**PRP Certification Adjudication Guidelines**

INSTRUCTIONS: The below document is identified as a draft to be customized in consultation with INSTITUTION NAME personnel to ensure it is accurately describing site procedures and requirements.

* **Black text** can be considered generic text that may be appropriate for inclusion.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.
1. **Scope**

This document applies to all personnel who will access to Personnel Reliability Program (PRP) governed areas at (INSTITUTION NAME).

1. **Purpose**

The purpose of this document is to describe the PRP certification adjudication guidelines that the Certifying Official(s)/Certifying Committee shall use to adjudicate initial and continuing PRP certifications at the INSTITUTION NAME. The aim of the document is to assist the Certifying Official(s)/Certifying Committee and Responsible Official(s) (ROs) in determining and certifying an individual’s eligibility as having the legitimate need to access biological restricted areas, Biological Safety Level (BSL)-2, BSL-3, BSL-4, containment areas, Biological Select Agent or Toxin (BSAT), Especially Dangerous Pathogens (EDP), and/or Valuable Biological Materials (VBM).

1. **Principle**
	1. The materials housed within PRP governed areas pose significant risks to human health, the environment, and to other INSTITUTION NAME staff members outside the PRP governed areas.
	2. Entry to the PRP governed areas is strictly limited to personnel who are specifically cleared to work in this space. PRP governed area access is a privilege, not a right.
	3. To ensure that the individuals that are granted access to PRP governed areas meet the highest standards of integrity, trust, and personal reliability, each individual will be subject to a PRP certification process prior to being granted to any PRP governed restricted area(s).
2. **Responsibility**

# It is the responsibility of all personnel who will access PRP governed areas at INSTITUTION NAME to follow the procedures described in this document.

#  It is the responsibility of the Certifying Official(s)/Certifying Committee to identify individuals who are eligible to access various PRP governed restricted areas. They are responsible for the screening of individuals who will be subjected to PRP suitability and reliability requirements.

# The RO will be responsible for the final ruling of who will have access to the PRP governed restricted areas for the locations they are the RO.

# It is the responsibility of the Occupational Health (or other medical) provider is to provide the Certifying Official(s)/Committee with sufficient and timely medical information in order to make a sound PRP certification judgment.

# The Biological Safety Officer (BSO)/Assistant Biological Safety Officer (ABSO), RO/Alternate Responsible Official, and Security Manager are responsible for supporting the Certifying Official(s)/Certifying Committee during the certification process.

#  Ultimate responsibility for certifying personnel for access to restricted areas at INSTITUTION NAME lies with the Director of INSTITUTION NAME.

1. **Definition and Abbreviations**

**Access Control System:** An electronic system consisting of software and hardware that is networked to a site’s electronic access control devices (e.g., electric locks, card readers). The system integrates advanced security technologies and networking capabilities to provide a centralized monitoring and management system for a site’s electronic access control points.

**Alternate Responsible Official:** The person with authority and responsibility to ensure security requirements for restricted and biological restricted areas are met in the absence of the RO.

**Assistant Biological Safety Officer (ABSO):** The person who is responsible for identification and management of biological safety in particular, and biological risks in general, throughout the INSTITUTION NAME, in liaison with other members of the Biorisk Management Committee, Department Heads, and the staff of the INSTITUTION NAME in the absence of the BSO.

**Biological Restricted Area:** Biological Safety Level (BSL) 2 and 3 laboratories and any areas containing identified Especially Dangerous Pathogens (EDPs) and Valuable Biological Materials (VBMs) or areas where access to EDPs/VBMs is possible. Entry will be subject to special access restrictions. Physical security controls will be used to control access and secure property and materials. Biological Restricted Areas may be of different types depending on the nature and varying degree of access to EDPs/VBMs, or other relevant matter contained in the area.

**Biological Safety Officer (BSO):** The individual responsible for the identification and management of biological safety in particular, and biological risks in general, throughout the INSTITUTION NAME, in liaison with other members of the Biorisk Management Committee, Department Heads, and the staff of the INSTITUTION NAME. The BSO is the senior RO for all matters related to safety and biological safety at INSTITUTION NAME.

**Central Alarm Station (CAS)/Secondary Alarm Station (SAS):** Physical locations that provide centralized monitoring capability for all security layers throughout a site.

**Certifying Official(s)**: The person (or committee of people) responsible for certifying personnel for access to Restricted and Biological Restricted Areas.

**Closed-Circuit Television (CCTV):** The use of video cameras to transmit a video signal to a specific place, on a limited set of monitors, also known as video surveillance. It is a means of remotely monitoring specific locations.

**Deputy Security Manager:** A full-time employee (FTE), the Deputy Security Manager Is responsible for assisting the Security Manager in managing the security operations for INSTITUTION NAME. In addition, in the absence of the Security Manager or when the Security Manager must fulfill other, exclusive functions (e.g., Incident Commander), the Deputy Security Manager is responsible for the day-to-day security of INSTITUTION NAME, its personal assets, equipment, materials, cultures, specimens, and the protection of the public and the environment as related to security and biological security at INSTITUTION NAME.

**Especially Dangerous Pathogen (EDP)**: Those pathogens on the United States Select Agents List and others that may be determined by the (enter governing body here), or other governing body, to have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products.

**Incident Commander:** The person with overall responsibility for all aspects of an emergency response, including quickly developing incident objectives, managing all incident operations, application of resources as well as responsibility for all persons involved.

**Information Technology Manager:** Manages the application of computers, computer networks, and other information distribution technologies (including but not limited to television and telephone technology) to store, study, retrieve, transmit, and manipulate data or information at INSTITUTION NAME.

**Personnel Reliability Plan:** The plan to ensure that each individual who is authorized to access EDPs, and to escort and/or supervise personnel with access to Biological Restricted Areas and EDPs, including BSO/ABSO, Security Managers, Responsible and Certifying Officials, meet the highest standards of integrity, trust, personal reliability, and accountability so as to ensure these individuals do not pose a risk to the public health and safety, the environment or national security.

**Responsible Official (RO):** An individual, as designated by the Director of INSTITUTION NAME, who has the authority and responsibility to ensure security requirements for restricted and biological restricted areas are met.

**Restricted Area:** An area designated by the Director of INSTITUTION NAME (or by request of the Responsible Official (RO), Security Manager, or BSO) that houses valuable, sensitive, or hazardous material and requires access control.

**Security Manager:** A full-time employee (FTE), the Security Manager is responsible for the day-to-day security of INSTITUTION NAME, its personal assets, equipment, materials, cultures, specimens, and the protection of the public and the environment as related to security and biological security at INSTITUTION NAME. The Security Manager is the senior RO for all matters related to the security and biosecurity at INSTITUTION NAME.

**Valuable Biological Materials (VBMs)**: Biological materials that require (according to their owners, users, custodians, caretakers, or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.

1. **Reagents:**

 Not applicable

1. **Materials:**

Not applicable

1. **Related Directives**

INSTITUTION NAME Security and Biosecurity Plan

INSTITUTION NAME Personnel Reliability Plan

INSTITUTION NAME Authorization for Access to PRP Governed Areas SOP

INSTITUTION NAME Job Description - Security Manager

INSTITUTION NAME Job Description – Deputy Security Manager

INSTITUTION NAME Job Description – Certifying Official

INSTITUTION NAME Job Description – Incident Commander

INSTITUTION NAME Job Description – Biological Safety Officer

INSTITUTION NAME Job Description – Assistant Biological Safety Officer

1. **Adjudication Guidelines**
	1. If during the INSTITUTION NAME Certifying Official(s)/Certifying Committee’s review (either during initial certification or ongoing evaluation) of the PRP candidate’s job/duty history, Personal Security Investigation (PSI) report(s), personnel/medical records, results of personal interview, Occupational Health (or other medical) provider evaluation, or any other information, they discover evidence of a lack of emotional and mental stability, trustworthiness, physical competency, or adequate training to perform the assigned duties, the individual will be disqualified or decertified and not be permitted access/have access revoked to the PRP governed area(s). Information that may qualify as evidence of a lack of suitability and should be reported includes:
		1. Leaving a job (including part-time/second jobs) under unfavorable circumstances.
		2. Willful non-compliance with regulations.
		3. Being charged with or convicted of any criminal offense.
		4. Illegal use of drugs/substances or illegal drug activity.
		5. Unauthorized work performed by an individual (or individuals) in a facility during normal work hours or off-work hours.
		6. Unlawfully carrying weapons (or carrying weapons in violation of (enter your organization and/or facility name here) rules).
		7. Any information that causes an individual to have concerns about his or her own ability to perform a job safely and securely.
		8. Providing false information on applications or other formal institutional documents.
		9. Laboratory work that does not correspond to official project work or goals.
		10. Requests for security or laboratory information without justification.
		11. Alcohol abuse and other PRP reportable incidents and behaviors, including serious driving infractions such as reckless driving, Driving Under the Influence, and Driving While Intoxicated.
		12. Acts of vandalism or property damage.
		13. Attempts to gain unauthorized access for friends or colleagues.
		14. Being a party to any public record court action.
		15. Significant changes in behavior, attitudes, demeanor, or actions. Types of concerning behavior may include:
			1. Mental health
			2. Interpersonal interactions
			3. The communication to a third party of the intent to do harm
			4. Quality of thinking or communication
			5. Work performance
			6. School performance
			7. Threats/confrontations (stated or implied)
			8. Anger
			9. Physical aggression
			10. Risk-taking
			11. Firearm behavior
			12. Violent media usage
			13. Rapid or unexplained changes in weight/eating
			14. Drug abuse
			15. Impulsivity
			16. Alcohol abuse
			17. Physical health
			18. Other (e.g., idolizing criminals)
			19. Sexual behavior
			20. Hygiene/appearance

* 1. In determining reliability, the Certifying Official(s)/Committee must evaluate all aspects of an individual's actions, considering both favorable and unfavorable information, along with mitigating circumstances and overall qualities of credibility to determine suitability (a “whole person” assessment). The context and timing of the concerning behavior are also important to note. Consideration may be given to:

* + 1. The nature of the event and whether the individual’s demonstrated behavior increases the risk in the facility or laboratory.
		2. The assessed individual’s circumstances at the time of an event.
		3. The time that has passed since the event of concern.
		4. Positive information about the person, including work performance and/or education since the derogatory event(s).
		5. The interpretation of the derogatory event(s) by supervisors at the time.
		6. How the individual being assessed interprets the derogatory event(s) during his or her interview.
		7. The nature of the event and whether the individual’s demonstrated behavior increases the risk in the facility or laboratory.
		8. The total number of events causing concern along with frequency and severity.
		9. Presence of a supportive family or support group.
		10. Presence of healthy social supports.
		11. Positive coping mechanisms.
		12. Access and receptiveness to assistance.
		13. Details of any criminal or legal incidents or events. The Certifying Official(s)/Committee may utilize INSTITUTION NAME security personnel and legal counsel to evaluate criminal conviction and arrest records.
	1. If the Certifying Official(s)/Committee determines that an individual has activity associated with them that meets the disqualifying standards under the INSTITUTION NAME PRP, they shall be designated a “Restricted Person.” (*See section 2.4 of the INSTITUTION NAME PRP plan for more information on disqualifying standards*.)
	2. A Restricted Person is ineligible for duties requiring PRP certification.

# Safety Instructions

# Comply with all INSTITUTION NAME safety policy, while following the procedures described in this document.

#  Reference

* INSTITUTION NAME Security and Biosecurity Plan
* INSTITUTION NAME Personnel Reliability Plan
* World Health Organization Biorisk Management Laboratory Biosecurity Guidance, September 2006
* European Committee for Standardization, Comité Europé De Normalisation (CEN) Europäisches Komitee Fűr Normung, Workshop Agreement (CWA) 15793
* United States Federal Select Agent Program