-being of members of the PIADC community or the theft, loss or release of BSAT.

Personnel Reliability Assessment Program: A combination of pre-access and ongoing reliability assessment practices, in conjunction with comprehensive and consistent review mechanisms, to determine the reliability of personnel to safely access Tier 1 BSAT and Tier 1 BSAT security information, and allowing individuals to report risks and threats to safety and security concerning Tier 1 BSAT to PIADC leadership and the Federal Select Agent Program.

Tier 1 BSAT: A subset of BSAT designated in the select agent regulations as "Tier 1" because these agents and toxins present the most significant risk for causing mass casualties or deleterious effects on the economy, critical infrastructure or public confidence.

"Whole Person" Assessment: A balanced assessment of an individual evaluating both positive and negative qualities of credibility and reliability in the context of an established behavioral baseline that considers the environments in which that person works, lives and socializes and any mitigating circumstances.

8.0 PROCEDURES FOR PRE-ACCESS RELIABILITY ASSESSMENT AND ONGOING MONITORING

The following personnel reliability assessment procedures are part of PIADC's select agent security plan that involves Tier 1 BSAT. These procedures cover pre-access reliability assessments and ongoing access reliability assessments.

8.1. Pre-Access Reliability Assessments

Individuals must meet all of the requirements in this section prior to being granted escorted access to Tier 1 BSAT and Tier 1 BSAT security information. These checks and the final decision are documented on the PIADC Personnel Reliability Enrollment Form.

8.1.1. Human Resources

Collection and verification of information from the person needing Tier 1 BSAT access for:

8.1.1.1. Work history
8.1.1.2. Educational history
8.1.1.3. Professional license(s) / certification(s)
8.1.1.4. References

(Note: This is not required for individuals that are not employed by PIADC but have a need for access based on their job function.)

Visitors from other entities with a current approved Security Risk Assessment who are added to PIADC's registration are excluded from this requirement.

8.1.2. Federal and Agency Security Checks

A successful pre entry-on-duty approval (by U.S. Department of Homeland Security Personnel Security Division) or Special Agency Check (by APHIS and USDA's Agricultural Research Service) (Attachment D) enables escorted access. Note: Unescorted access requires successful adjudication of a full Background Investigation (BI) conducted by the FBI (see Section 8.2.1).

8.1.2.1. A National Crime Information Center (NCIC) database check is acceptable to enable escorted access for visitors.

8.1.3. PIADC Select Agent Program Office

8.1.3.1. PIADC select agent program office reviews for completeness the FBI Security Risk Assessment Form FD-961 submitted by applicants before sending to the FBI's CJIS.

8.1.4. PIADC Supervisor or Designee

8.1.4.1. Ensures that work history and reference checks are conducted.
8.1.4.2. Interviews the Applicant and the Applicant's references using the PIADC Guidance for Supervisor Assessment of Personnel for Enrollment into PIADC Personnel Reliability Plan.
8.1.4.3. Evaluates the applicant's work history and/or performance and the need to

grant access to BSAT and BSAT security information for PIADC employees and visitors.

Note: A work history and performance evaluation is not required for individuals that are not employed by PIADC but have a need to access select agent exclusion areas to perform temporary work duties.

8.1.5. PIADC Occupational Health

After a tentative job offer, an Occupational Health Evaluation will be conducted according to the PIADC Occupational Health Program, including;

8.1.5.1. Pre-employment and random drug testing.

8.1.5.2. Pre-employment medical evaluation for applicants based on approved medical Standards. See **Attachment J**: *Occupational Health Supervisor Physical Exam Form*.

8.1.5.3. The applicant will complete PIADC Potentially Disqualifying Information Disclosure to Competent Medical Authority Form and provide it to the medical authority during the evaluation. This form will be filed in the applicant's confidential medical file and will not be provided to the CO.

8.1.5.4. Visitors are exempt from enrollement in the Occupational Health component.

8.1.6. Biosurety Officer (For visitors from other registered entities only)

8.1.6.1. Obtains a letter from the visitor's RO with information required to add them to PIADC's Select Agent Registration as a visitor and,

Obtains a memo from the visitor's RO, PI or supervisor stating that they believe this person merits access to Tier 1 agents based on need and previous performance.

8.1.7. Reviewing Medical Officer (Occupational Health Physician)

8.1.7.1. Specifies examination protocols appropriate to job hazards in compliance with applicable laws and standards.

8.1.7.2. The Reviewing Medical Officer is Board-certified in occupational medicine, is aware of the hazards in the facility, and has been provided the essential functional duties of each position at PIADC.

8.2. Ongoing Personnel Reliability Assessments

Staff with access to Tier 1 BSAT and Tier 1 BSAT security information must undergo ongoing full reliability assessments. These assessments include the following and are documented on the PIADC Annual Supervisor Assessment Form, and the PIADC Potentially Disqualifying Information Disclosure to Competent Medical Authority Form. At any time, a supervisor or medical or security authority may submit notification to the CO of Potentially Disqualifying Information.

8.2.1. A full Background Investigation in accordance with the Office of Personnel Management criteria consists of a National Agency Check, employment checks, education checks, residence checks, reference checks and law enforcement checks. The full BI also includes personal interviews with the individual and other sources and a credit history check and recurs every 5 years. Visitors are not required to have a full

BI for escorted access, but must have an NCIC check performed annually in order to have access to select agent exclusion areas.

8.2.2. A FBI Security Risk Assessment performed by the FBI's CJIS every three years, on behalf of the Attorney General of the United States.

8.2.3. Ongoing self- and peer-reporting of incidents or conditions that could affect an individual's ablity to access or work safely with Tier 1 BSATs or BSAT security information to prevent the theft, loss or release of BSAT by monitoring an individual's reliability (see Attachment B).

8.2.4. Compliance with the PIADC Personnel Reliability Program requires an annual Occupational Health Medical Evaluation for all personnel granted access to BSAT or BSAT security information. PIADC staff have 45-days after expiration of the previous annual evaluation to complete the next annual medical evaluation through the Federal Occupational Health clinic (ext. 3455). Individuals who have not completed a new medical evaluation within 45-days of the expiration date will be non-compliant with the PIADC PRP and their access to biocontainment will be revoked by the EO until successful completion of the medical evaluation. The medical evaluation is not required for vistors. See **Attachment J**: *Occupational Health Supervisor Physical Exam Form*.

8.2.5. Annual supervisor technical, biosafety, and security performance evaluations; and annual supervisor review of a person's duties and responsibilites to determine if access to Tier 1 BSAT is still required.

8.2.6. Training on entity policies and procedures for reporting, evaluations, and corrective actions concerning the assessment of personnel reliability of employees with access to Tier 1 BSAT and Tier 1 BSAT security information.

8.2.7. An ongoing reliability assessment to identify statutory prohibitions and restrictors for individuals with access to Tier 1 BSAT and Tier 1 BSAT security information. If any of the statutory prohibitions (see Attachment A) are recognized for an individual, that person's access to all BSAT and BSAT security information must be removed and the Agricultural Select Agent Program must be notified according to regulations.

8.2.8. Ongoing assessments of personnel by PIADC supervisors through annual review of staff performance and history of compliance with the select agent regulations to determine continued reliability for access to Tier 1 BSAT and Tier 1 BSAT security information.

8.2.9. Random drug testing administered by the PIADC on-site clinic with testing performed by a contracted laboratory. Results of testing will be reported to Agency Managers and the CO. Visitors are exempt from this requirement.

9.0 REPORTING

Reportable Conditions, Behaviors, or Other Reportable Information

Individuals shall share any reportable information and behaviors (see Attachment B) with their Entity Leadership (supervisors, RO, CO, the Director) regarding concerns for the well-being of themselves and others, or the safety and security of the entity, or Tier 1 BSAT and Tier 1 BSAT security information.

Reportable offenses to report to supervisors and PIADC Security Office include:

- Unlawfully carrying weapons (or carrying weapons in violation of institutional rules).
- Providing false information on applications or other formal institutional documentation.
- Unauthorized work performed by individuals in the facility.
- Arrests or criminal charges.

Other reportable circumstances, including self-reporting, include:

- The inability of an individual to perform his/her job in a safe and secure manner (e.g., performance of duties declines markedly, significant increase in distraction or mistakes, increase in risk-taking behaviors);
- Significant changes in behavior, attitudes, demeanor or actions impacting the individual's ability to perform his/her job in a safe and secure manner (e.g., increasingly withdrawn, significant and prolonged deterioration in appearance, unjustified anger or aggression, unexplained absences, signs of alcohol/drug abuse, criminal activity);
- Stated or implied threats to colleagues, institutions, the security of Tier 1 BSAT, the well-being of laboratory animals, or the general public;
- Non-compliance with federal select agent regulations or PIADC policies;
- Any information that causes an individual to have concerns about his or her own ability to perform a job safely and securely;
- Any circumstances that appear suspicious (e.g., laboratory work that does not correspond to official project work or goals, requests for security or laboratory information without justification, acts of vandalism or property damage, criminal mischief, attempts to gain unauthorized access for friends or colleagues, felonious behavior).

Examples of concerning workplace behaviors include:

- Unjustified anger or aggression;
- Sabotaging colleagues' research;
- Physical violence;
- Acts of vandalism or property damage;
- Laboratory work that does not correspond to an official project;
- Security breaches, accessing computer/e-mail passwords, stealing;
- Mention of plans to commit acts of violence on persons or property;
- Cruelty to animals.

10.0 HOW INFORMATION SHOULD BE REPORTED

10.1. Self-Reporting: Persons who are approved for access to Tier 1 BSAT and Tier 1 BSAT security information who think their access to Tier 1 BSAT should be suspended because of a need for a prolonged absence from work, a change in physical or mental health status, or another viable reason should report concerns to their supervisor. If the supervisor is unavailable, the person can report concerns to the Entity Official, RO or CO. Initial reporting can go through supervisors but all reportable circumstances and incidents must ultimately be reported to the RO. PIADC allows for voluntary "opt-out" self-reporting, where an individual can opt-out of access to Tier 1 BSAT for a defined period of time due to illness, leave or other personal needs. The

RO will coordinate with the self-reporting individual and use appropriate discretion authority in these situations. These types of "opt-outs" will not be reported to the Select Agent Program unless the RO has concerns. Note: A change in a person's medical condition (e.g., pregnancy, immune-compromised, mental health status) should be reported to the Occupational Health Clinic. The RO or any member of the PRAB may bring concerns to the PRAB for review.

10.2. Peer-Reporting: If a person suspects that a coworker who has access to Tier 1 BSAT and Tier 1 BSAT security information is behaving in a way that increases the risk that Tier 1 BSAT will be lost, stolen, or released, that person must immediately tell their supervisor, RO, ARO or CO. All staff will be trained on specific types of behavior that should be reported. The supervisor must immediately notify the RO to consider review of the report by the PRAB.

10.3. Anonymous Reporting: Persons may anonymously report concerns about inappropriate behavior regarding any BSAT through the mailbox in the Select Agent Program Office or the EO's Suggestion Box in the lobby of Building 100. Concerns reported by this method will be forwarded to the RO and the CO**.**

10.4. Mandatory Reporting: Individuals are required to report any arrests for criminal charges to the PIADC Security Department as soon as possible.

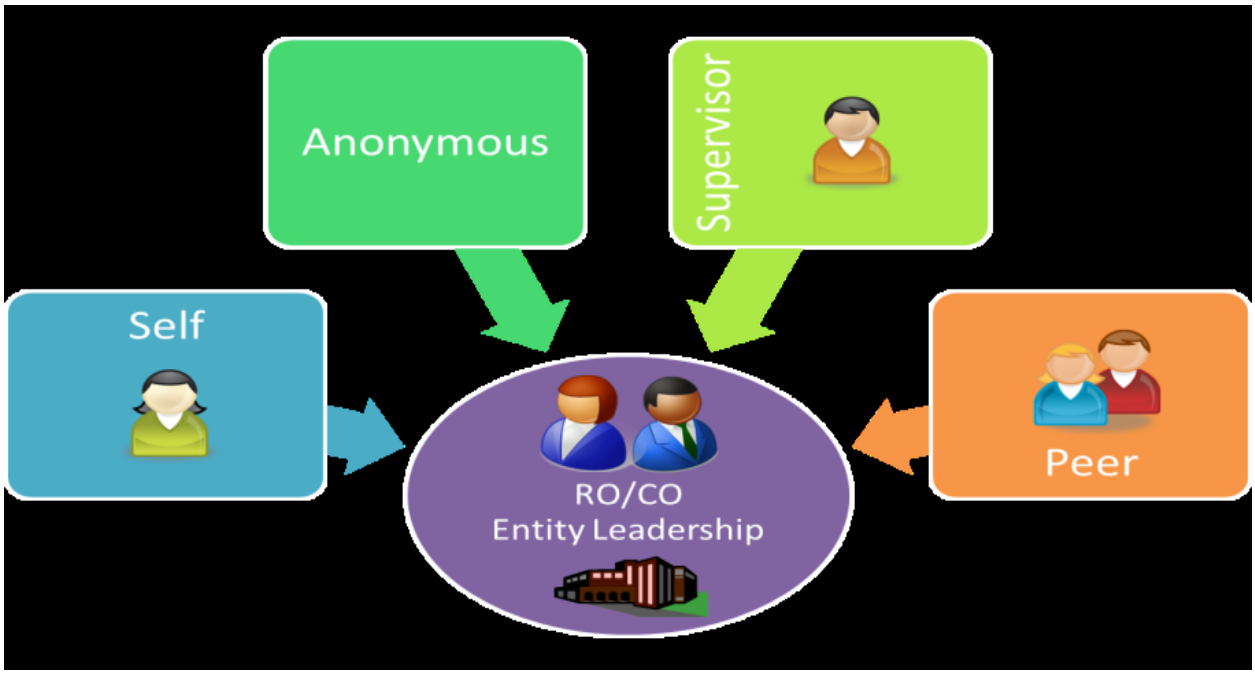


Figure 1. Example of Tier 1 BSAT reporting options for the communication of concerning behaviors, incidents, conditions, or other information.

11.0 INVESTIGATION PROCEDURES

Reportable conditions, behaviors or other reportable information must be brought to a supervisor as soon as possible after the incident or observation follow the reporting procedures above in Section 10 "How Information Should be Reported." If the PRAB is activated, then the investigation will follow the procedures described in the PIADC Personnel Reliability Assessment Board Charter, **Attachment I**.

11.1. For major concerns, the RO or CO will convene the PIADC PRAB and:

11.1.1. The PRAB will recommend to the RO whether the concern is one that should be processed through the personnel process (Human Capital); if appropriate, a member of the PRAB shall refer the person reporting the concern to the recommended procedure as soon as possible. If the concern refers to any potential criminal violation, then the referral is made to the Security Specialist (Criminal Investigator) for investigation. In this case, the information is shared with the Security Manager, RO and EO. The Security Specialist (Federal Criminal Investigator) will consult with the Privacy Office or other appropriate official before disclosing information involving investigations; Inform the reporting individual of the provisions of the reliability assessment procedures and provide a copy of the reporting procedure;

11.1.2. Inform the person for whom the concern is brought of its existence;

11.1.3. Refer the concern to the PIADC Security Department or PRAB SMEs for investigation;

11.1.4. Obtain available information and evidence, including the identity of any witnesses, from the reporting individual and the respondent;

11.1.5. Attempt to obtain information from the identified witnesses;

11.1.6. Maintain appropriate documentation;

11.1.7. Disclose appropriate information to others consistent with state and federal law;

11.1.8. Consider whether the individual for whom the information was reported is eligible for continued 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; and

11.1.9. Perform a Whole-Person Assessment of the individual, if deemed necessary.

During this process, the PRAB will keep the supervisor/administrator informed of the status of the concern and will seek input from the appropriate supervisor/administrator when implementing corrective action.

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

11.2.1. **False reporting:** The purpose of the reliability assessment procedures is to guard Tier 1 BSAT or BSAT security information from misuse by a PIADC 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 itself. Depending on the severity of the abuse, the person who commits the false reporting could have their access to Tier 1 BSAT and Tier 1 BSAT security information, or all access to BSAT, removed for a period of time or indefinitely.

11.2.2. **Investigative Data:** During the investigation, the PRAB will keep private the information gathered during the investigation to the extent permitted by state and federal law. The PRAB shall exercise due care in sharing identifiable information about staff or others involved.

11.2.3. **Summary Action:** The RO or CO may impose a summary suspension of access to BSAT or BSAT security information pending completion of the investigation and resolution of a concern when, in the judgment of the RO or CO, the reported individual's alleged behavior would constitute a severe threat to the safety and well-being of members of the PIADC community or the theft, loss or release of BSAT. If the alleged individual's access to Tier 1 BSAT and Tier 1 BSAT security information is suspended, the formal PRAB process should be completed within the shortest reasonable time period, usually within 10 working days. During the summary suspension, the accused individual may not have access to Tier 1 BSAT and Tier 1 BSAT security information without written permission from the RO or CO.

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

11.2.4. **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 parties' management of the additional estimated amount of time needed for the investigation. Upon conclusion, the PRAB will notify the reported indiviual's supervisor(s) of the results of the

investigation and required actions. 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 will make a recommendation for the suspension of access to the RO.

11.2.5. Notification to Agricultural Select Agent Program: Self-reporting and "opt-outs" voluntary removal (where defined periods of time are established) would not be reportable to the Select Agent Program, whereas denial or suspension enforced by the RO or CO, and termination of access based on employment or need for access, will be reported to the Federal Select Agent Program and an amendment will be filed that reflects this change.

11.2.6. Appeal Process: If an individual believes that a determination is made in error, he/she may appeal 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 determination, 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 delivered to the Responsible Official. The appeal must state all the facts and include documentation as to why the determination is in error. Original documentation, when appropriate, must be included and will not be returned. The denial of access to select agent and toxins will remain in effect during the appeal process. The RO will convene the PRAB and include The Office of National Laboratories (ONL) Director to review the appeal documentation. The EO has the authority to only reinstate biocontainment access, and does not have the authority to grant or deny access to BSAT or BSAT security information at PIADC. The RO has the ultimate decision making authority regarding BSAT access and can override recommendations made by the PRAB, or make a final decision when no consensus is reached among PRAB members. The reported individual will be informed of the final decision in writing within 30 days of receiving the appeal.

11.2.7. Restoration of access to Tier 1 BSAT: If a person has had access to Tier 1 BSAT and Tier 1 BSAT security information removed, or if a person has opted out of having Tier 1 BSAT access and believes he/she should regain that access, the PRAB shall recommend if that person may have access restored.

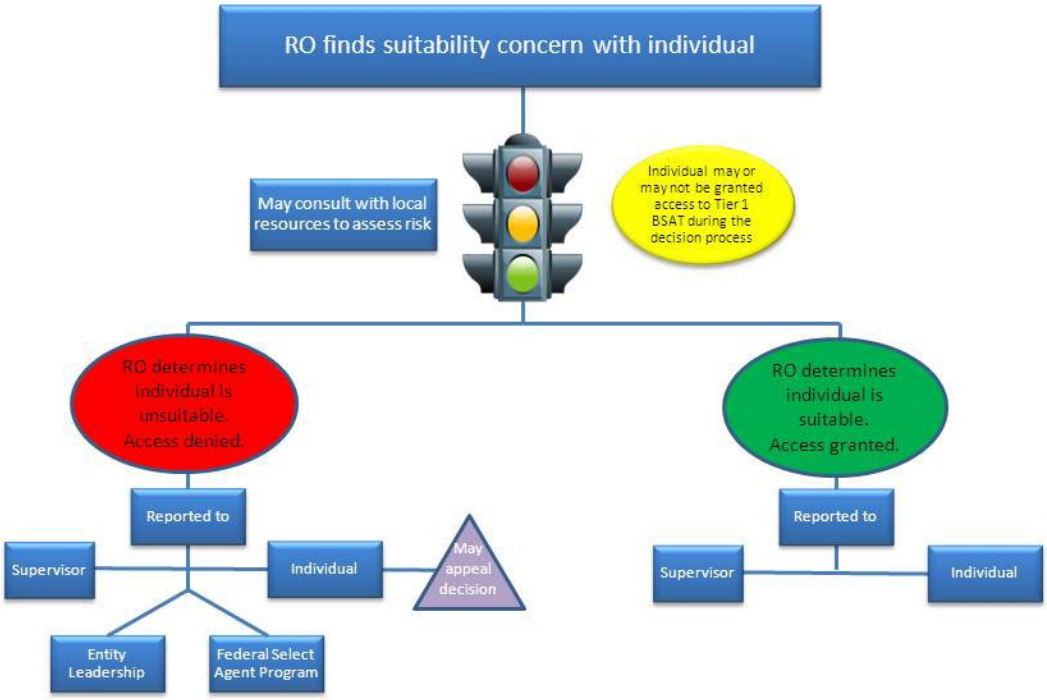


Figure 2. Reporting procedures for a reliability concern identified during ongoing monitoring of an individual with access to Tier 1 BSAT and Tier 1 BSAT security information.

12.0 TRAINING

The primary focus of the annual Tier 1 BSAT training is (a) to promote insider threat awareness and (b) to inform individuals with approved access to Tier 1 BSAT and Tier 1 BSAT security information of the policies and procedures contained in the PIADC personnel reliability assessment program.

12.1. The PIADC Select Agent Program Office is responsible for ensuring training is conducted and includes the following topics in addition to any other regulatory or agency-required modifications:

- **12.1.1.** Insider threat awareness
- **12.1.2.** Behaviors of concern (Attachment B)
- **12.1.3.** Workplace violence
- **12.1.4.** PIADC policy on pre-access reliability assessment concerning Tier 1 BSAT (Attachment D)
- **12.1.5.** Self- and peer-reporting procedures
- **12.1.6.** Statutory prohibitions (Attachment H)
- **12.1.7.** Tier 1 BSAT user evaluation process
- **12.1.8.** PIADC policy on ongoing reliability assessment procedures
- **12.1.9.** PIADC policy on ongoing reliability monitoring procedures
- **12.1.10.** Corrective actions, procedures, and policies
- **12.1.11.** Procedures for voluntary and involuntary removal of Tier 1 BSAT access
- **12.1.12.** Information security (e.g., need to know)

All training will be documented and training records will be kept in accordance with the select agent regulations or in accordance with the National Archives and Records Administration disposition schedules, whichever is the lengthier.

13.0 AFTER HOURS ACCESS

Personnel must obtain approval from their Agency Manager for overnight stays at PIADC. The Agency Manager must then notify security of this approval and identify the individual(s), the dates of overnight stay and where the individual will be sleeping. Staff shall not sleep in biocontainment areas.

Security will run a daily report of staff access to biocontainment after 16:30. A summary of these reports will be provided to Agency Managers, the RO and the CO at the end of each month. Agency Managers must confirm with Security and the CO that they reviewed each monthly report.

14.0 ATTACHMENTS

To monitor and document personnel reliability for access to Tier 1 BSATs and Tier 1 BSAT security information, the following select agent tracking documents will be coordinated and maintained by the CO.

- **Attachment A** - Table 1: Federal Select Agent Program SRA Clearance Prohibitions and Restrictors
- **Attachment B** - Table 2: Examples of Reportable Conditions, Behaviors, or Other Information (From Guidance for Suitability Assessments 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73)
- **Attachment C**: PIADC Guidance for Supervisor Assessment of Personnel for Enrollment into PIADC PRP (from the Guidance Document for Tier One)
- **Attachment D**: PIADC Pre-Access Reliability Assessment Process
- **Attachment E**: Personnel Reliability Enrollment Form: To be completed upon initial enrollment into the program during pre-access reliability
- **Attachment F**: PIADC Annual Supervisor Assessment Form
- **Attachment G**: PIADC Potentially Disqualifying Information Disclosure to Competent Medical Authority Form: To be completed during an interview with a medical authority
- **Attachment H**: PIADC Notification of Potentially Disqualifying Information
- **Attachment I**: PIADC Personnel Reliability Assessment Board Charter
- **Attachment J**: Occupational Health Supervisor Physical Exam Component Form

Attachment A: Table 1- Federal Select Agent Program SRA Clearance Prohibitions and Restrictors

Restricted categories under 18 USC § 175b
• Individual is under indictment for a crime punishable by imprisonment for a term exceeding 1 year.
• Individual has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year.
• Individual is a fugitive from justice.
• Individual is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 USC 802)).
• Individual is an alien illegally or unlawfully in the U.S.
• Individual has been adjudicated as a mental defective or has been committed to any mental institution.
• Individual is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 App. U.S.C. 2405 (j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40 (d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780 (d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism.
• Individual has been discharged from the Armed Services of the U.S. under dishonorable
• Individual who is a member of, acts for or on behalf of, or operates subject to the direction or control of, a terrorist organization as defined in section 212(a)(3)(B)(vi) of the Immigration and Nationality Act (8 USC 1182 (a)(3)(B)(vi)).
The Federal Select Agent Program may limit or deny access to individuals reasonably suspected by any Federal law enforcement or intelligence agency of:
• Committing a crime specified in 18 USC §2332b(g)(5) (Acts of Terrorism Transcending National Boundaries).
• Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 USC 2331) or with any other organization that engages in intentional crimes of violence.
• Being an agent of a foreign power (as defined in 50 USC 1801).

Attachment B: Table 2: Examples of Reportable Conditions, Behaviors, or Other Information

(From Guidance for Suitability Assessments 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73)

Examples of Reportable Conditions, Behaviors or Other Information
Individuals shall share with their leadership any information that may be of concern for the well-being of themselves and others, or the safety and security of the entity, or Tier 1 BSAT. Examples are provided below:
• Circumstances that may affect SRA status of an individual.
• Circumstances that may affect the ability of an individual to perform his or her job in a safe and secure manner (e.g., performance of duties declines markedly; significant increase in distraction or mistakes; increase in risk-taking behaviors).
• Significant changes in behavior, attitudes, demeanor, or actions (e.g., increasingly withdrawn; significant and prolonged deterioration in appearance; unjustified anger or aggression; unexplained absences; signs of alcohol/drug abuse; criminal activity; and unexplained absences).
• Stated or implied threats to colleagues, institutions, the security of Tier 1 BSAT, the well-being of laboratory animals, or the general public.
• Non-compliance with the select agent regulations.
• Any information that causes an individual to have concerns about his or her own ability to perform a job safely and securely.
• Any circumstances that appear suspicious such as laboratory work that does not correspond to official project work or goals, requests for security or laboratory information without justification, acts of vandalism or property damage, attempts to gain unauthorized access for friends or colleagues.
• Unlawfully carrying weapons (or carrying weapons in violation of institutional rules).
• Providing false information on applications or other formal institutional documents.
• Unauthorized work performed by an individual(s) in a facility during off-hours.

Attachment C: PIADC Guidance for Supervisor Assessment of Personnel for Enrollment into PIADC Personnel Reliability Program (From the Guidance Document for Tier One)

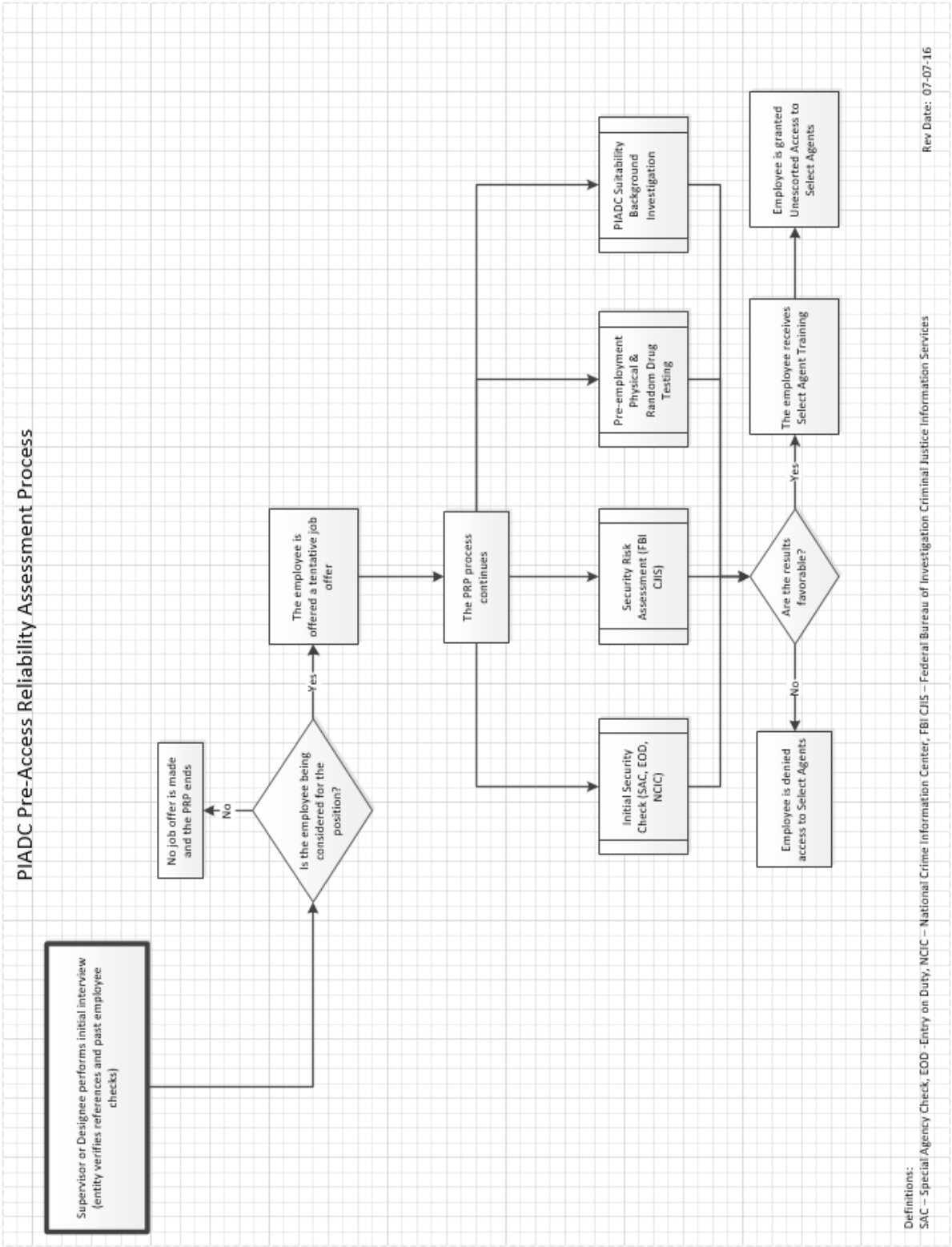
Interview of Applicant

- The interview provides an opportunity for PIADC to convey to all applicants critical information about the essential functions of the position to which the person has applied in order to ensure all applicants are informed of the requirements for the position as early in the hiring process as possible.
- The interview also allows for discussion of any missing or questionable information in the job application or resume, and provides an opportunity for PIADC to request additional information if there are concerns about incorrect, omitted or otherwise unfavorable information.
- Interviewers should use open-ended questions to allow a person to discuss their views and ideas.
- Interviewers should assess the applicant's attitudes toward biosafety, security, and Tier 1 requirements outlined in the select agent regulations.
- Discussions with individuals should include the benefits and challenges of work with Tier 1 BSATs, and PIADC's expectations for self-and peer-reporting, incidents or conditions that may affect Reliability, safety or security of Tier 1 BSATs.
- Red flags can include a defensive or hostile attitude, a history of frequent job changes, and a tendency to blame others for problems.
- **Note: It is not appropriate to discourage applicants from applying because of specific medical conditions, nor is it appropriate to ask questions that may illicit information about a disability or other protected classes (e.g. race, religion, age, parental status, genetic information, sexual orientation).**

Example Questions for Use in Reference Interviews

- References should be asked questions so the interviewer can understand the nature of the reference's relationship to the applicant, in what context they were acquainted, and how well the references knows the individual being assessed. Examples of such questions are:
    - What was the period of time in which you worked with the applicant?
    - Describe your relationship to the applicant while at your institution.
    - Did the applicant report directly to you or another supervisor?
- References should be asked specific questions about the applicant's work performance, ability, aptitude, or general qualifications and the applicant's character or loyalty.
    - What were the applicant's duties and how well did he/she perform while at your institution?
    - Can you describe the applicant's ability to work as part of a team?
    - Do you have any reason to question the applicant's character or loyalty?
    - Would you hire the applicant again?
- References should be able to describe the applicant's willingness to abide by applicable safety and security regulations or policies. This speaks to potential issues with authority that may cause an individual to have difficulties adhering to the principles of safety and security required for work with Tier 1 BSAT.
- Interviewers should attempt to confirm any information on the applicant's application. For example, references could be asked if they remember where the applicant undertook undergraduate or graduate training, or what city they may have lived in at a given time. Of course, these questions are not useful if the reference does not know the answers, but if their

answers are significantly different from the responses of the applicant, those details should be reviewed with the applicant for accuracy.

- References should be questioned as to whether they would hire the applicant again, and if not, why not.
- Note: When reference checking, the person completing the reference check may not ask questions about that may illicit information about a disability or other protected classes (e.g. race, religion, age, parental status, genetic information, sexual orientation).

Attachment D: PIADC Pre-Access Reliability Assessment Process